AEOLUS PHARMACEUTICALS, INC.
Form 424B3
June 14, 2013

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-188670
Prospectus

30,591,501

Common Stock

This prospectus relates to the offer and sale from time to time by the selling stockholders identified in this prospectus of up to 30,591,501 shares of our common stock, par value $0.01 per share. These shares include 14,462,000 shares of common stock and 14,462,000 shares issuable upon exercise of warrants which shares and warrants were issued in two private placements which closed on February 19, 2013 and March 4, 2013. The shares also include 377,501 shares issuable upon exercise of warrants issued to certain placement agents for services rendered as placement agents and 1,290,000 shares issuable upon exercise of warrants issued to services providers for consulting services rendered. The shares of common stock and warrants were issued in transactions made in reliance on Section 4(2) of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and Rule 506 promulgated thereunder. For additional information regarding the private placements, please see "Description of the Shares included in this Prospectus" beginning on page 21 of this prospectus.

We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders, however we will receive the proceeds of any cash exercise of the warrants.

The selling stockholders may sell the shares from time to time at the market price quoted on the OTC Bulletin Board at the time of offer and sale, or at prices related to such prevailing market prices, in negotiated transactions or in a combination of such methods of sale directly or through brokers. See "Plan of Distribution" beginning on page 99 for additional information on how the selling stockholders may conduct sales of their shares of common stock.

Other than underwriting discounts and commissions, and transfer taxes, if any, we have agreed to bear all expenses incurred in connection with the registration and sale of the common stock offered by the selling stockholders.

Our common stock is quoted on the OTC Bulletin Board under the symbol "AOLS." On May 8, 2013, the closing price of our common stock was $0.44 per share.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 3 for certain risks you should consider before purchasing any shares.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 14, 2013

TABLE OF CONTENTS

You should only rely on the information contained in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with additional information or information different from that contained in this prospectus. We are not making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, prospects, financial condition and results of operations may have changed since that date.

This document may only be used where it is legal to sell these securities. Certain jurisdictions may restrict the distribution of these documents and the offering of these securities. We require persons receiving these documents to inform themselves about, and to observe any, such restrictions. We have not taken any action that would permit an offering of these securities or the distribution of these documents in any jurisdiction that requires such action.

We own or have rights to trademarks or trade names that we use in conjunction with the operation of our business. Each trademark, trade name or service mark of any other company appearing in this prospectus belongs to its holder. Use or display by us of other parties' trademarks, trade names or service marks is not intended to and does not imply a relationship with, or endorsement or sponsorship by us of, the trademark, trade name or service mark owner

---

Industry and Market Data

Unless otherwise indicated, the market data and certain other statistical information used throughout this prospectus are based on independent industry publications, government publications, reports by market research firms or other published independent sources. Although we believe these third-party sources are reliable, we have not independently verified the information. Except as otherwise noted, none of the sources cited in this prospectus has consented to the inclusion of any data from its reports, nor have we sought their consent. In addition, some data are based on our good faith estimates. Such estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as our own management's experience in the industry, and are based on assumptions made by us based on such data and our knowledge of such industry and markets, which we believe to be reasonable. However, except as otherwise noted, none of our estimates have been verified by any independent source. Our estimates and assumptions involve risks and uncertainties and are subject to change based on various factors, including those discussed in the "Risk Factors" section of this prospectus and the other information contained herein. These and other factors could cause our actual results to differ materially from those expressed in the estimates and assumptions.

PROSPECTUS SUMMARY

This summary highlights certain information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read the entire prospectus, including ‘‘Risk Factors’’ and our financial statements and related notes before you decide whether to invest in our common stock. Investing in our common stock involves risks. See ‘‘Risk Factors’’ beginning on page 3. All dollar amounts referred to in this prospectus are in U.S. dollars unless otherwise indicated. Any discrepancies in the tables included herein between the amounts listed and the totals thereof are due to rounding.

Unless otherwise indicated or unless the context otherwise requires, all references in this document to “we,” “us,” “our,” the “Company” and similar expressions are references to Aeolus Pharmaceuticals, Inc.

Our Company and Business

Aeolus Pharmaceuticals, Inc. (“we,” “us” or the “Company”) is a Southern California-based biotechnology company leveraging significant government funding to develop a platform of novel compounds to protect against radiological and chemical threats and for use in oncology. The platform consists of over 200 compounds licensed from Duke University (“Duke”) and National Jewish Health (“NJH”). The Company’s lead compound, AEOL 10150, is a metalloporphyrin specifically designed to neutralize reactive oxygen and nitrogen species. The Company is developing AEOL 10150 as a medical countermeasure against the pulmonary effects of radiation exposure under a contract (“BARDA Contract”) valued at up to $118.4 million with the Biomedical Advanced Research and Development Authority (“BARDA”), a division of the Department of Health and Human Services (“HHS”). Additionally, Aeolus receives development support from the National Institutes of Health (“NIH”) for development of the compound as a medical countermeasure against radiation and chemical exposure.

Risks Associated with Our Business

Our business is subject to numerous risks. Please see the “Risk Factors” section beginning on page 3 of this prospectus.

Recent Developments

Resignation and Appointment of Directors

On May 8, 2013, each of Joseph J. Krivulka, Michael E. Lewis, Ph.D. and Peter D. Suzdak, Ph.D. notified us of his resignation from the Board of Directors (the “Board”) of Aeolus and from all committee memberships, as applicable. The decision of each of Mr. Krivulka, Dr. Lewis and Dr. Suzdak to resign from the Board was not due to any disagreement with Aeolus on any matter relating to Aeolus’ operations, policies or practices.

Concurrently with the resignations of Mr. Krivulka, Dr. Lewis and Dr. Suzdak from the Board, the Board appointed John Clerici, Mitchell D. Kaye and Jeffrey A. Scott, M.D. to serve as directors of the Board, effective May 8, 2013. Each of Mr. Clerici, Mr. Kaye and Dr. Scott will serve until such time as his respective successor is duly elected and qualified or until his earlier resignation or removal.

Corporate Information

We were incorporated in the State of Delaware in 1994. Our common stock trades on the OTC Bulletin Board under the symbol “AOLS.” Our principal executive offices are located at 26361 Crown Valley Parkway, Suite 150, Mission Viejo, California 92691, and our phone number at that address is (949) 481-9825. Our website address is www.aeoluspharma.com. However, the information in, or that can be accessed through, our web site is not part of the

registration statement of which this prospectus forms a part. We also make available free of charge through our website our most recent annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, which we refer to as the SEC.

THE OFFERING

Common stock offered by us	None
Common stock offered by selling stockholders	30,591,501
OTC Bulletin Board Symbol	“AOLS”
Proceeds to us	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus. However, we will receive the proceeds of any cash exercise of the warrants.
Risk factors	Investing in our common stock involves certain risks. You should read “Risk Factors” beginning on page 3 for a discussion of factors that you should consider carefully before deciding whether to purchase shares of our common stock.

RISK FACTORS

You should carefully consider the following information about risks described below, together with the other information contained in this prospectus and in our other filings with the SEC, before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this prospectus. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

We have operated at a loss and will likely continue to operate at a loss for the foreseeable future.

We have incurred significant losses over the past five years, excluding net income of approximately $1,698,000 and $299,000 for the years ended September 30, 2012 and 2011, respectively, and we had an accumulated deficit of approximately $182,469,000 as of March 31, 2013. Additionally, during the years ended September 30, 2012 and 2011, we incurred a gain of $4,069,000 and $3,887,000, respectively, to our warrant liability related to outstanding warrants, which are non-cash items and do not impact our financial operations or cash needs. Our operating losses have been due primarily to our expenditures for research and development on our drug candidates and for general and administrative expenses and our lack of significant, or sufficient, revenues to offset all of the expenditures. We are likely to continue to incur operating losses until such time, if ever, that we generate significant recurring revenues from product sales, whether to the U.S. government for the Strategic National Stockpile or to the general healthcare community for commercial indications, like oncology, epilepsy or Parkinson's disease. We anticipate it will take a minimum of two years (and possibly longer) for us to generate recurring revenues. We expect that it will take at least that long before the development of any of our licensed, or other current potential, products is completed, marketing approvals are obtained from the FDA and commercial sales of any of these products can begin, or that we might receive a procurement from the U.S. Government under an Emergency Use Authorization or Animal Rule Approval.

We need substantial additional funding to continue our operations and may be unable to raise capital when needed, or at all, which would force us to delay, curtail or eliminate our clinical programs and our product development programs.

We need to raise substantial additional capital to fund our operations and clinical trials and continue our research and development, unless and until we receive a procurement of sufficient size from the U.S. Government for the Strategic National Stockpile. In addition, we may need to raise substantial additional capital to enforce our proprietary rights, defend, in litigation or otherwise, any claims that we infringe third party patents or other intellectual property rights; and commercialize, for non-government related indications, any of our products that may be approved by the FDA or any international regulatory authority.

On March 30, 2012 and April 4, 2012, we closed a private placement through which we raised gross proceeds of approximately $660,000 through the sale of our common stock and warrants to a group of accredited investors. As of March 31, 2013, we had cash of approximately $1,926,000. On February 19, 2013 and March 4, 2013, we closed a private placement through which we raised gross proceeds of approximately $3.6 million through the sale of our common stock and warrants to a group of accredited investors. Currently, our monthly cash requirements to operate our business that are not reimbursed under the BARDA Contract are approximately $100,000. To the extent we do not have sufficient cash to fund our working capital requirements, we may not be able to pay our payables timely, which may cause vendors to cease providing services to us.

In order to fund on-going operating cash requirements, or to accelerate or expand our oncology and other programs we will need to raise significant additional funds. We are continuously considering strategic and financial options available to us, including public or private equity offerings, debt financings or collaboration arrangements. If we raise additional funds by issuing securities, our stockholders will experience dilution of their ownership interest. Debt financings, if available, may involve restrictive covenants and require significant interest payments. If we do not receive additional financing to fund our operations not reimbursed under the BARDA Contract, or if BARDA does not exercise any additional options under the BARDA Contract and we are unable to raise sufficient capital for operations, we would have to discontinue some or all of our activities, merge with or sell, lease or license some or all of our assets to another company, or cease operations entirely, and our stockholders might lose all or part of their investments.

In addition, if our catalytic antioxidant program shows scientific progress, we will need significant additional funds to move therapies through the preclinical stages of development and clinical trials. If we are unable to raise the amount of capital necessary, or do not receive a sufficient procurement from the U.S. Government for the Strategic National Stockpile, to complete development and reach commercialization of any of our catalytic antioxidant products, we will need to delay or cease development of one or more of these products or partner with another company for the development and commercialization of these products.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

In its audit opinion issued in connection with our consolidated balance sheets as of September 30, 2012 and 2011 and our consolidated statements of operations, stockholder's equity and cash flows for the years ended September 30, 2012 and 2011, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern given our recurring net losses, negative cash flows from operations and working capital deficiency. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

We have a history of operating losses and expect to continue to incur substantial losses and may never become profitable.

We have no products approved for commercialization in the United States or abroad. Our drug candidates are still being developed, and all but our AEOL 10150 candidate are still in early stages of development. Our drug candidates will require significant additional development, clinical trials, regulatory clearances or approvals by the FDA and additional investment before they can be commercialized in the United States.

Our likelihood of achieving profitability will depend on numerous factors, including success in:

developing our existing drug candidates and developing and testing new drug candidates;

carrying out our intellectual property strategy;

establishing our competitive position;

achieving third-party collaborations;

receiving regulatory approvals;

manufacturing and marketing products; and

receiving government funding and identifying new government funding opportunities.

Many of these factors will depend on circumstances beyond our control. We may not achieve sufficient revenues for profitability. Even if we do achieve profitability, we may not be able to can sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than we anticipate, or if operating expenses exceed our expectations or cannot be adjusted accordingly, then our business, results of operations, financial condition and cash flows will be materially and adversely affected.

The current turmoil impacting the financial markets and the possibility that financial institutions may consolidate or cease operations has resulted in a tightening in the credit markets, a low level of liquidity in many financial markets and extreme volatility in fixed income, credit, currency and equity markets. As a result, we may not be successful in obtaining sufficient financing on commercially reasonable terms, or at all. Our requirements for additional capital may be substantial and will be dependent on many factors, including the success of our research and development efforts, our ability to commercialize and market products, our ability to successfully pursue our licensing and collaboration strategy, the receipt of government funding, competing technological developments, costs associated with the

protection of our intellectual property and any future change in our business strategy.

As of March 31, 2013, we had an accumulated deficit of $182,469,000 from our research, development and other activities. We have not generated material revenues from product sales and do not expect to generate product revenues sufficient to support us for at least several more years.

Our research and development ("R&D") activities are at an early stage and therefore might never result in viable products.

Our catalytic antioxidant program is in the early stages of development, involves unproven technology, requires significant further R&D and regulatory approvals and is subject to the risks of failure inherent in the development of products or therapeutic procedures based on innovative technologies. These risks include the possibilities that:

- any or all of these proposed products or procedures are found to be unsafe or ineffective or otherwise fail to receive necessary regulatory approvals;
- the proposed products or procedures are not economical to market or do not achieve broad market acceptance;
- third parties hold proprietary rights that preclude us from marketing the proposed products or procedures; and
- third parties market a superior or equivalent product.

Further, the timeframe for commercialization of any product is long and uncertain because of the extended testing and regulatory review process required before marketing approval can be obtained. We may not be able to successfully develop or market any of our proposed products or procedures. If we are not able to successfully market any product, our business will suffer.

If our products are not successfully developed and eventually approved by the FDA, we may be forced to reduce or terminate our operations.

All of our drug candidates are at various stages of development and must be approved by the FDA or similar foreign governmental agencies before they can be marketed. The process for obtaining FDA and foreign regulatory approval is both time-consuming and costly, with no certainty of a successful outcome. This process typically requires extensive preclinical and clinical testing, which may take longer or cost more than we anticipate, and may prove unsuccessful due to numerous factors. Drug candidates that may appear to be promising at early stages of development may not successfully reach the market for a number of reasons. The results of preclinical and initial clinical testing of these drug candidates may not necessarily indicate the results that will be obtained from later or more extensive testing. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials.

Numerous factors could affect the timing, cost or outcome of our drug development efforts, including the following:

- difficulty in securing research laboratories to conduct research activities;
- difficulty in securing centers to conduct trials;
- difficulty in enrolling patients in conformity with required protocols or projected timelines;
- unexpected adverse reactions by patients in trials;

difficulty in obtaining clinical supplies of the product;

changes in the FDA's or other regulatory body's requirements for our testing during the course of that testing;

inability to generate statistically significant data confirming the efficacy of the product being tested;

modification of the drug during testing; and

reallocation of our limited financial and other resources to other clinical programs.

It is possible that none of the products we develop will obtain the regulatory approvals necessary for us to begin commercializing them. The time required to obtain FDA and other approvals is unpredictable but often can take years following the commencement of clinical trials, depending upon the nature of the drug candidate. Any analysis we perform on data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate and we may not have the financial resources to continue to develop our drug candidates and, as a result, may have to terminate our operations.

If we do not reach the market with our products before our competitors offer products for the same or similar uses, or if we are not effective in marketing our products, our revenues from product sales, if any, will be reduced.

We face intense competition in our development activities. Many of our competitors are fully integrated pharmaceutical companies and more established biotechnology companies, which have substantially greater financial, technical, sales and marketing and human resources than we do. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, competitors might develop technologies and products that are less expensive and perceived to be safer or more effective than those being developed by us, which could impair our product development and render our technology obsolete.

We are and expect to remain dependent upon collaborations with third parties for the development of new products, and adverse events involving these collaborations could prevent us from developing and commercializing our drug candidates and achieving profitability.

We currently license from third parties, and do not own, rights under patents and certain related intellectual property for the development of our drug candidates. In addition, we expect to enter into agreements with third parties to license rights to our drug candidates. We might not be able to enter into or maintain these agreements on terms favorable to us, if at all. Further, if any of our current licenses were to expire or terminate, our business, prospects, financial condition and results of operations could be materially and adversely affected.

Our research and development activities rely on technology licensed from third parties, and termination of any of those licenses would result in loss of significant rights to develop and market our products, which would impair our business, prospects, financial condition and results of operations.

