ADEONA PHARMACEUTICALS, INC.
Form 424B3
February 09, 2009

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File No. 333-156973

PROSPECTUS

9,965,671 Shares of Common Stock

This prospectus relates to the offer and sale from time to time by the selling stockholders identified in this prospectus, and their pledgees, assignees and successors-in-interest, of an aggregate of 8,816,918 shares of our common stock that are currently outstanding and 1,148,753 shares of common stock that are issuable upon the exercise of warrants. We are filing the registration statement of which this prospectus is a part in order to fulfill contractual requirements that we have with certain of the selling stockholders.

All of the shares and warrants described above were previously issued in private placement transactions completed prior to the filing of this registration statement.

The prices at which these selling stockholders may sell the shares in this offering will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the sale of the shares.

Our common stock is traded on the American Stock Exchange under the symbol “AEN.” On February 6, 2009, the last reported sale price of our common stock was $0.17 per share. We urge you to obtain current market quotations for our common stock.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 2.

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. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 9, 2009.

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Important Notice about the Information Presented in this Prospectus

You should rely only on the information contained or incorporated by reference in this prospectus or any applicable prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. For further information, see the section of this prospectus entitled “Where You Can Find More Information.” We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information appearing in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date on the front cover of this prospectus or the applicable prospectus supplement, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospectus supplement or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

## PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read this prospectus and the information and documents incorporated by reference carefully. These documents contain important information you should consider when making your investment decision. See "Incorporation of Certain Documents by Reference" on page ---12.

Unless the context otherwise requires, all references to "we," "our," "our company, or "the Company" in this prospectus refer to Adeona Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries, considered as a single enterprise.

### About Adeona Pharmaceuticals, Inc.

We are a development-stage, specialty pharmaceutical company that is focused on advancing its proprietary, late-stage drug candidates for the treatment of central nervous system and autoimmune diseases. Our strategy is to exclusively in-license clinical-stage drug candidates that have demonstrated preliminary efficacy in human clinical trials for unmet medical diseases. We are focused on drug candidates that address the following pharmaceutical market opportunities: Rheumatoid Arthritis (RA), Multiple Sclerosis (MS), Dry Age Related Macular Degeneration (AMD), and Fibromyalgia. All of our products are in the development stage.

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. The information on our website is not incorporated by reference into this prospectus.

### The Offering

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| Common stock offered by selling stockholders: | 9,965,671 shares |
| Use of proceeds: | We will not receive any proceeds from the sale of shares in this offering. |
| NYSE Alternext Symbol: | AEN |

## RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently consider immaterial may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose all or part of your investment.

### RISKS RELATING TO OUR BUSINESS

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

We are a development stage company that has experienced significant losses since inception and has a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. To date, we have generated no product revenues. As of September 30, 2008, we have expended approximately $22.4 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

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

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

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

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

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

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

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

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

On November 28, 2007, we filed a New Drug Application (NDA) with the Food and Drug Administration (FDA) seeking approval to market oral TTM (oral tetrathiomolybdate) for initially presenting neurologic Wilson's disease. On January 28, 2008 representing sixty (60) days from the date of NDA filing we received notification from the FDA that our NDA has not been accepted for further review and the FDA issued a refusal to file letter ("RTF"). In the RTF letter the FDA cited various deficiencies in the NDA filing, including, the the adequacy and quality of the clinical evidence to support the safety and efficacy of oral TTM for this indication, as well as chemistry, manufacturing and controls issues regarding the identity, strength and purity of oral TTM. Given the receipt of the RTF letter, our potential commercialization plan for oral TTM has been and is, expected to be significantly delayed.