We have exclusive worldwide rights to our antioxidant small molecule technology through license agreements with Duke and the NJH. Each license generally may be terminated by the licensor if we fail to perform our obligations under the agreement, including obligations to develop the compounds and technologies under license. If terminated, we would lose the right to develop the products, which could adversely affect our business, prospects, financial condition and results of operations. The license agreements also generally require us to meet specified milestones or show reasonable diligence in development of the technology. If disputes arise over the definition of these requirements or whether we have satisfied the requirements in a timely manner, or if any other obligations in the license agreements are disputed by the other party, the other party could terminate the agreement, and we could lose our rights to develop the licensed technology.

If new technology is developed from these licenses, we may be required to negotiate certain key financial and other terms, such as royalty payments, for the licensing of this future technology with these research institutions, and it might not be possible to obtain any such license on terms that are satisfactory to us, or at all.

We now rely, and will continue to rely, heavily on third parties for product and clinical development, manufacturing, marketing and distribution of our products.

We currently depend heavily and will depend heavily in the future on third parties for support in product development, clinical development, manufacturing, marketing and distribution of our products. The termination of some or all of our existing collaborative arrangements, or our inability to establish and maintain collaborative arrangements, could have a material adverse effect on our ability to continue or complete clinical development of our products.

We rely on contract clinical research organizations ("CROs") for various aspects of our clinical development activities including clinical trial monitoring, data collection and data management. As a result, we have had and continue to have less control over the conduct of clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Although we rely on CROs to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with the investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements.

The third parties on which we rely may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Any failure of such CROs to successfully accomplish clinical trial monitoring, data collection and data management and the other services they provide for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our products and obtain regulatory approval. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and would likely delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

If BARDA opts not to exercise its options under the BARDA Contract, we would be dependent upon grants from NIH for continued development of AEOL 10150 for Lung-ARS, or we would need to curtail our development program in this area significantly and we may be placed at a competitive disadvantage in addressing this market opportunity.

During the fiscal years ended September 30, 2012 and 2011, we received 100% of our revenues from our agreement with BARDA, for the development of AEOL 10150 as a MCM against Lung-ARS. These revenues have funded some of our personnel and other R&D costs and expenses. Pursuant to the BARDA Contract, we received approximately $10.4 million under the base period of the contract and could receive up to an additional approximately $108 million in options through February 2016, if the options are exercised by BARDA, for a total contract value of up to approximately $118.4 million. On April 9, 2012, we announced that BARDA had issued a Notice of Intent to Exercise two options valued at $9.1 million. On April 16, 2012, BARDA exercised the two options. The options include funding for murine and non-human primate efficacy studies in Lung-ARS, good manufacturing practice manufacturing and project management costs. Under the terms of the BARDA Contract, BARDA may elect not to exercise some or all of the additional options. Because a significant portion of our current revenues are generated from the BARDA Contract, if BARDA does not exercise its options under the BARDA Contract, our ability to develop AEOL 10150 as an MCM for Lung-ARS could be negatively impacted, which could harm our competitive position and materially and adversely affect our business, financial condition and results of operations.

Necessary reliance on the "Animal Rule" in conducting trials is time-consuming and expensive.

To obtain FDA approval for our drug candidate for a bioterrorism indication under current FDA regulations, we are required to utilize animal model studies for efficacy and provide animal and human safety data under the "Animal Rule." For many of the biological and chemical threats, animal models are not yet available, and as such we are developing, or will have to develop, appropriate animal models, which is a time-consuming and expensive research effort. Further, we may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these corollaries are difficult to establish and are often unclear. The FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place

restrictions on our ability to commercialize those products. Further, other countries do not, at this time, have established criteria for review and approval of these types of products outside their normal review process; i.e., there is no “Animal Rule” equivalent, and consequently we may not be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the U.S. and internationally have the capability to test animals with radiation, nerve agents, or other lethal biotoxins or chemical agents or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe, cost-effectively or at all.

Even if we succeed in commercializing our drug candidates, we may not become profitable and manufacturing problems or side effects discovered at later stages can further increase costs of commercialization.

Any drugs resulting from our research and development efforts may not become commercially available. Even if we succeed in developing and commercializing our drug candidates, we may never generate sufficient or sustainable revenues to enable us to be profitable. Even if effective, a product that reaches the market may be subject to additional clinical trials, changes to or re-approvals of our manufacturing facilities or a change in labeling if we or others identify side effects or manufacturing problems after a product is on the market. This could harm sales of the affected products and could increase the cost and expenses of commercializing and marketing them. It could also lead to the suspension or revocation of regulatory approval for the products.

We and our contract manufacturing organizations ("CMOs") will also be required to comply with the applicable FDA current good manufacturing practice ("cGMP") regulations. These regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved to supply licensed products to the commercial marketplace. We and our contract manufacturers may not be able to comply with the applicable cGMP requirements and other FDA regulatory requirements. Should we or our contract manufacturers fail to comply, we could be subject to fines or other sanctions or could be prohibited from marketing any products we develop.

Political or social factors may delay or impair our ability to market our products and our business may be materially adversely affected.

Products developed to treat diseases caused by, or to combat the threat of, bioterrorism will be subject to changing political and social environments. The political and social responses to bioterrorism have been unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business. Changes to favorable laws, such as Project BioShield, could have a material adverse effect on our business, prospects, financial condition and results of operations.

Legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and we cannot be certain that any such protection will apply to our products or if applied what the scope of any such coverage will be.

The U.S. Public Readiness Act was signed into law in December 2005 (the "Public Readiness Act") and creates general immunity for manufacturers of countermeasures, including security countermeasures (as defined in Section 319F-2(c)(1)(B) of the Public Readiness Act), when the U.S. Secretary of Health and Human Services issues a declaration for their manufacture, administration or use. The declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. Manufacturers are excluded from this protection in cases of willful misconduct. The Secretary of Health and Human Services may not make declarations that would cover any of our other drug candidates or the U.S. Congress may not act in the future to reduce coverage under the Public Readiness Act or it may repeal it altogether.

Upon a declaration by the Secretary of Health and Human Services, a compensation fund would be created to provide "timely, uniform and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." The "covered injuries" to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. A willful misconduct action could be brought against us if an individual(s) has exhausted his or her remedies under the compensation program, which could thereby expose us to liability. Furthermore, the Secretary of Health and Human Services may not issue a declaration under the Public Readiness Act to establish a compensation fund. We may also become subject to standard product liability suits and other third party claims if products we develop which fall outside of the Public

Readiness Act cause injury or if treated individuals subsequently become infected or otherwise suffer adverse effects from such products.

Healthcare reform measures and other statutory or regulatory changes could adversely affect our business.

The pharmaceutical and biotechnology industries are subject to extensive regulation, and from time to time legislative bodies and governmental agencies consider changes to such regulations that could have significant impact on industry participants. For example, in light of certain highly-publicized safety issues regarding certain drugs that had received marketing approval, the U.S. Congress is considering various proposals regarding drug safety, including some which would require additional safety studies and monitoring and could make drug development more costly. We are unable to predict what additional legislation or regulation, if any, relating to safety or other aspects of drug development may be enacted in the future or what effect such legislation or regulation would have on our business.

The business and financial condition of pharmaceutical and biotechnology companies are also affected by the efforts of governments, third-party payors and others to contain or reduce the costs of healthcare to consumers. In the United States and various foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system, such as proposals relating to the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price) and government control of prescription drug pricing. The pendency or approval of such proposals could result in a decrease in our share price or limit our ability to raise capital or to obtain strategic collaborations or licenses.

The current disruptions in the financial markets could affect our ability to obtain additional debt financing on favorable terms (or at all) and have other adverse effects on us.

The United States credit markets have experienced historic dislocations and liquidity disruptions which have caused financing to be unavailable in many cases and even if available caused spreads on prospective debt financings to widen considerably. These circumstances have materially impacted liquidity in the debt markets, making financing terms for borrowers able to find financing less attractive, and in many cases have resulted in the unavailability of certain types of debt financing. Continued uncertainty in the credit markets may negatively impact our ability to access debt financing on favorable terms or at all. In addition, Federal legislation to deal with the disruptions in the financial markets could have an adverse effect on our financial condition and results of operations.

We will need to enter into collaborative arrangements for the manufacturing and marketing of our drug candidates, or we will have to develop the expertise, obtain the additional capital and invest the resources to perform those functions internally.

We do not have the staff or facilities to manufacture or market any of the drug candidates being developed in our catalytic antioxidant program. As a result, we will need to enter into collaborative arrangements to commercialize, manufacture and market products that we expect to emerge from our catalytic antioxidant program, or develop the expertise within Aeolus. We might not be successful in entering into such third party arrangements on terms acceptable to us, if at all. If we are unable to obtain or retain third-party manufacturing or marketing on acceptable terms, we may be delayed in our ability to commercialize products, which could have a material adverse effect on our business, prospects, financial condition and results of operations. Substantial additional funds and personnel would be required if we needed to establish our own manufacturing or marketing operations. We may not be able to obtain adequate funding or establish these capabilities in a cost-effective or timely manner, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

A failure to obtain or maintain patent and other intellectual property rights would allow others to develop and sell products similar to ours, which could impair our business, prospects, financial condition and results of operations.

The success of our business depends, in part, on our ability to establish and maintain adequate protection for our intellectual property, whether owned by us or licensed from third parties. We rely primarily on patents in the United States and in other key markets to protect our intellectual property. If we do not have adequate patent protection, other companies could develop and sell products that compete directly with ours, without incurring any liability to us. Patent prosecution, maintenance and enforcement on a global basis are time-consuming and expensive, and many of these costs must be incurred before we know whether a product covered by the claims can be successfully developed or marketed.

Even if we expend considerable time and money on patent prosecution, a patent application may never issue as a patent. We can never be certain that we were the first to invent the particular technology or that we were the first to file a patent application for the technology because patent applications in the United States and elsewhere are not typically published for public inspection for at least 18 months from the date when they are filed. It is always possible

that a competitor is pursuing a patent for the same invention in the United States as we are and has an earlier invention date. In some jurisdictions outside of the United States, priority of invention is determined by the earliest effective filing date, not the date of invention. Consequently, if a third party pursues the same invention and has an earlier filing date, patent protection outside the United States would be unavailable to us. Also, outside the United States, an earlier date of invention cannot overcome a date of publication that precedes the earliest effective filing date. Accordingly, the patenting of our proposed products would be precluded outside the United States if a prior publication anticipates the claims of a pending application, even if the date of publication is within a year of the filing of the pending application.

Even if patents issue, the patent claims allowed might not be sufficiently broad to offer adequate protection for our technology against competitive products. Patent protection differs from country to country, giving rise to increased competition from other products in countries where patent coverage is either unavailable, weak or not adequately enforced, if enforced at all. Once a patent issues, we still face the risk that others will try to design around our patent or will try to challenge the validity of the patent. The cost of defending against a challenge to one or more of our patents could be substantial and even if we prevailed, there could be no assurance that we would recover damages.

If a third party were to bring an infringement claim against us, we would incur significant costs in our defense; if the claim were successful, we would need to develop non-infringing technology or obtain a license from the successful patent holder, if available.

Our business also depends on our ability to develop and market products without infringing on the proprietary rights of others or being in breach of our license agreements. The pharmaceutical industry is characterized by a large number of patents, patent filings and frequent and protracted litigation regarding patent and other intellectual property rights. Many companies have numerous patents that protect their intellectual property rights. Third parties might assert infringement claims against us with respect to our drug candidates and future products. If litigation were required to determine the validity of a third party's claims, we could be required to spend significant time and financial resources, which could distract our management and prevent us from furthering our core business activities, regardless of the outcome. If we did not prevail in the litigation, we could be required to pay damages, license a third party's technology, which may not be possible on terms acceptable to us, or at all, or discontinue our own activities and develop non-infringing technology, any of which could prevent or significantly delay pursuit of our development activities.

Protection of trade secret and confidential information is difficult, and loss of confidentiality could eliminate our competitive advantage.

In addition to patent protection, we rely on trade secrets, proprietary know-how and confidential information to protect our technology. We use confidentiality agreements with our employees, consultants and collaborators to maintain the proprietary nature of this technology. However, confidentiality agreements can be breached by the other party, which would make our trade secrets and proprietary know-how legally available for use by others. There is generally no adequate remedy for breach of confidentiality obligations. In addition, the competitive advantage afforded by trade secrets is limited because a third party can independently discover or develop something identical to our own trade secrets or know-how, without incurring any liability to us.

In addition, if our current or former employees, consultants or collaborators were to use information improperly obtained from others (even if unintentional), we may be subject to claims as to ownership and rights in any resulting know-how or inventions.

If we cannot retain or hire qualified personnel or maintain our collaborations, our programs could be delayed and may be discontinued.

As of March 31, 2013, we had five full-time employees. We utilize consultants to assist with our operations and are highly dependent on the services of our executive officers. We do not maintain "key person" life insurance on any of our personnel. We also are dependent on our collaborators for our research and development activities. The loss of key executive officers or collaborators could delay progress in our research and development activities or result in their termination entirely.

We believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific and managerial personnel. We face intense competition for these kinds of personnel from other companies,

research and academic institutions, government entities and other organizations. If we fail to identify, attract and retain personnel, we may be unable to continue the development of our drug candidates, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

We face the risk of product liability claims which could exceed our insurance coverage and deplete our cash resources.

The pharmaceutical and biotechnology industries expose us to the risk of product liability claims alleging that use of our drug candidates caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of pharmaceutical products and may be made directly by patients involved in clinical trials of our products, by consumers or healthcare providers or by organizations selling our products. Product liability claims can be expensive to defend, even if the product did not actually cause the alleged injury or harm.

Insurance covering product liability claims becomes increasingly expensive as a product candidate moves through the development pipeline to commercialization. We have limited product liability insurance coverage for our clinical trials and this coverage may not be sufficient to cover us against some or all potential losses due to liability, if any, or to the expenses associated with defending against liability claims. A product liability claim successfully asserted against us could exceed our insurance coverage, require us to use our own cash resources and have a material adverse effect on our business, financial condition and results of operations.

In addition, some of our licensing and other agreements with third parties require or might require us to maintain product liability insurance. If we cannot maintain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination.

The costs of compliance with environmental, safety and similar laws could increase our cost of doing business or subject us to liability in the event of noncompliance.

Our business is subject to regulation under state and federal laws regarding occupational safety, laboratory practices, environmental protection and the use, generation, manufacture, storage and disposal of hazardous substances. We may be required to incur significant costs in the future to comply with existing or future environmental and health and safety regulations. Our research activities involve the use of hazardous materials, chemicals and radioactive compounds. Although we believe that our procedures for handling such materials comply with applicable state and federal regulations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination, we could be liable for any resulting damages, which could have a material adverse effect on our business, financial condition and results of operations.

We are subject to intense competition that could materially impact our operating results.

We may be unable to compete successfully against our current or future competitors. The pharmaceutical, biopharmaceutical and biotechnology industry is characterized by intense competition and rapid and significant technological advancements. Many companies, research institutions and universities are working in a number of areas similar to our primary fields of interest to develop new products. There also is intense competition among companies seeking to acquire products that already are being marketed. Many of the companies with which we compete have or are likely to have substantially greater research and product development capabilities and financial, technical, scientific, manufacturing, marketing, distribution and other resources than at least some of our present or future strategic partners or licensees.

As a result, these competitors may:

- succeed in developing competitive products sooner than us or our strategic partners or licensees;
- obtain FDA and other regulatory approvals for their products before approval of any of our products;
- obtain patents that block or otherwise inhibit the development and commercialization of our drug candidates;
- develop products that are safer or more effective than our products;
- devote greater resources to marketing or selling their products;

introduce or adapt more quickly to new technologies or scientific advances;

introduce products that render our products obsolete;

withstand price competition more successfully than us or our strategic partners or licensees;

negotiate third-party strategic alliances or licensing arrangements more effectively; or

take advantage of other opportunities more readily.

Currently, there are three drugs approved as radiation protection agents. Amifostine (Ethyol®) is marketed by MedImmune, Inc. for use in reduction of chemotherapy-induced kidney toxicity and radiation-induced xerostomia (damage to the salivary gland). KepivanceTM (palifermin) is marketed by Amgen, Inc. for use in the treatment of severe oral mucositis (mouth sores) in patients with hematologic (blood) cancers. Salagen Tablets (pilocarpine hydrochloride) is marketed by MGI Pharma in the United States as a treatment for the symptoms of xerostomia induced by radiation therapy in head and neck cancer patients. However, there are also many companies working to develop pharmaceuticals that act as a radiation protection agent.

Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will harm our business.

Even if approved for marketing, our products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory approvals for the indications that we are studying;
- the establishment and demonstration in the medical community of the safety, clinical efficacy and cost-effectiveness of our products and their potential advantages over existing therapeutic products;
- marketing and distribution support;
- the introduction, market penetration and pricing strategies of competing and future products; and
- coverage and reimbursement policies of governmental and other third-party payors such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, purchase, utilize or recommend any of our products.

We may be required to make milestone payments and other payments relating to the commercialization of our products.

Our agreements by which we acquired rights to our drug candidates provide for milestone payments by us upon the occurrence of certain regulatory filings and approvals related to the acquired products. In the event that we successfully develop our drug candidates, these milestone payments could be significant. In addition, our agreements require us to pay a royalty interest on worldwide sales. Also, any future license, collaborative or other agreements we may enter into in connection with our development and commercialization activities may require us to pay significant milestone, license and other payments in the future.

We are continually evaluating our business strategy, and may modify this strategy in light of developments in our business and other factors.

We continue to evaluate our business strategy and, as a result, may modify this strategy in the future. In this regard, we may, from time to time, focus our development efforts on different drug candidates or may delay or halt the development of our drug candidates. In addition, as a result of changes in our strategy, we may also change or refocus our existing drug discovery, development, commercialization and manufacturing activities.

Our short-term investments, marketable securities and restricted investments, if any, are subject to certain risks which could materially adversely affect our overall financial position.

We invest our cash in accordance with an established internal policy and customarily in instruments which historically have been highly liquid and carried relatively low risk. However, the capital and credit markets have been experiencing extreme volatility and disruption. Over the past few years, the volatility and disruption have reached unprecedented levels. We maintain a portfolio of investments in short-term investments, marketable debt securities and restricted investments, which are recorded at fair value. Certain of these transactions expose us to credit risk in the event of default of the issuer. To minimize our exposure to credit risk, we invest in securities with strong credit ratings. Should any of our short-term investments, marketable securities or restricted investments lose value or have their liquidity impaired, it could materially and adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing may not be available on commercially attractive terms or at all.

Our insurance policies are expensive and protect us only from some business risks, which could leave us exposed to significant, uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. We currently maintain general liability, property, auto, workers' compensation, products liability, fiduciary and directors' and officers' insurance policies. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. For example, the premiums for our directors' and officers' insurance policy have increased in the past and may increase in the future, and this type of insurance may not be available on acceptable terms or at all in the future. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We may have a limitation on the use of net operating loss carryforwards and tax credits.

Our ability to utilize our net operating loss carryforwards, or NOLs, and tax credits may be limited if we undergo or have undergone an ownership change, as defined in Section 382 of the Internal Revenue Code, as a result of changes in the ownership of outstanding stock. An ownership change generally occurs if the percentage of stock owned by one or more stockholders who own, directly or indirectly, 5% or more of the value of our outstanding stock (or are otherwise treated as 5% stockholders under Section 382 and the regulations promulgated thereunder) has increased by more than 50 percentage points over the lowest percentage of our outstanding stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOLs.

We are exposed to risks if we are unable to comply with changes to laws affecting public companies, including the Sarbanes-Oxley Act of 2002 and the Dodd–Frank Wall Street Reform and Consumer Protection Act of 2010, and also to increased costs associated with complying with such laws.

Laws and regulations affecting public companies in the U.S., including the provisions of the Sarbanes-Oxley Act of 2002 and the Dodd–Frank Wall Street Reform and Consumer Protection Act of 2010, will cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. Delays or a failure to comply with the new laws, rules and regulations could result in enforcement actions, the assessment of other penalties and civil suits. These laws and regulations make it more expensive for us under indemnities provided by us to our officers and directors and may make it more difficult for us to obtain certain types of insurance, including liability insurance for directors and officers; as such, we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, or as executive officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services — all of which could cause our general and administrative costs to increase beyond what we currently have planned.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, coverage and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices, governmental authorities may not find that our business practices comply with current or future administrative or judicial interpretations of potentially applicable laws and regulations. If we fail to comply with any of these laws and regulations, we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate,

restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Risks Related to Our Dependence on U.S. Government Grants and Contracts

Even with the BARDA Contract, we may not be able to fully fund our research and development of AEOL 10150 as a MCM for Lung-ARS.

The BARDA Contract is a cost-plus-fixed-fee reimbursement contract that only reimburses certain specified activities that have been previously authorized by BARDA. Additional activities may be needed and, if so, BARDA may not reimburse us for these activities. Additionally, we have no experience meeting the significant requirements of a federal government contractor, which includes having appropriate accounting, project tracking and earned-value management systems implemented and operational, and we may not be able to meet these requirements in a timely way or at all. Performance under the BARDA Contract requires that we comply with appropriate regulations and operational mandates, with which we have minimal or no operational experience. Our ability to be regularly and fully reimbursed for our activities will depend on our ability to comply and demonstrate compliance with such requirement.

The BARDA Contract award does not guarantee that we will be successful in future clinical trials or that AEOL 10150 will be approved by the FDA.

The BARDA Contract provides a cost-plus-fixed-fee reimbursement opportunity for certain specified clinical and development activities, but we remain fully responsible for conducting these activities. The award of BARDA Contract does not guarantee that any of these activities will be successful. Our inability to be successful with certain key clinical or development activities could jeopardize our ability to obtain FDA approval for AEOL 10150.

Most of our immediately foreseeable future revenues are contingent upon grants and contracts from the U.S. government and we may not achieve sufficient, if any, revenues from these agreements to attain profitability.

For the foreseeable future, we believe our main customer, if any, will be national governments, primarily the U.S. government. We may not receive any grants from national governments. The process of obtaining government contracts is lengthy and uncertain and we will have to compete with other companies for each contract. We may not be awarded any contracts to supply the U.S. or other governments with our drug candidates as such awards may be made, in whole or in part, to our competitors. If the U.S. government makes significant future contract awards for the supply to the U.S. emergency stockpile of a competing product, our business will be harmed and it is unlikely that we will ultimately be able to supply that particular treatment or product to foreign governments or other third parties. Further, changes in government budgets and agendas, or advances by our competitors, may result in a decreased and de-prioritized emphasis on procuring the biodefense products we are developing.

Due to the current economic downturn, the accompanying fall in tax revenues and the U.S. government's efforts to stabilize the economy, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government contract awards or that the government would procure products from us.

The U.S. government's determination to award any contracts may be challenged by an interested party, such as another bidder, at the Government Accountability Office ("GAO") or in federal court. If such a challenge is successful, a contract may be terminated.

The laws and regulations governing procurements of goods and services by the U.S. government provide procedures by which other bidders and other interested parties may challenge the award of a government contract. If we are awarded a government contract, such challenges or protests could be filed even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of goods and services and payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate the contract and reselect bids. The government could even be directed to award a potential contract to one of the other bidders.

Our business may become subject to audit by the U.S. government and a negative audit could adversely affect our business.

U.S. government agencies such as the Defense Contract Audit Agency (the “DCAA”), routinely audit and investigate government contractors. These agencies review a contractor’s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

termination of contracts;

forfeiture of profits;

suspension of payments;

fines; and

suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under these contracts. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively regulate the procurement, formation, administration and performance of government contracts;

the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and Foreign Corrupt Practices Act;

export and import control laws and regulations; and

laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Foreign governments typically also have laws and regulations governing contracts with their respective agencies. These foreign laws and regulations could affect how we conduct business and, in some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to obtain contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

Because we depend on clinical research centers and other contractors for clinical and non-clinical testing, including testing under the "Animal Rule", and for certain research and development activities, the results of our clinical trial, non-clinical animal efficacy studies, and research and development activities are largely beyond our control.

The nature of studies, clinical trials and our business strategy of outsourcing substantially all of our research and development and manufacturing work require that we rely on clinical research centers and other contractors to assist us with research and development, clinical and non-clinical testing (including animal efficacy studies under the "Animal Rule"), patient enrollment and other activities. As a result, our success depends largely on the success of these third parties in performing their responsibilities. Although we prequalify our contractors and believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Furthermore, we have to compete with other biodefense companies for access to this limited pool of highly specialized resources. If our contractors do not perform their obligations in an adequate and timely manner or we are unable to enter into contracts with them because of prior commitments to our competitors, the pace of clinical or non-clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed and our prospects could be adversely affected.

Data obtained from clinical trials is susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

Data already obtained, or obtained in the future, from pre-clinical studies, non-clinical studies and clinical trials does not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the drug candidate, which would result in delays to commercialization and could materially harm our business. Our studies and clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and our proposed drugs may not be approved for marketing.

We may encounter delays or rejections based on additional government regulation from future legislation or administrative action or changes in FDA policy during the period of development, clinical trials and FDA regulatory review. We may encounter similar delays in foreign countries. If any of our products are approved for commercialization, sales of the products outside the U.S. would be subject to foreign regulatory approvals that vary from country to country. The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We may be unable to obtain requisite approvals from the FDA or foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the uses that we request.

Even if we do ultimately receive FDA approval for any of our drug candidates, these drug candidates will be subject to extensive ongoing regulation, including regulations governing manufacturing, labeling, packaging, testing, dispensing, prescription and procurement quotas, record keeping, reporting, handling, shipment and disposal of any such drug. Failure to obtain and maintain required registrations or to comply with any applicable regulations could further delay or preclude development and commercialization of our drugs and subject us to enforcement action.

Unfavorable provisions in government contracts, some of which may be customary, may harm our business, financial condition and operating results.

Government contracts customarily contain provisions that give the government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the government to:

terminate existing contracts, in whole or in part, for any reason or no reason;

unilaterally reduce or modify contracts or subcontracts, including equitable price adjustments;

cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;

decline to exercise an option to renew a contract;

exercise an option to purchase only the minimum amount specified in a contract;

decline to exercise an option to purchase the maximum amount specified in a contract;

claim rights to products, including intellectual property, developed under the contract;

take actions that result in a longer development timeline than expected;

audit and object to the contractor's contract-related costs and fees, including allocated indirect costs;

direct the course of a development program in a manner not chosen by the government contractor;

suspend or debar the contractor from doing business with the government or a specific government agency;

pursue criminal or civil remedies under the False Claims Act and False Statements Act; and

control or prohibit the export of products.

Generally, government contracts contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination.

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

Risks Related to Owning Our Stock

Our principal stockholders own a significant percentage of our outstanding common stock and are, and will continue to be, able to exercise significant influence over our affairs.

As of May 8, 2013, Xmark Opportunity Partners, LLC ("Xmark") possessed voting power over 96,931,944 shares, or 72%, of our outstanding common stock as of such date, through its management of Goodnow Capital, L.L.C. ("Goodnow"), Xmark Opportunity Fund, L.P., Xmark Opportunity Fund, Ltd. and Xmark JV Investment Partners, LLC (collectively, the "Xmark Funds"), and through a voting trust agreement by and among Biomedical Value Fund, L.P., Biomedical Value Fund, Ltd., Xmark and us (the "Xmark voting Trust") with respect to 1,000,000 shares. As a result, Xmark is able to determine a significant part of the composition of our board of directors, holds significant voting power with respect to matters requiring stockholder approval and is able to exercise significant influence over our operations. The interests of Xmark may be different than the interests of other stockholders on these and other matters. This concentration of ownership also could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which could reduce the price of our common stock.

David Cavalier, an employee and our Chairman of the board of directors, is affiliated with Xmark, which possessed voting power of 72% of our outstanding common stock as of May 8, 2013. Accordingly, Mr. Cavalier currently has, and will continue to have, a significant influence over the outcome of all corporate actions requiring stockholder approval.

Our executive officers and directors and holders of greater than five percent of our outstanding common stock, together with entities that may be deemed affiliates of, or related to, such persons or entities, beneficially owned greater than 73.3% of our outstanding common stock as of May 8, 2013. As a result, these stockholders, acting together, may be able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. The interests of our current major stockholders may not always coincide with the

interests of other stockholders and they may take actions to advance their respective interests to the detriment of other stockholders.

We may need to sell additional shares of our common stock, preferred stock or other securities to meet our capital requirements and these future sales could cause dilution and adversely affect our stock price.

Sales of substantial amounts of capital stock, or the perception that such sales could occur, could adversely affect the prevailing market price of the common stock and our ability to raise capital. We may issue additional common stock in future financing transactions or as incentive compensation for our executive management and other key personnel, consultants and advisors. Issuing any equity securities would be dilutive to the equity interests represented by our then-outstanding shares of common stock. The market price for our common stock could decrease as the market takes into account the dilutive effect of any of these issuances.

In the event of the conversion of our preferred stock and exercises of currently outstanding options and warrants, the ownership interests of our current stockholders could be substantially diluted, which would reduce the market price of our common stock and could make it more difficult for us to raise funds in the future.

As of May 8, 2013, we had 134,550,068 shares of common stock outstanding. We may grant to our employees, directors and consultants, options to purchase shares of our common stock under our 2004 Stock Incentive Plan. In addition, as of May 8, 2013, options to purchase 12,145,917 shares were outstanding at exercise prices ranging from $0.23 to $1.85 per share, with a weighted average exercise price of $0.63 per share, and 12,854,083 shares were reserved for issuance under the 2004 Stock Incentive Plan. In addition, as of May 8, 2013, warrants to purchase 17,879,627 shares of common stock were outstanding at exercise prices ranging from $0.258 to $2.50 per share, with a weighted exercise price of $0.29 per share.

In connection with prior collaborations and financing transactions, we also issued 526,080 shares of Series B preferred stock and warrants to purchase 896,037 shares of Series B preferred stock to affiliates of Elan Corporation, plc ("Elan").These securities generally are exercisable and convertible at the option of the Elan affiliates. The conversion of all or a portion of these securities would dilute the ownership interests of our stockholders.

Our common stock is not listed on a national securities exchange, is illiquid and is characterized by low and/or erratic trading volume, and the per share price of our common stock has fluctuated from $0.21 to $1.10 during the last two fiscal years.

Our common stock is quoted on the OTCQB under the symbol "AOLS." An active public market for our common stock is unlikely to develop as long as we are not listed on a national securities exchange. Even if listed, the market for our stock may be impaired because of the limited number of investors, the significant ownership stake of Xmark, and our small market capitalization, which is less than that authorized for investment by many institutional investors.

Historically, the public market for our common stock has been characterized by low and/or erratic trading volume, often resulting in price volatility. For the fiscal year ended September 30, 2012, the average daily trading volume for our common stock was approximately 20,000 shares. Although trading in our common stock increased slightly over the course of fiscal year 2012, we continued to have very light trading activity in our common stock, with the fourth fiscal quarter averaging only approximately 15,000 shares per day. In addition, the price of our common stock has been volatile. Our common stock had a closing price of $0.42 on October 1, 2011 and ended fiscal year 2012 at a closing price of $0.37. During the twelve month period ended September 30, 2012, our common stock had a low closing price of $0.21, which occurred on July 2, 2012, and had a high closing price of $0.48, which occurred on November 4, 2011.

The market price of our common stock is subject to wide fluctuations due to factors that we cannot control, including the results of preclinical and clinical testing of our products under development, decisions by collaborators regarding product development, regulatory developments, market conditions in the pharmaceutical and biotechnology industries, future announcements concerning our competitors, adverse developments concerning proprietary rights, public concern as to the safety or commercial value of any products and general economic conditions.

Furthermore, the stock market has experienced significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations can adversely affect the market price and volatility of our common stock.

If registration rights that we have previously granted are exercised, or if we grant additional registration rights in the future, the price of our common stock may be adversely affected.

Upon receiving notice from Elan, we are obligated to register with the SEC shares of common stock underlying the Series B Convertible Preferred Stock and warrants to purchase Series B Convertible Preferred Stock held by the Elan affiliates. If these securities are registered with the SEC, they may be sold in the open market. We expect that we also will be required to register any securities sold in future private financings. The sale of a significant amount of shares in the open market, or the perception that these sales may occur, could cause the trading price of our common stock to decline or become highly volatile.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue up to 7,150,000 shares of "blank check" preferred stock without stockholder approval. As a result, our board of directors has the power to issue shares without stockholder approval, and such shares can be issued with such rights, preferences, and limitations as may be determined by our board of directors. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of any holders of preferred stock that may be issued in the future. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We do not expect to pay cash dividends on our common stock for the foreseeable future.