On February 26, 2008, we completed a Type A meeting with the FDA to discuss the deficiencies raised in the RTF letter. Based on this meeting with the FDA, we believe we reached an understanding with the FDA on a course of action to resolve all of the filing issues raised in the RTF letter. Given the issues raised by the FDA in its RTF letter of January 28, 2008 as well as the FDA's written clinical hold letter sent to the IND holder forwarded to us on March 26, 2008, at the present time it appears that the FDA will not deem the three existing clinical trials of oral TTM to be sufficient for a NDA of oral TTM for initially presenting neurologic Wilson's disease, Given the limited number of patients afflicted by this disease, an additional clinical trial of oral TTM for this indication will necessarily take a substantial amount of time and resources to plan, enroll and complete. Should we elect to abandon our efforts to seek U.S. and/or European approval of oral TTM for neurologically presenting Wilson's disease, we will most likely not have sufficient resources to pursue all of the additional indications for oral TTM that are the subject of our research and development, including, idiopathic pulmonary fibrosis, Alzheimer's disease, primary biliary cirrhosis and Huntington's disease. We are seeking potential business development corporate partners and potential licensees that may assist in supporting the further development of oral TTM for Wilson's disease and other indications. If we are are unable to identify interested corporate partners or licensees for oral TTM, we may elect to abandon our efforts to develop oral TTM for any or all indications, including, initially presenting neurologic Wilson's disease.

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

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

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

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

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

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

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

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

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

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

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

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central-nervous-system and autoimmune diseases include: Pfizer, Inc., Rigil Pharmaceuticals, Incyte Pharmaceuticals, Chelsea Therapeutics International, Inc., Aton Pharma, GlaxoSmithKline Pharmaceuticals, Alcon, Inc., Shire Pharmaceuticals, Plc., Schering-Plough, Organon NV, Merck & Co., Eli Lilly & Co., Serono, SA, Biogen Idec, Inc., Achillion, Ltd., Active Biotech, Inc., Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Inc., Merch-Schering AG, Forest Laboratories, Inc., Attenuon, LLC, Cypress Biosciences, Inc., Genentech, Neurotech, Amgen, Inc., Centocor/Johnson and Johnson, UCB Group, Abbott, Wyeth, OM Pharma, Cel-Sci Pharmaceuticals, Novartis, Axcan Pharma, Inc., Teva Pharmaceuticals, Inc., Intermune, Inc. Fibrogen, Inc., Active Biotech, CNSBio, Pty., Rare Disease Therapeutics, Inc., Prana Biotechnology, Inc., Merz & Co., AstraZeneca Pharmaceuticals, Inc., Chiesi Pharmaceuticals, Inc., Alcon, Inc., Bausch and Lomb, Inc., Targacept, Inc., and Johnson & Johnson, Inc. Alternative technologies or alternative delivery or dosages of already approved therapies are being developed to treat dry AMD, autoimmune inflammatory, rheumatoid arthritis, psoriasis, Fibromyalgia, MS, Huntington's, Alzheimer's and Wilson's diseases, several of which may be approved or are in early and advanced clinical trials, such as zinc based combinations, Syk inhibitors, Jak inhibitors, connective tissue growth factors (CTGF), FTY-720, Laquinimod, pirfenidone, milnacipram, Lyrica, anti-depressant combinations, Rituxan, Enbrel, Cimzia, Humira, Remicade, Cymbalta, Effexor, Actimmune and other interferon preparations. Unlike us, many of our competitors have significant financial and human resources. In addition, academic research centers may develop technologies that compete with our TRIMESTA, Zinthionein, dnaJP1, CD4 inhibitors, EFFIRMA, CORRECTA and oral TTM technologies. Should clinicians or regulatory authorities view these therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers.

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

Since we do not have composition of matter patent claims for oral TTM, EFFIRMA, 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 EFFIRMA 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 EFFIRMA 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 EFFIRMA or TRIMESTA in various formulations or delivery systems that might adversely affect our ability to develop and market these products in the US. We are aware that other companies have intellectual property protection using the active ingredients and have conducted clinical trials of EFFIRMA, oral TTM and TRIMESTA for different applications that what we are developing. Should a competitor obtain FDA approval for their product for any indication prior to us, we might be precluded under the Waxman-Hatch Act to obtain approval for our product candidates for a period of five years. We cannot provide any assurances that our products will be FDA approved prior to our competitors.