We have never paid cash dividends on our common stock and do not anticipate that any cash dividends will be paid on the common stock for the foreseeable future. The payment of any cash dividend by us will be at the discretion of our board of directors and will depend on, among other things, our earnings, capital, regulatory requirements and financial condition. Furthermore, the terms of some of our financing arrangements directly limit our ability to pay cash dividends on our common stock.

We have identified a material weakness in internal controls over financial reporting.

A material weakness is a significant deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As a result of the determination that our diluted net income (loss) per share calculations did not include the net income effect of changes in fair value related to dilutive, liability classified warrants for the fiscal years ended September 30, 2012 and 2011, and the quarterly periods included therein, management has determined that a material weakness in internal controls existed as of September 30, 2012 and led to the restatement discussed at Note K of our Form 10-K/A audited financials for the fiscal years ended September 30, 2012 and 2011. Management believes the weakness is due to a deficiency in technical resources over financial reporting and is evaluating mitigating controls to prevent future misstatements.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, that relate to future events or our future financial performance. You can identify forward-looking statements by terminology such as “may,” “might,” “will,” “could,” “should,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “intend,” “potential” or “continue” or the negative of these or other comparable terminology. Our actual results might differ materially from any forward-looking statement due to various risks, uncertainties and contingencies, including but not limited to those identified in the section entitled “Risk Factors” beginning on page 3 of this prospectus, as well as those discussed in our other filings with the SEC and the following:

- our need for, and our ability to obtain, additional funds;
- our ability to obtain grants to develop our drug candidates;
- uncertainties relating to non-clinical studies, clinical trials and regulatory reviews and approvals;
- uncertainties relating to our pre-clinical trials and regulatory reviews and approvals;
- our dependence on a limited number of therapeutic compounds;
- the early stage of the drug candidates we are developing;
- the acceptance of any future products by physicians and patients;
- competition with and dependence on collaborative partners;
- loss of key consultants, management or scientific personnel;
- our ability to obtain adequate intellectual property protection and to enforce these rights; and
- our ability to avoid infringement of the intellectual property rights of others.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

DESCRIPTION OF THE SHARES INCLUDED IN THIS PROSPECTUS

2013 Private Placement and 2013 Placement Agent Warrants

On February 19, 2013 and March 4, 2013, we entered into a Securities Purchase Agreement, which we refer to as the Purchase Agreement, with certain accredited investors to sell and issue to such investors an aggregate of approximately 14,462,000 units, which we refer to as the 2013 Units, at a purchase price of $0.25 per unit, resulting in aggregate gross proceeds to us of approximately $3.6 million, we refer to this transaction throughout the prospectus as the 2013 private placement. Each 2013 Unit consists of (i) one share of common stock and (ii) a five year warrant to purchase one share of our common stock. The warrants in the 2013 private placement have an initial exercise price of $0.25 per share. In addition, we issued an additional 365,000 warrants to purchase common stock to placement agents for services rendered in connection with the 2013 private placement. The warrants issued to the placement agents are substantially the same as those warrants comprising the 2013 Units, which we refer to as the 2013 Placement Agent Warrants.

One of the investors who participated in the February 19, 2013 closing of the 2013 private placement was JAK Investments, LLC whose managing partner is Joseph Krivulka, who served as a member of our Board of Directors from 2004 to May 8, 2013. JJK Partners purchased 400,000 of the 2013 Units, resulting in aggregate proceeds of $100,000 to us.

In connection with the Purchase Agreement, we entered into a Registration Rights Agreement with the investors who participated in the 2013 private placement, which we refer to as the RRA. Pursuant to the RRA, we agreed to file a registration statement with the SEC, within 45 days from closing to register the resale of the common stock and the shares issuable upon exercise of the warrants issued in the 2013 private placement, which we refer to collectively as the Registrable Securities. We also agreed to use our best efforts to have the registration statement declared effective as promptly as possible after the filing thereof, but in any event within 120 days (180 days if the we receive comments from the SEC) from the filing date. We agreed to keep the registration statement continuously effective until the earlier to occur of (i) the date after which all of the Registrable Securities registered thereunder have been sold and (ii) the date on which all of the Registrable Securities covered by the registration statement may be sold without volume restrictions pursuant to Rule 144 under the Securities Act.

In the event (i) the registration statement has not been filed by the agreed upon filing date, (ii) an acceleration request has not been filed within five trading days of the date which we are notified that the registration statement will not be reviewed by the SEC staff or is not subject to further review and comment by the SEC staff, (iii) the registration statement has not been declared effective by the required effectiveness date, or (iv) sales cannot be made pursuant to such registration statement for any reason (other than by reason of a permissible delay under the terms of the RRA) after the registration statement has been declared effective by the SEC (each such event, a “Registration Default”), then we have agreed to pay each of the investors as liquidated damages an amount equal to 0.5% of the purchase price paid by each such investor with respect to any Registrable Securities then held and not registered pursuant to an effective registration statement, per each 30-day period or portion thereof during which the Registration Default remains uncured thereafter. However, liquidated damages, if any, payable as a result of any Registration Default shall cease to accrue, in any event, after the date that is six (6) months after the closing.

We granted the investors in the 2013 private placement customary indemnification rights in connection with the registration statement. These investors have also granted us customary indemnification rights in connection with the registration statement.

The foregoing description of the 2013 private placement does not purport to be complete and is qualified in its entirety by reference to the Form of Securities Purchase Agreement, the Form of RRA and the Form of warrant for each of the

February 19, 2013 and March 4, 2013 closings of the 2013 private placement, copies of which are attached as Exhibits 10.1, 10.2 and 10.3, respectively, to the Form 8-Ks we filed with the SEC on February 19, 2013 and March 4, 2013, respectively.

Placement Agent Warrants in connection with 2012 Private Placement

In connection with a private placement that closed in March and April 2012, we entered into securities purchase agreements with certain accredited investors in which we issued to the selling stockholders named in this prospectus units consisting of an aggregate of (i) 2,200,166 shares of common stock and (ii) warrants to purchase up to 1,650,126 shares of common stock, which we refer to as the 2012 Private Placement. In connection with the 2012 Private Placement we issued an aggregate of 8,334 warrants to purchase common stock for placement agent services to co-placement agents in the transaction which are being registered hereunder, we refer to these warrants as the 2012 Placement Agent Warrants.

Warrants issued for Consulting Services

This registration statement also includes 1,290,000 shares issuable upon warrants which we issued to the selling stockholders for consulting services rendered to us.

.

USE OF PROCEEDS

All proceeds from the sale of our common stock covered by this prospectus will belong to the selling stockholders who offer and sell their shares. We will not receive any proceeds from the sale of the common stock by the selling stockholders. A portion of the shares covered by this prospectus are issuable upon exercise of warrants to purchase our common stock. Upon any exercise of the warrants for cash, the selling stockholders would pay us the exercise price of the warrants. Under certain conditions set forth in the warrants, the warrants are exercisable on a cashless basis. If any warrants are exercised on a cashless basis, we would not receive any cash payment from the selling stockholders upon any exercise of such warrants.

DETERMINATION OF OFFERING PRICE

This offering is being made solely to allow the selling stockholders to offer and sell shares of common stock to the public. The selling stockholders may offer for resale some or all of their shares at the time and price that they choose. On any given day, the price per share is likely to be based on the quoted price for the common stock on the OTC Bulletin Board on the date of sale, unless shares are sold in private transactions. Consequently, we cannot currently make a determination of the price at which shares offered for resale pursuant to this prospectus may be sold.

MARKET INFORMATION / PRICE RANGE OF COMMON STOCK / DIVIDENDS

Price Range of Common Stock

Our common stock is quoted on the OTC Bulletin Board under the symbol "AOLS." The following sets forth the quarterly high and low trading prices as reported by the OTC Bulletin Board for the periods indicated. These prices are based on quotations between dealers, which do not reflect retail mark-up, markdown or commissions, and do not necessarily represent actual transactions.

	High	Low
Fiscal Year Ending September 30, 2011		
October 1, 2010 through December 31, 2010	$0.70	$0.37
January 1, 2011 through March 31, 2011	$1.10	$0.46
April 1, 2011 through June 30, 2011	$0.71	$0.31
July 1, 2011 through September 30, 2011	$0.53	$0.36
Fiscal Year Ending September 30, 2012		
October 1, 2011 through December 31, 2011	$0.55	$0.30
January 1, 2012 through March 31, 2012	$0.41	$0.30
April 1, 2012 through June 30, 2012	$0.41	$0.21
July 1, 2012 through September 30, 2012	$0.44	$0.21
Fiscal Year Ending September 30, 2013		
October 1, 2012 through December 31, 2012	$0.39	$0.23
January 1, 2013 through March 31, 2013	$0.47	$0.26
April 1, 2013 through May 8, 2013	$0.47	$0.30

On May 8, 2013, the last reported sales price of our common stock on the OTC Bulletin Board was $0.44 per share.

Approximate Number of Equity Security Holders

As of May 8, 2013 the number of record holders of our common stock was 108, and we estimate that the number of beneficial owners was approximately 4,000.

Dividend Policy

We have never paid a cash dividend on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future.

Moreover, any additional preferred stock to be issued and any future credit facilities might contain restrictions on our ability to declare and pay dividends on our common stock. We plan to retain all earnings, if any, for the foreseeable future for use in the operation of our business and to fund future growth.

25

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to our financial statements included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this prospectus.

Operations Summary

Business

Aeolus Pharmaceuticals, Inc. is a biopharmaceutical company that is developing a platform of a new class of broad-spectrum, catalytic antioxidant compounds based on technology discovered at Duke University and National Jewish Health. These compounds, known as metalloporphyrins, scavenge reactive oxygen species ("ROS") at the cellular level, mimicking the effect of the body's own natural antioxidant enzyme, superoxide dismutase. While the benefits of antioxidants in reducing oxidative stress are well-known, research with our compounds indicates that metalloporphyrins can be used to affect signaling via ROS at the cellular level. In addition, there is evidence that high-levels of ROS can affect gene expression and this may be modulated through the use of metalloporphyrins. We believe this could have a profound beneficial impact on people who have been exposed, or are about to be exposed, to high-doses of radiation, whether from cancer therapy or a nuclear event.

Our lead compound, AEOL 10150, is a metalloporphyrin specifically designed to neutralize reactive oxygen and nitrogen species. The neutralization of these species reduces oxidative stress, inflammation, and subsequent tissue damage-signaling cascades resulting from radiation exposure. We are developing AEOL 10150 in both oncology and as a medical countermeasure for high-dose radiation exposure.

We are developing AEOL 10150 as a medical countermeasure against the pulmonary effects of radiation exposure ("Lung-ARS") under a contract valued at up to $118.4 million with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Department of Health and Human Services. Additionally, we receive development support from the National Institutes of Health for development of the compound as a medical countermeasure against radiation and chemical exposure.

On February 11, 2011, we signed an agreement with BARDA for the development of AEOL 10150 as a medical countermeasure against the pulmonary sub-syndrome of acute radiation syndrome (the "BARDA Contract"), pursuant to which we will receive $10.4 million from BARDA in the base period of performance and up to an additional $108 million in options exercisable over four years following the base period of performance, if the options are exercised by BARDA for a contract value of up to $118.4 million. On April 16, 2012, we announced that BARDA had exercised two contract options worth approximately $9.1 million. The bulk of the options are for the period of performance beginning April 1, 2012 and ending September 30, 2013.

We are leveraging the significant investment made by U.S. government agencies to develop this novel compound for use in oncology indications, where it would be used in combination with radiation and chemotherapy. Data have been published showing that AEOL 10150 not only does not interfere with the therapeutic benefit of radiation therapy in prostate and lung cancer preclinical studies, but also helps increase tumor control when used in combination with radiation and chemotherapy. Oxidative stress is a more potent stabilizer of the pro-angiogenic transcription factor, HIF-1a, than hypoxia (Dewhirst et al., Cycling hypoxia and free radicals regulate angiogenesis and radiotherapy

response, Nature Reviews, Volume 8, June 2008). By reducing oxidative stress, AEOL10150 suppresses HIF-1a stabilization, thereby improving tumor vascularization and tissue oxygenation. Poorly perfused/oxygenated tumor tissue is resistant to radiation as oxygen is required for radiation-induced cell kill. Thus, by improving tumor oxygenation, AEOL10150 improves impact of radiation on tumors. Radiotherapy is a key therapy in non-small cell lung cancer. It is the treatment of choice for patients with unresectable Stage I-II disease, and is recommended, in combination with chemotherapy, for patients with unresectable stage IIIB disease (Pipeline Insight: Cancer Overview – Lung, Brain, Head and Neck, Thyroid; Datamonitor 2008, 37.).

NIAID's Radiation/Nuclear Medical Countermeasures development program is currently testing AEOL 10150 as a countermeasure for GI-ARS caused by exposure to high levels of radiation due to a radiological or nuclear event. Similarly, the NIH's Countermeasures Against Chemical Threats ("CounterACT") program has tested, and continues to test, AEOL 10150 as a medical countermeasure for exposure to chemical vesicants such as chlorine gas, phosgene gas and mustard gas for exposure to nerve agents.

AEOL 10150 has already performed well in animal safety studies, been well-tolerated in two human clinical safety studies, demonstrated efficacy in two species in acute radiation syndrome ("ARS") studies and demonstrated statistically significant survival efficacy in an acute radiation-induced lung injury model. AEOL 10150 has also demonstrated efficacy in validated animal models for GI-ARS, chlorine gas exposure, and sulfur mustard gas exposure. Efficacy has been demonstrated in Lung-ARS in both mouse and non-human primate studies ("NHP"), with AEOL 10150 treated groups showing significantly reduced weight loss, inflammation, oxidative stress, lung damage, and most importantly, mortality in the mouse study. Therapeutic efficacy was demonstrated when delivered after exposure to radiation (24 hours after exposure for mice in the GI-ARS study and NHPs in the Lung-ARS studies, and two hours after exposure for mice in the Lung-ARS studies). Additionally, AEOL 10150 was shown to reduce lung damage after Neupogen® treatment (current standard of care for H-ARS) following radiation exposure, and to reduce oxidative stress and nerve damage following exposure to nerve agents.

We have an active Investigational New Drug Application ("IND") on file with the U.S. Food and Drug Administration (the "FDA") for AEOL 10150 as a potential treatment for amyotrophic lateral sclerosis ("ALS"). We plan to file an IND for cancer with the oncology division of the FDA as well as with the Division of Medical Imaging Products for Lung-ARS. Extensive toxicology and pharmacology packages are already in place. We have already completed two Phase 1 safety studies in 50 humans demonstrating the drug to be safe and well tolerated. Chemistry, Manufacturing, and Controls work has been completed, and pilot lots have been prepared. At the current time, we have no plans to conduct further clinical trials in ALS.

We have two programs underway for the development of our second drug candidate, AEOL 11207, for the treatment of epilepsy and Parkinson's disease. These programs are being funded, in part, by private foundations, including the Michael J. Fox Foundation and Citizens United for Research in Epilepsy ("CURE"), and government grants. In February 2011, data were published in the Journal Neurobiology of Disease from the CURE study indicating AEOL 11207 significantly reduced both the frequency and duration of spontaneous seizures in a pre-clinical epilepsy model. Additionally, the study showed an increase in average life span, protection against neuronal death and no difference in seizure severity.

We were incorporated in the State of Delaware in 1994. Our common stock trades on the OTCQB Board under the symbol "AOLS." Our principal executive offices are located at 26361 Crown Valley Parkway, Suite 150 Mission Viejo, California 92691, and our phone number at that address is (949) 481-9825. Our website address is www.aeoluspharma.com. However, the information on, or that can be accessed through, our website is not part of this report. We also make available free of charge through our website our most recent annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC.

We do not generate revenue from sales, only from development contracts and grants from the U.S. government. Therefore, we must rely on public or private equity offerings, debt financings, collaboration arrangements or grants to finance our operations. Our strategy is to use non-dilutive capital wherever possible to develop our exciting platform of broad-spectrum catalytic antioxidant compounds in important unmet indications of national strategic importance. We plan to continue to leverage that capital, like the investments made by U.S. government agencies, such as the NIAID's and NIH's CounterACT program, in AEOL 10150 as a medical countermeasure, to concurrently develop these promising compounds for use in significant unmet medical indications, like oncology. We are currently doing this with AEOL 10150, where we are developing the compound as a medical countermeasure against the pulmonary sub-syndrome of acute radiation syndrome under the BARDA Contract.

BARDA Contract

On February 11, 2011, we signed the BARDA Contract. Pursuant to the BARDA Contract, we were awarded approximately $10.4 million in the base period of the contract. On April 16, 2012, we announced that BARDA had exercised two options under the BARDA Contract worth approximately $9.1 million, bringing the total exercised contract value to date to approximately $19.5 million. We may receive up to an additional $98.9 million in options exercisable over the years following the base period. If all of the options are exercised by BARDA, the total value of the contract would be approximately $118.4 million. Once the EUA is filed, it would be possible for BARDA to begin procuring AEOL 10150 for the strategic national stockpile. Procurements from BARDA may result in significant revenues, and profitability, for Aeolus

We recognized approximately $859,000 and $2,201,000 during the three and six months ended March 31, 2013 related to the BARDA Contract.

Activities conducted during the base period and options exercised by BARDA to date included developing animal models with radiation survival curve studies, dosing studies, bulk drug manufacturing, final drug product manufacturing, validation testing, compliance studies and preparation of the filing of IND, an orphan drug status application and a fast track designation application with the FDA. In the event BARDA exercises additional options to provide additional funding under the BARDA Contract, activities to be conducted would include, among other things, bulk drug and final drug product manufacturing, stability studies, animal pivotal efficacy studies, human clinical safety studies and Phase I, Phase II and pre-new drug application ("NDA") meetings and applications with the FDA.

Following the commencement of the BARDA Contract, we entered into a series of agreements with various parties in furtherance of our efforts under the BARDA Contract, which are described in this paragraph. On February 18, 2011, we entered into a Research and Manufacturing Agreement with Johnson Matthey Pharmaceutical Materials, Inc. (d/b/a Johnson Matthey Pharma Services) ("JMPS"), pursuant to which we engaged JMPS to, among other things, assess and develop a reliable separations or manufacturing process for certain chemical compounds as required by us and to perform such additional work as may be required or agreed upon by the parties and to manufacture compounds for us. Each project performed by JMPS under the agreement will have a detailed project description and separate fee agreement based on the nature and duration of the project and the specific services to be performed by JMPS. The term of the agreement with JMPS will continue until February 16, 2016 or the date on which all projects under the agreement have been completed or terminated. On February 23, 2011, we and Booz Allen Hamilton Inc. ("Booz Allen") entered into a General Management Consulting Assignment, pursuant to which we engaged Booz Allen to, among other things, provide us with evaluation, operational and transitional support during the establishment and enhancement of our quality assurance, document management, earned value management and program management systems. We have agreed to pay Booz Allen on a time-and-materials basis. On March 16, 2011, we and the Office of Research and Development of the University of Maryland, Baltimore ("UMB") entered into a Sub-award Agreement, pursuant to which we engaged UMB to, among other things, develop a whole thorax lung irradiation model for use in studies supporting the licensure of AEOL 10150. The Sub-award Agreement is a fixed fee agreement inclusive of all direct and indirect costs. As a result of the contract modification and no-cost extension with BARDA mentioned below, the term of the Sub-award Agreement will continue through at least September, 2013. On April 12, 2011, we and Duke University ("Duke") entered into a Sponsored Research Agreement (Non-Clinical), pursuant to which we engaged Duke to perform a program of scientific research entitled "Murine Studies for the Development of AEOL 10150 as a Medical Countermeasure Against ARS and DEARE" (Delayed Effects of Acute Radiation Exposure), which will include, among other things, studies and models of optimum dosing of AEOL 10150 in mice. We entered into the Sponsored Research Agreement in furtherance of our efforts under the BARDA Contract. The Sponsored Research Agreement is a cost plus fee agreement inclusive of all direct and indirect costs.

On February 14, 2012, the Aeolus team presented the results and deliverables that had been produced during the first twelve months under the base period of the BARDA Contract at an "In-Progress Review" meeting with BARDA, and requested the exercise of additional contract options, which contain additional key items required in the advanced development of AEOL 10150.

On February 15, 2012, we announced that we entered into a contract modification and no-cost extension with BARDA. The modification and extension allowed us to continue operating under the base period of the contract awarded in February 2011, and restructured the timing and components of the options that could be awarded under the remaining four years of the agreement. The changes did not impact the total potential value of the contract, which remains at approximately $118.4 million. The contract restructure was driven by our ability to generate cost savings in

the base year contract and to allow BARDA to better manage contract options to expedite the development program.

On April 16, 2012, we announced that BARDA had exercised two contract options worth approximately $9.1 million. BARDA's exercise of the options was in response to the presentation of the deliverables and progress made under the contract at the meeting on February 14, 2012. Among the key items in the options BARDA exercised are animal efficacy studies, mechanism of action research and manufacturing and process validation work. All of these items build off of work successfully completed during the contract base period. The contract is designed to produce the data necessary for an approval under the FDA "Animal Rule" and for a potential EUA. An approval or EUA would allow the federal government to buy AEOL 10150 for the Strategic National Stockpile under Project Bioshield. Project Bioshield is designed to accelerate the research, development, purchase and availability of effective medical countermeasures for the Strategic National Stockpile

Since February 11, 2011, we have been actively developing AEOL 10150 under the BARDA Contract. Among the key deliverables accomplished in the program, we hired the necessary personnel required under the contract, completed the radiation dose studies in mice and NHPs, manufactured a GMP batch for use in human safety studies and a non-GMP batch of material for use in animal efficacy studies, developed significant improvements to the process for manufacturing compound which will reduce the cost of producing the drug; made several discoveries related to the mechanism of damage of radiation and mechanism of action of AEOL 10150; met twice with the FDA to discuss our IND filing for Lung-ARS; and designed and initiated quality, reporting, risk management and project management programs required under the BARDA Contract. We have also initiated a number of animal efficacy studies for which we expect to report data during 2013.

Duke Licenses

Pursuant to our license agreements with Duke University ("Duke"), we have obtained exclusive worldwide rights from Duke to products using antioxidant technology and compounds developed by Dr. Irwin Fridovich and other scientists at Duke. We are obligated under the licenses to pay Duke royalties ranging in the low single digits of net product sales during the term of the Duke licenses, and we must make payments upon the occurrence of certain development milestones in an aggregate amount of up to $2,000,000. In addition, we are obligated under the Duke licenses to pay patent filing, prosecution, maintenance and defense costs. The Duke licenses are terminable by Duke in the event of breach by us and otherwise expire when the last licensed patent expires.

National Jewish Medical and Research Center License

We have obtained an exclusive worldwide license from the NJMRC to develop, make, use and sell products using proprietary information and technology developed under a previous Sponsored Research Agreement within the field of antioxidant compounds and related discoveries. We must make milestone payments to the NJMRC in an aggregate amount of up to $250,000 upon the occurrence of certain development milestones. Our royalty payment obligations to the NJMRC under this license agreement are in the low single digits of net product sales. We are also obligated to pay patent filing, prosecution, maintenance and defense costs. This NJMRC license agreement is terminable by the NJMRC in the event of breach and otherwise expires when the last licensed patent expires.

National Jewish Health License

In 2009, we obtained an additional exclusive worldwide license from National Jewish Health ("NJH") to develop, make, use and sell products using proprietary information and technology developed at NJH related to certain compounds as a medical countermeasure against mustard gas exposure. Under this license agreement, we must make milestone payments to NJH in an aggregate amount of up to $500,000 upon the occurrence of certain development milestones. In addition, we must make royalty payments to NJH under this license agreement ranging in the low-single digits as a percentage of all sublicensing fees, milestone payments and sublicense royalties that we receive from sublicenses granted by us pursuant to this license agreement. We are also obligated to pay patent filing, prosecution, maintenance and defense costs. This NJH license agreement is terminable by NJH in the event of breach and otherwise expires when the last licensed patent expires.

Our lead compound, AEOL 10150, is expected to enter human clinical trials in oncology, where it will be used in combination with radiation therapy. AEOL 10150 has previously been tested in two Phase I clinical trials with no serious adverse events reported. The compound is also being developed as a medical countermeasure against Lung-ARS as well as GI-ARS, both caused by exposure to radiation due to a radiological or nuclear event. It is also being developed for use as a countermeasure for exposure to chemical vesicants such as chlorine gas and sulfur mustard gas. AEOL 10150 has already performed well in animal efficacy and safety studies in each of these potential indications. A significant portion of the funding for the medical countermeasure development programs to date has

come from various government entities. Although we expect this funding to continue, there is no guarantee that it will.

February/March 2013 Financing

On February 19, 2013 and March 4, 2013, we entered into Securities Purchase Agreements (the “Purchase Agreements”) with certain accredited investors (the “Purchasers”). Under the terms of the agreements, we received $3,616,000 in gross proceeds in exchange for the issuance of an aggregate of approximately 14,462,000 units (the “Units”), consisting of 14,462,000 shares of common stock and 14,462,000 warrants, at a purchase price of $0.25 per unit. Each Unit consists of (i) one share of common stock (the “Common Shares”) and (ii) a five year warrant to purchase one share of our common stock (the “Warrants”). The Warrants have an initial exercise price of $0.25 per share.

On February 19, 2013, we received $3,225,000 in gross proceeds in exchange for the issuance of an aggregate of 12,900,000 Units, which consisted of 12,900,000 shares of common stock and 12,900,000 warrants.

On March 4, 2013, we received $390,000 in gross proceeds in exchange for the issuance of an aggregate of approximately 1,562,000 Units, which consisted of 1,562,000 shares of common stock and 1,562,000 warrants.

Net cash proceeds from the February/March 2013 Financing, after deducting for expenses, were approximately $3,558,000We also incurred non-cash expenses in the form of 365,000 warrants issued to consultants, at similar terms as the financing Warrants, for services provided. We issued a total of 14,827,000 warrants as of March 31, 2013 in connection with the February/March 2013 Financing.

The fair value of the February/March Financing warrants was estimated to be $4,791,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 154.84%, risk free interest rate of 0.87% and an expected life of five years. The proceeds from the February/March 2013 Financing were allocated based upon the relative fair values of the February/March 2013 Financing Warrants and the February/March 2013 Common Shares.

Results of Operations

Three months ended March 31, 2013 versus three months ended March 31, 2012

We had net loss of $5,782,000 (including a non-cash adjustment for increases in valuation of liability classified warrants of $5,020,000) and net income of $2,763,000 (including a non-cash gain for decreases in valuation of liability classified warrants of $3,324,000), and cash outflows from operations of $1,634,000 and $1,181,000 for the three months ended March 31, 2013 and March 31, 2012, respectively.

Revenue for the three months ended March 31, 2013 was $859,000, which compares to $2,231,000 in revenue for the three months ended March 31, 2012. The decrease is primarily attributable to decreased level of development work in progress under the BARDA Contract as of March 31, 2013 compared to March 31, 2012.

Research and Development

Research and Development ("R&D") expenses decreased $1,309,000, or 68%, to $618,000 for the three months ended March 31, 2013 from $1,927,000 for the three months ended March 31, 2012. The decrease is primarily attributable to work related to the BARDA Contract. R&D expenses for our antioxidant program have totaled $51,201,000 from inception through March 31, 2013. We currently have ten development programs in progress: studies of AEOL 10150 as a medical countermeasure against the effects of sulfur mustard gas, phosgene gas, chlorine gas on the lungs, against the effects of radiation on the lungs and on the gastro-intestinal tract, against the effects of nerve agents, and as a treatment for cancer, studies of AEOL 11207 and several other compounds as potential treatments for Parkinson's disease and epilepsy, and a study of Hexyl as protectant against radiation exposure. Because of the uncertainty of our research and development and clinical studies, we are unable to predict the total level of spending on the program or the program completion date. We expect R&D expenses during fiscal year 2013 will be similar to fiscal year 2012.

General and Administrative

General and administrative ("G&A") expenses increased $138,000, or 16%, to $1,003,000 for the three months ended March 31, 2013 from $865,000 for the three months ended March 31, 2012. Consulting stock expense increased by $83,000 due to additional warrants issued for consulting services associated with the financings during the three months ended March 31, 2013.

Six months ended March 31, 2013 versus six months ended March 31, 2012

We had net loss of $1,755,000 (including a non-cash adjustment for increases in valuation of liability classified warrants of $510,000) and net income of $5,740,000 (including a non-cash gain for decreases in valuation of liability classified warrants of $7,012,000), and cash outflows from operations of $1,913,000 and cash outflows from operations of $513,000 for the six months ended March 31, 2013 and March 31, 2012, respectively.

Revenue for the six months ended March 31, 2013 was $2,201,000, which compares to $4,446,000 revenue for the six months ended March 31, 2012. The decrease is primarily attributable to a decreased level of development work in progress under the BARDA contract as of March 31, 2013 compared to March 31, 2012.

Research and Development

Research and Development ("R&D") expenses decreased $2,211,000, or 55%, to $1,787,000 for the six months ended March 31, 2013 from $3,998,000 for the six months ended March 31, 2012. The decrease is primarily attributable to a decreased level of development work in progress under the BARDA contract as of March 31, 2013 to March 31, 2012.

General and Administrative

General and administrative ("G&A") expenses decreased $61,000, or 4%, to $1,659,000 for the six months ended March 31, 2013 from $1,720,000 for the six months ended March 31, 2012. The decrease is primarily due to a decrease in consulting stock expense of $39,000 and a decrease in salaries and wages of $32,000 six months ended March 31, 2013.

Fiscal Year Ended September 30, 2012 Compared to Fiscal Year Ended September 30, 2011

We had net income of $1,698,000 (including a non-cash gain for decreases in valuation of warrants of approximately $4,069,000) for the fiscal year ended September 30, 2012, versus net income of $299,000 (including a non-cash gain for decreases in valuation of warrants of $3,887,000) for the fiscal year ended September 30, 2011.

Revenue for the fiscal year ended September 30, 2012 was approximately $7,293,000, compared to $4,821,000 revenue for the fiscal year ended September 30, 2011. The revenue is from the collaboration with BARDA announced on February 11, 2011. Since being awarded the BARDA Contract, we generate contract revenue from a cost-plus fee arrangement. Revenues on reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. We consider fixed fees under cost-plus fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract.

Research and Development

Research and development expenses increased by $1,413,000, or 28%, to approximately $6,468,000 for the fiscal year ended September 30, 2012 from approximately $5,055,000 for the fiscal year ended September 30, 2011. R&D expenses were higher during the fiscal year ended September 30, 2012 versus September 30, 2011 due to work related to the BARDA Contract. For the fiscal year ended September 30, 2012, consultant expenses increased by $626,000 due to costs associated with the BARDA Contract. Preclinical fees increased about $202,000 over the comparable period in 2011 due to increased animal studies to support our ARS development program. The increase also reflected production and development of AEOL 10150 for planned upcoming BARDA studies, for which manufacturing expenses increased about $590,000. We currently have eight development programs in progress: studies of AEOL 10150 as a medical countermeasure against the effects of sulfur mustard gas and chlorine gas on the lungs, against the effects of radiation on the lungs and on the gastro-intestinal tract, and as a treatment for cancer, studies of AEOL 11207 and several other compounds as potential treatments for Parkinson’s disease and epilepsy, and a study of Hexyl as protectant against radiation exposure.

R&D expenses for our antioxidant program have totaled approximately $48,723,000 from inception through September 30, 2012. Because of the uncertainty of our research and development and clinical studies, we are unable to predict the total level of spending on the program or the program completion date. However, we expect R&D expenses during fiscal year 2013 will be comparable to fiscal 2012 since we will continue development under the BARDA Contract. We anticipate that much of the R&D spending should be reimbursed under that contract.

General and Administrative

General and administrative (“G&A”) expenses include corporate costs required to support Aeolus, our employees and consultants and our stockholders. These costs include personnel and outside costs in the areas of legal, human resources, investor relations and finance. Additionally, we include in general and administrative expenses such costs as rent, repair and maintenance of equipment, depreciation, utilities, information technology and procurement costs that we need to support the corporate functions listed above.