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

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

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

Our competitiveness may be adversely affected if we are unable to protect our proprietary technologies. Other than our CD4 inhibitor, oral dnaJP1 and Zinthionein program, we do not have composition of matter patents for TRIMESTA, EFFIRMA, oral TTM or their respective active ingredients estriol, flupirtine, and tetrathiomolybdate. We also expect to rely on patent protection from an issued U.S. Patent for the use of oral TTM and related compounds to treat inflammatory and fibrotic diseases (U.S. Patent No 6,855,340). These patents have been exclusively licensed to us. We have also filed various pending patent applications which cover various formulations, packaging, distribution & monitoring methods for oral TTM. We rely on issued patent and pending patent applications for use of TRIMESTA to treat MS (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have exclusively licensed issued U.S. Patent No. 5,773,570, 6,153,200, 6,946,132, 6,989,146, 7,094,597, 7,301,005, including foreign equivalents along with several patent applications which cover dnaJP1, methods and its uses, We have also exclusively licensed an issued patent for the treatment of fibromyalgia with EFFIRMA .

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

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

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Amendments," to protect some of our current product candidates, specifically oral TTM, dnaJP1, TRIMESTA, zincmonocystine, Anti-CD4 802-2, EFFIRMA 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 January 20, 2009, we have 3 full-time employees and 3 part-time employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. We intend to recruit certain key executive officers, including a Chief Medical Officer and/or Vice President of Regulatory Affairs during 2009. Our future performance will depend in part on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

Currently, we have not entered into a written employment agreement with Mr. Stergis, our cofounder and Chief Executive Officer. We intend to enter into an employment agreement with Mr. Stergis in a form substantially similar to our other former executive officers. However, we cannot provide any assurances that we will be able to enter into this agreement with Mr. Stergis. Certain of our directors, (including Jeffrey Kraws, a director and former VP of Business Development, Jeffrey Wolf, a director, and Dr. Kuo, a director) scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies which might be developing competitive products to ours. 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.

We can expect this to also be the case with personnel that we engage in the future. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

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

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

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

In order to successfully commercialize our product candidates, we must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, manufacture of the active ingredient in oral TTM and Zinthionein is a complex process that can be difficult to scale up for purposes of producing large quantities. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. Furthermore, the active ingredient of Zinthionein has been difficult to scale up at larger quantities. As such, we can give no assurances that we will be able to scale up the manufacturing of Zinthionein. Oral TTM is also known to be subject to a loss of potency as a result of prolonged exposure to moisture and other normal atmospheric conditions. The active ingredient of our dnaJP1 program is a 15 amino acid peptide. Traditionally, peptide manufacturing is costly, time consuming, resulting in low yields and poor stability. We cannot give any assurances that we will not encounter this issues when scaling up manufacturing for dnaJP1. We are developing proprietary formulations and specialty packaging solutions to overcome this stability issue, but we can give no assurances that we will be successful in meeting the stability requirements required for approval by regulatory authorities such as the FDA or the requirements that our new proprietary formulations and drug product will demonstrate satisfactory comparability to less stable formulations utilized in prior clinical trials for oral TTM. We may experience delays in demonstrating satisfactory stability requirements and drug product comparability requirements that could delay our planned clinical trials of for any of our products.

For manufacturing and nonclinical information for TRIMESTA, we rely upon an agreement with Organon, a division of Schering-Plough for access to clinical, nonclinical, stability and drug supply relating to estriol, the active ingredient in TRIMESTA which is currently in a phase IIb clinical trial for MS. Should Organon terminate our agreement, 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.

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 commercial manufacturing facility for oral TTM product in Ann Arbor, MI and we have hired and trained our employees to comply with the extensive regulations applicable to such a facility. Given the delay of our NDA for oral TTM, we are currently exploring strategic options for our GMP facility. This might include sale of the equipment and/or sublease of the 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.