G&A expenses decreased approximately $472,000, or 13%, to approximately $3,196,000 for the fiscal year ended September 30, 2012 from about $3,668,000 for the fiscal year ended September 30, 2011. Consulting fees decreased by about $456,000 due to shifting some contractors to employees. As a result, the decrease in consulting fees was partially offset by an increase in salaries and wages of about $304,000. Consulting stock expense decreased by about $356,000 as a result of fewer awards and a lower stock price for the period.

Other Income or Expense

As previously disclosed, certain of our warrants to purchase common stock were deemed to be a liability upon adoption of a new accounting pronouncement on October 1, 2009. Subsequent changes to the fair market value resulted in an offsetting gain in the statements of operations of approximately $4,069,000 for the fiscal year ended September 30, 2012, as compared to approximately $3,887,000 for the fiscal year ended September 30, 2011. The warrant liability and revaluations have not and will not have any impact on our working capital, liquidity or business

operations.

Fiscal Year Ended September 30, 2011 Compared to Fiscal Year Ended September 30, 2010

We had net income of $299,000 (including a non-cash gain for decreases in valuation of warrants of approximately $3,887,000) for the fiscal year ended September 30, 2011, versus a net loss of $25,869,000 (including a non-cash charge for increases in valuation of warrants of $21,347,000) for fiscal year ended September 30, 2010.

Revenue for the fiscal year ended September 30, 2011 was approximately $4,821,000, which compares to zero revenue for the fiscal year ended September 30, 2010. The revenue is from the collaboration with BARDA announced on February 11, 2011. Since being awarded the BARDA Contract, we generate contract revenue from a cost-plus fee arrangement. Revenues on reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. We consider fixed fees under cost-plus fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract.

Research and Development

Research and development expenses increased by about $3,365,000, or 199%, to approximately $5,055,000 for the fiscal year ended September 30, 2011 from approximately $1,690,000 for the fiscal year ended September 30, 2010. R&D expenses were higher during the fiscal year ended September 30, 2011 versus September 30, 2010 due to work related to the BARDA Contract. For the fiscal year ended September 30, 2011, consultant expenses increased by about $264,000 due to costs associated with the aforementioned consultant. Preclinical fees increased about $1,907,000 over the comparable period in 2010 due to increased animal studies to support our ARS development program. The increase also reflected the initiation of production of a compound for oncology studies anticipated that began in fiscal year 2011, for which manufacturing expenses increased about $1,118,000. We currently have eight development programs in progress: studies of AEOL 10150 as a medical countermeasure against the effects of sulfur mustard gas and chlorine gas on the lungs, against the effects of radiation on the lungs and on the gastro-intestinal tract, and as a treatment for cancer, studies of AEOL 11207 and several other compounds as potential treatments for Parkinson’s disease and epilepsy, and a study of Hexyl as protectant against radiation exposure.

R&D expenses for our antioxidant program have totaled approximately $42,255,000 from inception through September 30, 2011. Because of the uncertainty of our research and development and clinical studies, we are unable to predict the total level of spending on the program or the program completion date. However, we expect R&D expenses during fiscal year 2012 will be higher than fiscal 2011 since we have been awarded the BARDA Contract. We anticipate that much of the increase in R&D spending should be reimbursed under that contract.

General and Administrative

General and administrative (“G&A”) expenses include corporate costs required to support our company, our employees and consultants and our stockholders. These costs include personnel and outside costs in the areas of legal, human resources, investor relations and finance. Additionally, we include in general and administrative expenses such costs as rent, repair and maintenance of equipment, depreciation, utilities, information technology and procurement costs that we need to support the corporate functions listed above.

G&A expenses increased approximately $1,714,000, or 88%, to approximately $3,668,000 for the fiscal year ended September 30, 2011 from about $1,954,000 for the fiscal year ended September 30, 2010. Salaries and wages increased by about $646,000 due to the addition of a Chief Financial Officer, a Vice President of Manufacturing, a Director of Quality Assurance and Quality Control, and Corporate Controller. Consulting stock expense increased by about $422,000 as a result of the hiring of the aforementioned staff and also due to decreased stock compensation activity in the prior comparable period. Investor relations expenses increased by $118,000, due to increased IR-related activities performed by outside consultants. Legal fees increased by $143,000 as a result of higher reliance on our outside legal counsel for review and compliance related to SEC filings during the current quarter, as well as the review of the BARDA Contract and related contracts.

Other Income or Expense

We incurred interest expense of approximately $21,000 for the fiscal year ended September 30, 2011 compared to interest expense of about $878,000 for the fiscal year ended September 30, 2010. Interest expense in fiscal year 2011 reflects about $21,000 incurred by the second quarter of fiscal year 2011, due to conversion of the Elan note payable compared to the conversion of the Senior Convertible Notes during the prior comparable period.

As previously disclosed, certain of our warrants to purchase common stock were deemed to be a liability upon adoption of a new accounting pronouncement on October 1, 2009. Subsequent changes to the fair market value resulted in an offsetting gain in the statements of operations of approximately $3,887,000 for the fiscal year ended September 30, 2011, as compared to approximately $21,347,000 for the fiscal year ended September 30, 2010. The warrant liability and revaluations have not and will not have any impact on our working capital, liquidity or business operations.

Liquidity and Capital Resources

We had cash and cash equivalents of $1,926,000 on March 31, 2013, and $281,000 on September 30, 2012. The increase in cash was primarily due to the net impact of cash used in operations and cash raised in the February/March 2013 Financing. We had accounts receivable of $1,620,000 on March 31, 2013, and $882,000 on September 30, 2012. We had accounts payable of $2,023,000 on March 31, 2013, and $2,272,000 on September 30, 2012. The decrease was primarily due to the payoff of accounts due after receipt of funds from the February/March 2013 Financing.

We had net loss of $1,755,000 (including a non-cash adjustment for increases in valuation of liability classified warrants of $510,000) for the six months ended March 31, 2013. We had cash outflows from operations of $1,913,000. We expect to incur additional losses and negative cash flow from operations during the remainder of fiscal year 2013 and potentially for several more years.

On February 11, 2011, we were awarded the BARDA Contract to fund the development of AEOL 10150 as a medical countermeasure for Lung-ARS from its current status to FDA approval in response to Special Instructions Amendment 4 to a Broad Agency Announcement (BAA-BARDA-09-34) for advanced research and development of medical countermeasures for chemical, biological, radiological and nuclear threats. The contract value could be up to $118.4 million depending on options exercised by BARDA and the requirements for approval by the FDA. Under the BARDA Contract, substantially all of the costs of the development of AEOL 10150 as a medical countermeasure for pulmonary injuries resulting from an acute exposure to radiation from a radiological/nuclear accident or attack, particularly injuries associated with ARS or Delayed Effects of Acute Radiation Exposure would be paid for by the U.S. government through BARDA funding. We recognized $2,201,000 in revenue during the six months ended March 31, 2013 related to the BARDA Contract. The BARDA Contract includes provisions to cover some, but not all, general corporate overhead as well as a small provision for profit. The net impact of the contract on our liquidity is that our projected cash burn has been reduced. Certain costs, typically those of being a public company, like legal costs associated with being a public company, IR/PR costs and patent-related costs, are not included in overhead reimbursement in the BARDA Contract.

We do not have any revenues from product sales and, therefore, we rely on investors, grants, collaborations and licensing of our compounds to finance our operations. We generate limited revenue from reimbursable, cost-plus R&D contracts and grants. Revenues on reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. We consider fixed fees under cost-plus fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract.

Since the terms of the BARDA Contract include provisions to cover some general corporate overhead as well as a small provision for profit, the result on our liquidity is that our projected cash burn has been reduced. In order to fund on-going operating cash requirements or to accelerate or expand our oncology and other programs we may need to raise significant additional funds.

We have incurred significant losses from operations to date. Our ongoing future cash requirements will depend on numerous factors, particularly the progress of our catalytic antioxidant program, potential government procurements for the national stockpile, clinical trials and/or ability to negotiate and complete collaborative agreements or out-licensing arrangements. In addition, we might sell additional shares of our stock and/or debt and explore other strategic and financial alternatives, including a merger or joint venture with another company, the sale of stock and/or debt, the establishment of new collaborations for current research programs, that include initial cash payments and ongoing research support and the out-licensing of our compounds for development by a third party.

There are significant uncertainties as to our ability to access potential sources of capital. We may not be able to enter into any collaboration on terms acceptable to us, or at all, due to conditions in the pharmaceutical industry or in the

economy in general or based on the prospects of our catalytic antioxidant program. Even if we are successful in obtaining collaboration for our antioxidant program, we may have to relinquish rights to technologies, product candidates or markets that we might otherwise develop ourselves. These same risks apply to any attempt to out-license our compounds.

Similarly, due to market conditions, the illiquid nature of our stock and other possible limitations on equity offerings, we may not be able to sell additional securities or raise other funds on terms acceptable to us, if at all. Any additional equity financing, if available, would likely result in substantial dilution to existing stockholders.

With the proceeds of the February/March 2013 Financing, our management believes that we possess sufficient working capital to fund our operations for at least the next 12 months.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is forward-looking information, and actual results could vary.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources as defined under the rules of SEC Release No. FR-67. We do not have any capital leases.

Relationship with Goodnow Capital, LLC and Xmark Opportunity Partners, LLC

In July 2003, we initiated a series of transactions that led to our corporate reorganization and recapitalization. We obtained an aggregate of $8,000,000 in secured bridge financing in the form of convertible promissory notes we issued to Goodnow Capital, LLC ("Goodnow"). A portion of this financing allowed us to pay our past due payables and become current. We used the remainder for our operations, including a toxicology study for our catalytic antioxidant compounds under development as a treatment for ALS.

We completed our corporate reorganization on November 20, 2003. The reorganization involved the merger of our former parent company into one of our wholly owned subsidiaries. Subsequent to our 2003 reorganization, we completed a number of equity and debt financings, the majority of which included Xmark as investors. As of May 8, 2013, Xmark Opportunity Partners, LLC, through its management of Goodnow and the Xmark Funds, and through the Xmark Voting Trust and options held by David Cavalier, an affiliate of Xmark and the Chairperson of our Board of Directors, had voting power over 72% of our outstanding common stock and had beneficial ownership, calculated based on SEC requirements, of approximately 72.1% of our common stock. As a result of this significant ownership, Xmark Opportunity Partners, LLC and its affiliates is able to control future actions voted on by our stockholders.

Effective February 19, 2013, the Company and each of Xmark JV Investment Partners, LLC, Xmark Opportunity Fund, Ltd. and Xmark Opportunity Fund, L.P. (collectively, the "Xmark Entities") entered into a Warrant Repricing, Exercise and Lockup Agreement (the "Xmark Warrant Agreement") pursuant to which the Company agreed to reduce the exercise price of outstanding warrants to purchase an aggregate of up to 59,149,999 shares of Common Stock held by the Xmark Entities (the "Xmark Warrants") to $0.01 per share. In consideration for the reduction of the exercise price of the Xmark Warrants, each of the Xmark Entities agreed to immediately exercise all of the Xmark Warrants. The Xmark Warrant Agreement also provides that the Xmark Enities will not transfer the shares issuable upon exercise of the Xmark Warrants (the "Xmark Warrant Shares") until the Company either (i) declares a cash dividend on its common stock or otherwise makes a cash distribution or (ii) effects a Change of Control, subject in each case to the terms of the Xmark Warrant Agreement.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, which require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis as the situation changes, and regularly discuss financial events, policies, and issues with our independent registered public accounting firm and members of our audit committee. We routinely evaluate our estimates and policies regarding revenue recognition; clinical trial, preclinical, manufacturing and patent related liabilities; license obligations; inventory; intangible assets; share-based payments; and deferred tax assets.

35

We generally enter into contractual agreements with third-party vendors to provide clinical, preclinical and manufacturing services in the ordinary course of business. Many of these contracts are subject to milestone-based invoicing and the contract could extend over several years. We record liabilities under these contractual commitments when we determine an obligation has been incurred, regardless of the timing of the invoice. Patent-related liabilities are recorded based upon various assumptions or events that we believe are the most reasonable to each individual circumstance, as well as based upon historical experience. License milestone liabilities and the related expense are recorded when the milestone criterion achievement is probable. We have not recognized any assets for inventory, intangible items or deferred taxes as we have yet to receive regulatory approval for any of our compounds. Any potential asset that could be recorded in regards to any of these items is fully reserved. In all cases, actual results may differ from our estimates under different assumptions or conditions.

Warrant Liability

On October 1, 2009, we adopted new accounting guidance, originally referred to as EITF 07-5 and recently codified by FASB as ASC Topic 815. The guidance revised previously existing guidance for determining whether an Instrument (or Embedded Feature) is indexed to an entity's own stock. Equity-linked instruments (or embedded features) that otherwise meet the definition of a derivative are not accounted for as derivatives if certain criteria are met, one of which is that the instrument (or embedded feature) must be indexed to the entity's own stock. We applied the new guidance to outstanding instruments as of October 1, 2009. The fair value of the warrants affected by the new guidance at the dates of issuance totaled $8,282,000 and was initially recorded as a component of additional paid-in capital. Upon adoption of the new guidance, we recorded a decrease to the opening balance of additional-paid-in capital of $8,142,000 and recorded a decrease to accumulated deficit totaling $4,353,000, representing the decrease in the fair value of the warrants from the date of issuance to October 1, 2009. The fair value of the warrants at October 1, 2009 of $3,789,000 was classified as a liability in the balance sheet as of that date.

Increases or decreases in fair value of the warrants are included as a component of other income (expenses) in the accompanying statement of operations for the respective period. As of September 30, 2012, the liability for warrants decreased to approximately $19,319,000, resulting in an additional gain to the statements of operations for the fiscal year ended September 30, 2012 of approximately $4,069,000. The warrant liability and revaluations have not and will not have any impact on our working capital, liquidity or business operations. As a result of the Xmark Warrant Agreement effective as of February 19, 2013, the warrant liability has decreased to $0 and no further quarterly adjustments will be required.

Revenue Recognition

We do not currently generate revenue from product sales, but do generate revenue from the BARDA Contract. We recognize revenue from the BARDA Contract in accordance with the authoritative guidance for revenue recognition. Revenue is recognized when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured. We also comply with the authoritative guidance for revenue recognition regarding arrangements with multiple deliverables.

The BARDA Contract is classified as a "cost-plus-fixed-fee" contract. We recognize government contract revenue in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contracts. Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and indirect costs. In addition, we receive a fixed fee under the BARDA Contract, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under this BARDA Contract, including the fixed fee, are generally recognized as revenue in the period the reimbursable costs are incurred and become billable.

36

BUSINESS

General

Overview

Aeolus Pharmaceuticals, Inc. ("we," "us" or "Aeolus") is a Southern California-based biotechnology company leveraging significant government funding to develop a platform of novel compounds to protect against radiological and chemical threats and for use in oncology. The platform consists of over 200 compounds licensed from Duke University ("Duke") and National Jewish Health ("NJH").

Our lead compound, AEOL 10150, is being developed as a medical countermeasure ("MCM") against the pulmonary sub-syndrome of acute radiation syndrome ("Pulmonary Acute Radiation Syndrome" or "Lung-ARS") as well as the gastrointestinal sub-syndrome of acute radiation syndrome ("GI-ARS"). Both syndromes are caused by acute exposure to high levels of radiation due to a radiological or nuclear event. It is also being developed for use as a MCM for exposure to chemical vesicants such as chlorine gas, sulfur mustard gas and nerve agents. AEOL 10150 has already demonstrated safety and efficacy in animal studies in each of these potential indications. AEOL 10150 has previously been tested in two Phase I clinical trials in humans with no drug-related serious adverse events reported.

We were incorporated in the State of Delaware in 1994. Our common stock trades on the OTCQB under the symbol "AOLS." Our principal executive offices are located at 26361 Crown Valley Parkway, Suite 150 Mission Viejo, California 92691, and our phone number at that address is (949) 481-9825. Our website address is www.aeoluspharma.com. However, the information on, or that can be accessed through our website is not part of this report. We also make available, free of charge through our website, our most recent annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC.

Strategy

Our strategy is to use non-dilutive capital wherever possible to develop our promising platform of broad-spectrum, catalytic antioxidant compounds in important unmet medical indications of clinical and national strategic importance.

We are currently executing this strategy with our lead compound, AEOL 10150, where we are leveraging a substantial (up to $118.4 million) government investment in the development of AEOL 10150 as a MCM for Lung-ARS to develop the compound for use in combination with radiation and chemotherapy for cancer.

To date, we, and/or our research collaborators, have been awarded more than $150 million in non-dilutive funding for two of our leading compounds, AEOL 10150 and AEOL 10171 (also known as Hexyl). This includes grants and contracts from U.S. government agencies, such as the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Department of Health and Human Services ("HHS"), The National Institutes of Health ("NIH"), the National Institute of Allergy and Infectious Diseases ("NIH-NIAID") and the National Institutes of Health's Countermeasures Against Chemical Threats ("NIH-CounterACT"). Additionally, research is currently being conducted on several other compounds, including AEOL 11207 and similar compounds, which is funded by private foundations, such as the Michael J. Fox Foundation and Citizens United for Research in Epilepsy ("CURE").

The expected benefit of this strategy is threefold. First, a significant portion of the research to be completed under the government funding mechanisms, particularly the contract with BARDA, is applicable to our AEOL 10150

development program for radiation therapy and oncology. In addition to funding the development of the compound for the target indication of Lung-ARS, the contract with BARDA benefits our oncology development program through data generated in areas like safety, toxicology, pharmacokinetics and Chemistry, Manufacturing and Controls ("CMC"). Second, cost-plus development contracts, like our contract with BARDA, include funds for overhead and profit. These amounts above and beyond the actual direct cost of the contract result in a significantly reduced cash burn rate for our company, which results in our needing to raise less capital from outside investors in dilutive financings. Third, the purpose of the BARDA development contract is to fund AEOL 10150 so that procurements can be made for the national stockpile. Procurements may be made if either the drug meets the requirements for approval by the U.S. Food and Drug Administration (the "FDA") under the "Animal Rule" or under an Emergency Use Authorization ("EUA"). Most of BARDA's procurements to date have been under an EUA.

Procurements could generate significant cash and profit that could be re-invested to further develop AEOL 10150 for radiation oncology indications (and other compounds for additional indications). The amount of any potential procurement is undisclosed by BARDA at this time and is unknown to us. Based on publicly available information, as well as other procurements made by the agency under EUAs, we believe the agency may purchase sufficient courses of therapy to treat a minimum of one hundred thousand people, with options to purchase an additional two hundred thousand courses of treatment. This would provide sufficient funding to complete numerous clinical studies, including potentially large Phase III programs in radiation oncology. This funding would allow us to fund these studies without having to partner the compounds or to raise as much money through equity offerings, which would lead to greater value for our stockholders.

Business Overview

We are developing a new class of broad-spectrum, catalytic antioxidant compounds based on technology discovered at Duke University and National Jewish Health, developed by Drs. Irwin Fridovich, Brian Day and others. Dr. Fridovich discovered Superoxide Dismutase ("SOD"), which is a central enzyme in the human body for the detoxification of harmful oxygen free radicals formed by the metabolism of organisms. One source of increased production of free radicals is exposure to ionizing radiation.

These compounds, known as metalloporphyrins, scavenge reactive oxygen species ("ROS") at the cellular level, mimicking the effect of the body's own natural antioxidant enzyme, SOD. While the benefits of antioxidants in reducing oxidative stress are well-known, research with our compounds indicates that metalloporphyrins can be used to affect signaling via ROS at the cellular level. In addition, there is evidence that high-levels of ROS can affect gene expression and this may be modulated through the use of metalloporphyrins. We believe this could have a profound beneficial impact on people who have been exposed, or are about to be exposed, to high-doses of radiation, whether from cancer therapy or a nuclear event.

Our lead compound, AEOL 10150, is a metalloporphyrin specifically designed to neutralize reactive oxygen and nitrogen species. The neutralization of these species reduces oxidative stress, inflammation, and subsequent tissue damage-signaling cascades resulting from radiation or chemical exposure. We are developing AEOL 10150 in both oncology and as a biodefense medical countermeasure.

AEOL 10150 is currently being developed as a MCM for GI-ARS and Lung-ARS, both of which are caused by exposure to high levels of radiation due to a radiological or nuclear event. On February 11, 2011, we signed an agreement with BARDA for the development of AEOL 10150 as a MCM against Lung-ARS (the "BARDA Contract"). Pursuant to the BARDA Contract we were awarded approximately $10.4 million in the base period of the contract. On April 16, 2012, we announced that BARDA had exercised two options under the BARDA Contract worth approximately $9.1 million, bringing the total exercised contract value to date to approximately $19.5 million. We may receive up to an additional $98.9 million in options exercisable over the years following the base period. If all of the options are exercised by BARDA, the total value of the contract would be approximately $118.4 million. Pursuant to the Statement of Work in the BARDA Contract, we expect to provide the data necessary for filing an EUA in the second half of 2013. Once the EUA is filed, it would be possible for BARDA to begin procuring AEOL 10150 for the strategic national stockpile. Procurements from BARDA may result in significant revenues, and profitability, for Aeolus.

Until February 2011, the Lung-ARS program was principally funded by us and the work was performed at Duke University and the University of Maryland. Since February 11, 2011, substantially all of the costs for the Lung-ARS program have been funded by the BARDA Contract. To date, the GI-ARS development program has been funded by the NIH-NIAID through programs at the University of Maryland and Epistem, Ltd., and the chlorine, mustard gas and nerve agent programs have been funded by NIH-CounterACT through programs at National Jewish Health and the

University of Colorado.

We are leveraging the significant investment made by U.S. government agencies to develop this promising compound for use in oncology indications, where it would be used in combination with radiation and chemotherapy, and is currently in development for use as both a therapeutic and prophylactic drug. Studies have already demonstrated that AEOL 10150 does not interfere with the benefit of radiation therapy in prostate and lung cancer preclinical studies and has its own anti-tumor activity as well.

Upon the successful completion of the Phase I study and approval of a protocol by the FDA and the appropriate Institutional Review Boards ("IRBs"), we expect to begin a Phase II study in non-small cell lung cancer ("NSCLC") patients. Radiation therapy is a key therapy in NSCLC. It is the treatment of choice for patients with unresectable Stage I-II disease, and is recommended, in combination with chemotherapy, for patients with unresectable stage IIIB disease. (Pipeline Insight: Cancer Overview – Lung, Brain, Head and Neck, Thyroid; Datamonitor 2008, 37.). Radiation therapy lowers the level of the lung's surfactant, a substance that helps the lungs expand. This can result in a dry cough or shortness of breath. Radiation pneumonitis is an inflammatory response of the lungs to radiation, which can occur one to six months following the completion of radiation therapy. Pulmonary fibrosis, which refers to the formation of scar tissue in the lungs, can also occur from radiation therapy for lung cancer.

NIAID's Radiation/Nuclear Medical Countermeasures development program is currently testing AEOL 10150 as a countermeasure for GI-ARS caused by exposure to high levels of radiation due to a radiological or nuclear event. Similarly, the NIH-CounterACT program has tested, and continues to test, AEOL 10150 as a medical countermeasure for exposure to chemical vesicants such as chlorine gas and mustard gas. In October 2011, we announced that National Jewish Health was awarded a $12.5 million contract from NIH-CounterACT to continue the development of AEOL 10150 as a MCM against chlorine gas exposure. Also included in the grant is support for research in looking at tissue plasminogen activator (TPA) and Silabilin as MCMs against sulfur mustard gas exposure. The ultimate objective of the sulfur mustard and chlorine gas work at National Jewish Health will be to complete all work necessary to initiate pivotal efficacy studies for both indications. This would include: running efficacy studies in the rat model for higher doses of sulfur mustard and chlorine gas; establishing endpoints, optimal dosing and duration of treatment for pivotal efficacy studies; and characterizing the natural history from sulfur mustard and chlorine gas damage. NIH-CounterACT has also awarded a contract, worth approximately $735,000, to the University of Colorado to develop AEOL 10150 as a MCM against nerve agents.

AEOL 10150 has already performed well in animal safety studies, been well-tolerated in two human clinical safety studies, demonstrated efficacy in two species in acute radiation syndrome ("ARS") studies and demonstrated statistically significant survival efficacy in an acute radiation-induced lung injury model. AEOL 10150 has also demonstrated efficacy in validated animal models for GI-ARS, chlorine gas exposure, and sulfur mustard gas exposure. Efficacy has been demonstrated in Lung-ARS in both mouse and non-human primate studies ("NHP"), with AEOL 10150 treated groups showing significantly reduced weight loss, inflammation, oxidative stress, lung damage, and most importantly, mortality in the mouse study. Therapeutic efficacy was demonstrated when delivered after exposure to radiation (24 hours after exposure for mice in the GI-ARS study and NHPs in the Lung-ARS studies, and two hours after exposure for mice in the Lung-ARS studies). Additionally, AEOL 10150 was shown to reduce lung damage after Neupogen® treatment (current standard of care for H-ARS) following radiation exposure, and to reduce oxidative stress and Nerve damage following exposure to nerve agents.

We have an active Investigational New Drug Application ("IND") on file with the FDA for AEOL 10150 as a potential treatment for amyotrophic lateral sclerosis ("ALS"). In 2013, we expect to file an IND for Lung-ARS with the Division of Medical Imaging Products. Later, we plan to file an IND for cancer with the oncology division of the FDA, and may also file INDs for the GI-ARS and chlorine gas indications. We have already completed two Phase I safety studies in 50 humans demonstrating that the drug is safe and well tolerated. CMC work has been completed, pilot lots have been prepared and production is beginning to scale up under the BARDA Contract. Currently, we have no plans to conduct further clinical trials in ALS.

We have two programs underway for the development of our second drug candidate, AEOL 11207, for the treatment of epilepsy and Parkinson's disease. These programs are being funded, in part, by private foundations, including the Michael J. Fox Foundation, CURE and government grants. In February 2012, data was published in the Journal Neurobiology of Disease from the CURE study indicating AEOL 11207 significantly reduced both the frequency and duration of spontaneous seizures in a pre-clinical epilepsy model. Additionally, the study showed an increase in average life span, protection against neuronal death and no difference in seizure severity.

Our third drug candidate, AEOL 10171 (also known as Hexyl), is the subject of a $20 million research grant from NIH-NIAID, for development as a potential MCM for ARS.

Aeolus' Catalytic Antioxidant Program

The findings of research on natural antioxidant enzymes and antioxidant scavengers support the concept of antioxidants as a broad new class of therapeutic drugs, if certain limitations noted below could be overcome. We established our research and development program to explore and exploit the therapeutic potential of small molecule

catalytic antioxidants. We have achieved our initial research objectives and begun to extend our preclinical accomplishments into non-clinical studies, clinical trials and drug development programs.

Our catalytic antioxidant program is designed to:

- Retain the catalytic mechanism and high antioxidant efficiency of the natural enzymes, and
- Create and develop stable and small molecule antioxidants without the limitations of SOD so that they:
  Have broader antioxidant activity,
  Have better tissue penetration,
  Have a longer life in the body, and
  Are not proteins, which are more difficult and expensive to manufacture.

We created a class of small molecules that consume reactive oxygen and nitrogen species catalytically; that is, these molecules are not themselves consumed in the reaction. Our class of compounds is a group of manganoporphyrins (an anti-oxidant containing manganese) that retain the benefits of antioxidant enzymes, are active in animal models of disease and, unlike the body's own enzymes, have properties that make them suitable drug development candidates.

Our most advanced compound, AEOL 10150 (Figure 1), is a small molecule, broad-based, catalytic antioxidant that has shown the ability to scavenge a broad range of reactive oxygen species, or free radicals. As a catalytic antioxidant, AEOL 10150 mimics, and thereby amplifies, the body's natural enzymatic systems for eliminating these damaging compounds. Because oxygen- and nitrogen-derived reactive species are believed to have an important role in the pathogenesis of many diseases, we believe that our catalytic antioxidants and AEOL 10150 may have a broad range of potential therapeutic uses.

Figure 1

AEOL 10150 Overview	
Product Type	√ Catalytic antioxidants (manganoporphyrin)
Administration Route	√ Subcutaneous administration; self-injection possible
Indications in Development	√ Oncology (Used in combination with radiation and chemo) √ Pulmonary ARS/DEARE √ GI-ARS; Sulfur Mustard; Chlorine Gas
TRL Level	√ TRL 7/8 for Pulmonary Effects of ARS/DEARE
Regulatory Status	√ Active IND (IND-67741) Phase I (2 studies, 50 patients total 37 treated, 13 placebo)

AEOL 10150 has shown efficacy in a variety of animal models as a protectant against radiation injury, sulfur mustard gas exposure, ALS, stroke, pulmonary diseases, and diabetes. We filed an IND for AEOL 10150 in April 2004, under which clinical trials were conducted as more fully described below under the heading "AEOL 10150 in Amyotrophic Lateral Sclerosis." In 2013, we plan to file an IND for Lung-ARS with the medical imaging products division of the FDA and an additional IND with the oncology division of the FDA. For a more detailed description of antioxidants see the section below under the heading "Background on Antioxidants."

AEOL 10150 Medical Countermeasure Development Program

AEOL 10150 has performed well in animal safety studies, was well-tolerated in two human clinical trials, and has demonstrated statistically significant survival efficacy in an acute radiation-induced lung injury model. AEOL 10150 has also demonstrated efficacy in validated animal models for GI-ARS, chlorine gas exposure, sulfur mustard gas exposure and nerve agent exposure. Based on this research, we and our research partners have been awarded in excess of $139 million for the development of AEOL 10150 as a dual-use, broad spectrum medical countermeasure. The table below details the indications currently under development and the sources of funding from the US Government.

Indication	Funding Source	Amount of Grant/Contract	Research Partners
Lung-ARS	BARDA	Up to $118.4 million	University of Maryland
GI-ARS	NIH-NIAID	Undefined	Epistem, Ltd. University of Maryland
Chlorine Gas	NIH CounterACT	$20.3 million	National Jewish Health
Mustard Gas	NIH CounterACT	Part of the NIH-CounterACT contract above	National Jewish Health University of Colorado
Nerve Agents	NIH CounterACT	$735,000	University of Colorado
Phosgene	Institute of Chemical Defense	Undefined	Institute of Chemical Defense

AEOL 10150 as a potential medical countermeasure against the effects of Pulmonary Acute Radiation Syndrome

Overview

During recent years, the threat of nuclear attack on U.S. soil has increased. The lack of efficient post-exposure treatments for victims experiencing acute radiation toxicity presents a serious problem should an attack with a radiological device occur.

Immediately after exposure, the most critical components of acute radiation syndrome are the hematopoietic (bone marrow) and early-onset GI-ARS because symptoms begin very quickly and can be lethal. However, depending on the level and location of radiation exposure, much of the lethality of both hematopoietic and early-onset gastrointestinal syndromes are potentially avoidable with proper treatment, including supportive care (fluids and antibiotics) and Neupogen® (granulocyte colony-stimulating factor, or G-CSF), leaving complications to later responding tissues, like the lungs, subsequently becoming a major problem, and in some cases, becoming a cause of death.

In situations of accidental exposure, it was initially assumed that a whole-body dose exceeding 10 Gray (“Gy”) was inevitably fatal. However, experience with nuclear accident victims suggests that when patients survive gastrointestinal and bone marrow syndromes, respiratory failure becomes a major cause of death. This effect is known as a delayed effect of acute radiation exposure (“DEARE”).

Research has shown that damage associated with the exposure to upper half body irradiation or total body irradiation is an acute, but delayed, onset of radiation pneumonitis (inflammation of lung tissue) followed by lung fibrosis (scarring caused by inflammation).The incidence of radiation pneumonitis rises very steeply at relatively low radiation doses. A nuclear incident is likely to result in a wide, inhomogeneous distribution of radiation doses to the body that allows hematological recovery. But a higher exposure to the thorax leaves open the risk of serious pulmonary complications.

For the government, interested in saving as many citizens' lives as possible, it makes little sense to provide care to allow people to survive the short-term effects of radiation exposure following an event, to merely have them die several weeks or months later due to the delayed effects of radiation exposure.