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

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

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

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

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

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

Physicians and patients may not accept and use our technologies.

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

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

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

We depend on researchers who are not under our control.

Since we have in-licensed all of our product candidates, we depend upon independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the

amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data. Should any of these scientific inventors/advisors become disabled or die unexpectedly, we may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense could harm our competitive position. For example, we are highly dependent on scientific collaborators for our dnaJP1, TRIMESTA, Zinthionein, CD4 Inhibitor, EFFIRMA and oral TTM 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 physican sponsored clinical trials or physician sponsored INDs for our programs. We cannot provide any assurances that we will not experience any additional delays in the future. For example, the clinical trials for oral TTM for the treatment of neurologic Wilson's disease have been conducted and completed prior to us licensing this technology from the University of Michigan. Due to various patient privacy regulations and other administrative matters, we have experienced delays and/or an inability to obtain clinical trial data relating to oral TTM. We have also experienced similar difficulties with our Zinthionein program. As such, this delay or inability to obtain any data might result our inability to advance our products through the regulatory process or obtain pharmaceutical partners for them.

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

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

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

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

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

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

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

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

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

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

developing drugs;
undertaking pre-clinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of drugs;
formulating and manufacturing drugs; and
launching, marketing and selling drugs.

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

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

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

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

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

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

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement is available from government and health administration authorities, private health maintenance organizations, health insurers, and other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, or may be inadequate, to cover the cost of our drugs. This could affect our ability to commercialize our products.

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

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

RISKS RELATING TO OUR STOCK

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

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

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

Currently, our directors, executive officers, and principal stockholders beneficially own a majority of our common stock. As a result, they will be able to exert substantial influence over the election of our board of directors and the vote on issues submitted to our stockholders.

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

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

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

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

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

We cannot assure you that we will be able to maintain the listing standards of the NYSEAlternext formerly the American Stock Exchange. The NYSEAlternext requires companies to meet certain listing criteria including certain minimum stockholders' equity and equity prices per share. We may not be able to maintain such minimum stockholders' equity or prices per share or may be required to effect a reverse stock split to maintain such minimum prices and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSEAlternext.

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

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

We have never paid dividends.

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

RISKS RELATED TO OUR INDUSTRY

Government Regulation

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

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

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

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

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

effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, as occurred with oral TTM, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials.

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

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

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

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

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

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

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

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

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

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

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

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

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

Other Regulatory Requirements

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

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

European Product Approval

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

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

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

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

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

Pricing Controls

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

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

Third-Party Reimbursements

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

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

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

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

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

Fraud and Abuse Laws

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

Patent Restoration and Marketing Exclusivity

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

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

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

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

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference contain, in addition to historical information, forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements include statements that reflect the current view of our senior management with respect to our financial performance and future events with respect to our business and our industry in general and can be identified by the use of forward-looking terminology such as "may," "could," "expect," "anticipate," "estimate," "continue" other similar words. These forward-looking statements are based on management's current expectations and are subject to a number of factors and uncertainties which could cause actual results to differ materially from those described in these statements. We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a

result of various factors including, but not limited to, those described in the Risk Factors section of this prospectus. We cannot assure you that we have identified all the factors that create uncertainties. Readers should not place undue reliance on forward-looking statements. We undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events, other than as required by law.

## USE OF PROCEEDS

The proceeds from the sale of each selling stockholder's shares of common stock will belong to that selling stockholder. We will not receive any proceeds from those sales.

## SELLING STOCKHOLDERS

This prospectus relates to the resale from time to time of up to a total of 9,965,671 shares of our common stock by the selling stockholders, comprising:

- 1,148,753 shares of common stock issuable upon exercise of warrants;
- 8,816,918 shares of common stock already issued and outstanding;

The following table, based upon information currently known to us, sets forth as of January 20, 2009: (i) the number of shares held of record or beneficially by the selling stockholders as of that date; (ii) the percentage of the outstanding shares that the shares held by the selling stockholder represents (iii) the number of shares that may be offered under this prospectus, and (iii) a footnote reference to any material relationship between us and the selling stockholder, if any.

The number of shares beneficially owned by each selling stockholder named in the table below is determined under rules of the Securities and Exchange Commission (SEC) and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares to which the individual or entity has sole or shared voting power or investment power and also any shares that the individual or entity has the right to acquire within 60 days after January 20, 2009 through the exercise of any warrant or other right, or conversion of any security. The inclusion in the table below of any shares deemed beneficially owned does not constitute an admission of beneficial ownership of those shares.

None of the selling stockholders is a broker-dealer or an affiliate of a broker-dealer, except Accredited Venture Capital, Steve H. Kanzer are affiliates of Accredited Equities, a broker dealer, and BioMed Cap, HefCap Holdings, Kosta J. Moustakas and Sean A. Kund are affiliates of a broker dealer. Noble International Investments, Inc., MidSouth Capital, Inc., Redchip Securities, Inc., are broker dealers.

Each selling stockholder's percentage of ownership in the following table is based on 20,911,121 shares of common stock outstanding as of January 20, 2009.

| | Shares beneficially owned prior to the offering | | Number of common shares registered in this prospectus | Shares beneficially owned after offering | |
|---|---|---|---|---|---|
| Selling Stockholder | Number | Percent | | Number | Percent |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Accredited Venture Capital, LLC | 7,086,380 | (1) | 33.45% | 7,086,380 | - | | 0.00% |
| Steve H. Kanzer, CPA, JD | 7,732,684 | (2) | 36.51% | 7,461,626 | 271,058 | (3) | 1.28% |
| Nicholas and Jennifer Stergis | | | | | - | | |
| Tenancy by Entirety | 1,939,917 | (4) | 9.02% | 1,709,361 | 230,556 | (5) | 1.09% |
| BioMed Cap, LLC | 41,342 | (6) | * | 41,342 | - | | 0.00% |
| HefCap Holdings, LLC | 41,342 | (6) | * | 41,342 | - | | 0.00% |
| RedChip Securities, Inc. | 4,594 | (6) | * | 4,594 | - | | 0.00% |
| Midsouth Capital Inc. | 4,594 | (6) | * | 4,594 | - | | 0.00% |
| Warrant Stratagies | 30,000 | (6) | * | 30,000 | - | | 0.00% |
| Brio Capital | 30,000 | (6) | * | 30,000 | - | | 0.00% |
| Sean A. Kund | 11,909 | (6) | * | 11,909 | - | | 0.00% |
| A. Joseph Rudick, M.D. | 194,729 | (7) | 0.93% | 114,904 | 22,621 | (14) | * |
| Kosta J. Moustakas | 10,711 | (8) | * | 10,711 | - | | 0.00% |
| Stanley G. Bisgaier Trust, 1/23/04 | 12,388 | (8) | * | 12,388 | - | | 0.00% |
| Dena G. Bisgaier Trust, 1/23/04 | 12,388 | (8) | * | 12,388 | - | | 0.00% |
| Bisgaier Family LLC | 24,776 | (8) | * | 24,776 | - | | 0.00% |
| Noble International Investments, Inc. | 327,456 | (6) | 1.54% | 327,456 | - | | 0.00% |
| Redington, Inc. | 100,000 | (9) | * | 100,000 | - | | 0.00% |
| Rachel Glicksman | 28,281 | (10) | * | 28,281 | - | | 0.00% |

* Represents less than 1% of the outstanding shares.

(1), (2), (3) These 7,086,380 shares are held in the name of Accredited Venture Capital, LLC, Pharmainvestors, LLC is the managing member of Accredited Venture Capital, LLC, and Steve H. Kanzer is the managing member of Pharmainvestors, LLC. As such, Mr. Kanzer may be considered to have control over the voting and disposition of the shares registered in the name of Accredited Venture Capital, LLC. Mr. Kanzer disclaims beneficial ownership of those shares, except to the extent of his pecuniary interest. Mr. Kanzer currently serves as
Chairman of our Board of Directors and the 7,732,684 shares listed as beneficially owned by him includes the 7,086,380 shares held by Accredited Venture Capital, LLC described above as to which Mr. Kanzer disclaims beneficial ownership except to the extent of his pecuniary interest, 375,246 shares purchased by Mr. Kanzer in the open market during 2007 and 2008 and 271,058 options issued under our stock option plan exercisable at $2.01 per share.

(4), (5) 354,069 of these shares are issuable upon the exercise of warrants. 230,556 of these shares are issuable upon exercise of presently exercisable options. Mr. Stergis is our Chief Executive Officer and our vice chairman of our board of directors. Jennifer Stergis is Mr. Stergis's wife.

(6) All of these shares are issuable upon the exercise of presently exercisable warrants.

(7) 114,904 of these shares are issuable upon the exercise of warrants. 22,621 of these shares are issuable upon exercise of presently exercisable. Dr. Rudick was a member of our Board of Directors and was our Chief Medical Officer until August 2007.

(8) All of these shares are issuable upon the exercise of presently exercisable warrants. Charles L. Bisgaier and Patricia L. Bisgaier are the trustees of this trust. Mr. Bisgaier was a member of our Board of Directors and was our President and Corporate Secretary until July 1, 2008, at which time he resigned from all three positions.

(9) All of these shares are issuable upon the exercise of warrants. 50,000 warrants remain unvested.

(10) Represents shares of common stock.

PLAN OF DISTRIBUTION

Each selling stockholder and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of his, her or its shares on the American Stock Exchange or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any of these methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of shares, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares in the course of hedging the positions they assume. The selling stockholders may also sell shares short and deliver these shares to close out their short positions, or loan or pledge shares to broker-dealers that in turn may sell these shares. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to that broker-dealer or other financial institution of shares offered by this prospectus, which shares that broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect that transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with those sales. In that event, any commissions received by those broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%) of the gross proceeds of any sale.

Because selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 there under. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares may not be sold 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.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations there under, including Regulation M, which may limit the timing of purchases and sales of the shares by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this

prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

## LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus has been passed upon for Adeona Pharmaceuticals, Inc. by Miller, Canfield, Paddock & Stone PLC of Detroit, Michigan.

## EXPERTS

The financial statements incorporated into this Prospectus by reference from the Company's Annual Report on Form 10-KSB for the year ended December 31, 2007, 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, which report expresses an unqualified opinion. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file with the SEC at the Public Reference Room (Room 1580), 100 F Street, N.W., Washington, D.C. 20549. You may also obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website (www.sec.gov) that contains the reports, proxy and information statements, and other information that we file electronically with the SEC.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and the securities, including exhibits. You can obtain a copy of the registration statement from the SEC at the above address or from the SEC's Internet site.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information contained in documents that we file with the SEC, which means that we can disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 prior to the termination of this offering:

(1) Our Annual Report on Form 10-KSB for the year ended December 31, 2007 filed on March 31, 2008 as amended by an amendment on Form 10KSB filed on August 29, 2008;

(2) Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2008, June 30, 2008 and September 30, 2008;

(3) Our Current Reports on Form 8-K filed with the SEC on January 29, 2008, February 29, 2008, March 10, 2008, March 18, 2008, April 1, 2008, May 2, 2008, May 16, 2008, July 8, 2008, July 9, 2008; August 14, 2008, October 16, 2008, November 14, 2008, January 6, 2009 and January 20, 2009.

(4) The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on January 29, 1993 (File NO. 000-21156).

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost, by contacting:

Adeona Pharmaceuticals, Inc.
3930 Varsity Drive
Ann Arbor, MI 48108

Attention: Corporate Secretary
Tel.: (734) 332-7800