AEOL 10150 has already performed well in animal safety studies, been well-tolerated in two human clinical trials, demonstrated efficacy in two species in ARS studies and demonstrated statistically significant survival efficacy in an acute radiation-induced lung injury model. AEOL 10150 has also demonstrated efficacy in validated animal models for GI-ARS, chlorine gas exposure, and sulfur mustard gas exposure. Efficacy has been demonstrated in both Lung-ARS and DEARE in both rodent and NHP studies, with AEOL 10150 treated groups showing significantly reduced weight loss, inflammation, oxidative stress, lung damage, and most important, mortality. Therapeutic efficacy was demonstrated when delivered after exposure to radiation (24 hours after exposure for mice in the GI-ARS studies and NHPs in the Lung-ARS studies, and two hours after exposure for mice in the Lung-ARS studies).We expect to look at longer post exposure periods in future studies. Additionally, AEOL 10150 was shown to reduce lung damage after Neupogen® treatment (current standard of care for H-ARS) following radiation exposure, and to reduce oxidative stress and Nerve damage following exposure to nerve agents.

Pre-clinical studies

Clinical experience and experience with nuclear accident victims points out that one of the primary concerns associated with radiation exposure is an acute, but delayed onset of radiation pneumonitis with an incidence that rises very steeply at relatively low radiation doses (to 90-percent occurrence at 11 Gy).To evaluate AEOL 10150's ability to mitigate acute radiation-induced lung injury, mice were exposed to 15 Gy of upper half body irradiation ("UHBI") and subsequently treated with AEOL 10150.

In a study led by Zeljko Vujaskovic, M.D., Ph.D. at Duke University Medical Center, C57BL/6 female mice were randomized into six groups. Each of the groups was paired to include irradiated and non-irradiated groups of animals that were untreated, treated with a low dose (10 mg/kg) of AEOL 10150, or treated with a high dose of AEOL 10150 (20 mg/kg).Animals received treatments subcutaneously beginning 2 hours after irradiation (20 and 40 mg/kg initial loading dose, respectively) followed by a maintenance dose of half the initial dose three times per week for 4 weeks. Survival, wet lung weights and body weights, histopathology, and immunohistochemistry were used to assess lung damage. Results demonstrate that treatment with AEOL 10150 increased survival (Fig.6), maintained body weight (Fig.7), protected lung tissue (Fig.8 and 9), and reduced oxidative stress (via DNA and protein oxidation analysis) compared with untreated irradiated animals.

Figure 2. Kaplan Meier survival curves for C57BL/6J mice after upper half body irradiation. The survival data displayed that there were no deaths in the sham-irradiated animals and animals receiving drug alone. In contrast, 9/20 (45%) of the animals that received 15 Gy UHBI died during the 6-week follow-up period. Treatment with low/high doses of AEOL 10150 markedly reduced radiation-induced mortality to only 10% (2/20).

Figure 3. Average body weight changes among groups. UHBI alone mice demonstrated significant weight loss beginning 3 weeks post-exposure compared with UHBI + low/high doses of AEOL 10150 groups.

Figure 4. Wet lung weights. Wet lung weights were measured as an index of pulmonary edema and consolidation. UHBI alone mice had significantly higher wet lung weights than did the UHBI + low/high doses AEOL 10150 groups.*=$p < 0.05$

Figure 5. Hematoxylin and Eosin Staining of Lung Tissue. Lung histology at 6 weeks revealed a significant decrease in lung structural damage in UHBI + low/high doses of AEOL 10150 groups, in comparison with UHBI alone .20x magnification.

Data from a study in which AEOL 10150 was administered to 40 mice that had been exposed to radiation also show a statistically significant increase in survival rates among mice that were treated with AEOL 10150 compared to controls. Additionally, mice receiving AEOL 10150 experienced a reversal in weight loss seen in the untreated mice. The six month study, led by Zeljko Vujaskovic, M.D., Ph.D. at Duke University Medical Center, was designed to test the efficacy of AEOL 10150 as a treatment for damage to the lungs due to exposure to radiation. At 45 days, all of the animals in the untreated group had either died or been sacrificed based on animal care rules. The remaining animals that received AEOL 10150 did not need to be sacrificed based on animal care rules, but a majority were sacrificed in order to increase the numbers that could be compared to the untreated animals sacrificed at 45 days, since there would be no untreated animals for comparison at the end of six months. In addition to the statistically significant ($P< 0.05$) survival advantage, statistically significant differences in body weights and wet lung weights were seen over the first six weeks of the study. Untreated mice experienced a steady decline in body weight over the six weeks, while treated animals experienced weight gain that was just slightly less than that seen in the controls (animals not receiving radiation). AEOL 10150 also demonstrated statistically significant reductions in markers for oxidative stress and inflammation, which were secondary endpoints for the study.

A number of other preclinical studies by Zeljko Vujaskovic, MD, PhD; Mitchell Anscher, MD, et al at Duke University have demonstrated the efficacy of AEOL 10150 in radioprotection of normal tissue. Chronic administration of AEOL 10150 by continuous, subcutaneous infusion for 10 weeks has demonstrated a significant protective effect from radiation-induced lung injury in rats. Female Fisher 344 rats were randomly divided into four different dose groups (0, 1, 10 and 30 mg/kg/day of AEOL 10150), receiving either short-term (one week) or long-term (ten weeks) drug administration via osmotic pumps. Animals received single dose radiation therapy of 28 Gy to the right hemithorax. Breathing rates, body weights, histopathology and immunohistochemistry were used to assess lung damage. For the long term administration, functional determinants of lung damage 20 weeks post-radiation were significantly decreased by AEOL 10150. Lung histology at 20 weeks revealed a significant decrease in structural damage and fibrosis. Immunohistochemistry demonstrated a significant reduction in macrophage accumulation, collagen deposition and fibrosis, oxidative stress and hypoxia in animals receiving radiation therapy along with AEOL 10150. Figure 6 below shows a semi-quantitative analyses of lung histology at 20 weeks which revealed a significant decrease in structural damage and its severity in animals receiving 10 and 30 mg/kg/day after radiation in comparison to radiation therapy along with placebo group or radiation therapy along with 1 mg/kg of AEOL 10150 ($p = 0.01$).

Figure 6

Figure 6 above shows that AEOL 10150 treatment decreases the severity of damage and increases the percentage of lung tissue with no damage from radiation therapy (Rabbani et al Int J Rad Oncol Biol Phys 67:573-80, 2007).

Two additional studies examining the effect of subcutaneous injections of AEOL 10150 on radiation-induced lung injury in rats have been completed. The compound was administered subcutaneously by a b.i.d. dosing regimen (i.e., 2.5 mg/kg or 5.0 mg/kg) on the first day of radiation and daily for five consecutive weeks. Radiation was fractionated rather than single dose, with 40 Gy divided in five 8 Gy doses. Preliminary immunohistologic analyses of the lung tissue from these two studies showed a dose dependent decrease in the inflammatory response quantified by the number of activated macrophages or areas of cell damage. These in vivo studies employing subcutaneous administration of AEOL 10150, either by continuous infusion via osmotic pump or BID injection, demonstrate that AEOL 10150 protects healthy lung tissue from radiation injury delivered either in a single dose or by fractionated radiation therapy doses. AEOL 10150 mediates its protective effect(s) by inhibiting a number of events in the inflammatory cascade induced by radiation damage.

Additional in vivo studies have been performed that provide support for manganoporphyrin antioxidant protection of lung tissue from radiation. Treatment with a related manganoporphyrin compound, AEOL 10113 significantly improved pulmonary function, decreased histopathologic markers of lung fibrosis, decreased collagen (hydroxyproline) content, plasma levels of the profibrogenic cytokine, transforming growth factor beta (TGF-) and, as demonstrated by immunohistochemistry of lung tissue, collagen deposition and TGF- .

In 2011, we announced positive results from study of AEOL 10150 and Neupogen® as combination therapy for treatment of ARS. The study was conducted by Christie Orschell, PhD of Indiana University. The primary endpoint of the study was to determine drug-drug interactions between Neupogen® and AEOL 10150, as well as to monitor safety and tolerability of the two treatments given simultaneously. Results of the study confirmed that AEOL 10150 does not interfere with the positive effects of Neupogen® on the hematopoietic, or bone marrow, syndrome of Acute Radiation Syndrome (ARS), and the two products in combination were safe and well tolerated. In 2012, we announced further data from this study, which demonstrated that treatment of the hematopoetic sub-syndrome of acute radiation syndrome (Heme-ARS) with Neupogen® exacerbates radiation damage to the lung. The study also confirmed that treatment with AEOL 10150 in combination with Neupogen® significantly reduced the lung damage.

44

The study entitled “Pilot Study to Test the Effects of Aeolus 10150 on Neupogen®-Induced ANC Recovery in Sub-Lethally Irradiated C57Bl/6 Mice” was initiated at the request of Shigetaka Asano, MD of Waseda University and Arinobu Tojo, MD, PhD and Tokiko Nagamura, MD at the Institute of Medical Science at the University of Tokyo to determine whether there would be any interference with the demonstrated efficacy of Neupogen® as a medical countermeasure against the hematopoietic complications of radiation exposure. In previous treatment of radiation accident victims at Tokai-mura, Dr. Asano and others were able to use Granulocyte Colony Stimulating Factor (G-CSF) and supportive care to enable victims of 8 to 12 Gy exposure to survive the hematopoietic (heme) syndrome. Unfortunately, these patients later died due to lung and multi-organ complications. As AEOL 10150 has shown efficacy against lung and GI complications in mice and in Lung-ARS in non-human primates, it was important to test whether the two compounds can be used in tandem, if necessary.

The use of Neupogen® or other G-CSFs or Neulasta® or other Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) products is recommended by the Radiation Emergency Assistance Center/Training Site (REAC/TS) at radiation exposures greater than 2 to 3 Gy to mitigate damage to the hematopoietic system. REAC/TS is a response asset of the U.S. Department of Energy and provides treatment capabilities and consultation assistance nationally and internationally. In animal studies G-CSF's have been shown to be effective in increasing survival at levels up to 7.5 Gy due to their positive effects on the hematopoietic damage created by radiation exposure. This class of compounds has not demonstrated an effect on the two other major sub-syndromes -- GI and Lung. AEOL 10150 has demonstrated efficacy in treating the GI sub-syndrome in pilot studies conducted by NIH-NIAID, by protecting crypt cells and reducing diarrhea. More extensive studies of the drug in treating the pulmonary effects of radiation at Duke University and the University of Maryland have shown improved survival and enhanced lung function and improved histology at exposures up to 15 Gy in mice and 11.5 Gy in non-human primates. These exposure levels caused death in 100 percent of untreated animals. Studies at Duke University have also shown a significant survival advantage for animals treated with AEOL 10150 after 15 Gy upper half body irradiation, which causes lethal damage to both the GI tract and the lungs.

In summary, AEOL 10150 has consistently shown a protective effect against the harmful effects in radiation, including when the drug is administered up to 72 hours after exposure.

During fiscal year 2010, we initiated another study in mice to determine the optimal length of treatment with AEOL 10150 when used as an MCM to Lung-ARS. This study, led by Zeljko Vujaskovic, M.D., Ph.D. at Duke University, was designed to build on the previously completed study that demonstrated the efficacy of AEOL 10150 as a treatment for damage to the lungs due to exposure to radiation (described in detail above), and determine the most effective duration of delivery for treatment after exposure. The results from the study showed that treatment for 4 to 10 weeks after exposure appears to be optimal. Under the BARDA Contract, additional studies will be performed to further refine the timeline and analyze whether extending treatment beyond 10 weeks would be beneficial. Treatment for 4, 6 and 10 weeks showed the greatest impact on body weight and lung damage as shown in figures 7 and 8 below.

Non- clinical studies

In 2010, we initiated a study to confirm the efficacy of AEOL 10150 as an MCM to nuclear and radiological exposure in non-human primates. The study was designed to test the efficacy of AEOL 10150 as a treatment for Lung-ARS and to begin establishing an animal model that can be validated and could be utilized by the FDA for approval of an MCM for Pulmonary Acute Radiation Syndrome under the "Animal Rule". The FDA "Animal Rule" enumerates criteria whereby the FDA can rely on animal efficacy data when "evidence is needed to demonstrate efficacy of new drugs against lethal or permanently disabling toxic substances when efficacy studies in humans, ethically cannot be conducted." The criteria are discussed below.

Preliminary results from the study were reported during the fiscal year, showing that AEOL 10150 promotes survival in a non-human primate model of Lung-ARS. The primary objective of the study was to determine if AEOL 10150 could mitigate radiation-induced lung injury and enhance survival in rhesus macaques exposed to whole thorax lung irradiation ("WTLI") and administered supportive care. Two cohorts of NHPs were exposed to 11.5Gy LINAC-derived photon radiation in the WTLI protocol. The control cohort had n=6 and AEOL 10150-treated cohort was n=7.This model showed 100% incidence of severe radiation-induced lung damage. AEOL 10150 was administered subcutaneously at 5mg/kg beginning at day 1 post WTLI and continued as a single, daily injection for 28 consecutive days. The final results were presented at the 14th International Congress of Radiation Research in Warsaw, Poland in September 2011. Key findings in the study include:

1. Exposure of the whole thorax to 11.5 Gy resulted in radiation-induced lung injury in all NHPs in the study and proved 100% fatal in the control animals, despite supportive care including dexamethasone. 11.5 Gy is, therefore, equal to or greater than the LD100/180dose for the WTLI model.

2. AEOL 10150, as administered in this pilot study (daily on d1-28 at 5mg/kg SC), demonstrated potential efficacy as a mitigator against fatal radiation-induced lung injury. Treatment with the drug resulted in 28.6% survival following exposure to a radiation dose that proved to be 100% fatal in the untreated control group.

3. Serial CT scans demonstrated less quantitative radiographic injury (pneumonitis, fibrosis, effusions) in the AEOL 10150 treated cohort, suggesting that the drug reduces the severity of the radiographically detectable lung injury.

4. Dexamethasone administration yielded a transient benefit on both clinical and radiographic evidence of pneumonitis. The AEOL 10150 treated cohort required 1/3 less dexamethasone support due to reduced pulmonary injury in the AEOL 10150 treated group, resulting in less frequent clinical "triggers" (respiratory rate≥80) to treat with dexamethasone.

5. The results of this pilot study are encouraging and suggest that treatment with AEOL 10150 results in reduced clinical, radiographic and anatomic evidence of radiation-induced lung injury, which also results in improved survival. AEOL 10150 merits further study as a post-exposure MCM against radiation-induced lung injury.

In rodents, non-human primates and humans, radiation of the lungs can cause reduced breathing capacity, pneumonitis, fibrosis, weight loss and death and is characterized by oxidative stress, inflammation and elevated macrophage counts. AEOL 10150 has proven to be an effective countermeasure to radiation exposure of the lungs in mice and rats in published studies such as Rabbani et al Int J Rad Oncol Biol Phys 67:573-80, 2007, Rabbani et al Free Rad Res 41:1273-82, 2007 and Gridley et al Anticancer Res 27:3101-9, 2007.

Clinical studies

We believe our two previous Phase I clinical studies can be utilized in any potential IND and New Drug Application ("NDA") filing with the FDA for AEOL 10150 as an MCM for ARS. We do not have any clinical trials currently underway, but we are in the process of planning additional safety studies, which we expect to commence in 2013.

Future Development Plans

Our objective is to develop AEOL 10150 as an MCM against Lung-ARS, via the FDA's "Animal Rule". This development pathway requires demonstration of the key study efficacy parameter of AEOL 10150 treatment in two animal models relevant to the human radiation response and its treatment, demonstration of safety in humans, demonstration of relevant dosing and administration in humans, and clear identification of the mechanism of radiation-induced damage to the lung and its amelioration by the drug candidate.

AEOL 10150 has several distinct advantages as an MCM, including the following:

- Demonstrated survival increase in animal studies when administered 2 hours after exposure (P<0.05),
- Demonstrated reduction in lung fibrosis in animal studies up to 24 hours post exposure (P<0.05),
- Demonstrated histological improvement in lung tissue post-radiation exposure,
- Addresses an unmet medical need as an MCM to Lung-ARS,
- Established safety profile in both clinical and pre-clinical studies,
- Subcutaneous self-administration possible by exposed individuals during emergency,
- Rapid administration, allowing large numbers of patients to be treated quickly,
- Stable for up to 4½ years at 0–8°C and 1 year at room temperature,
- Requires no non-standard storage conditions (i.e., not photosensitive),
- Currently in development as an adjunct to radiation therapy; if approved will provide a pre-existingdistribution and stockpile resource at oncology centers in the event of a radiological emergency,
- Demonstrated advantage when used in combination with Neupogen®,
- Demonstrated potential as both a therapeutic and prophylactic,
- Demonstrated potential to address multiple sub-syndromes of ARS,
- Demonstrated potential to address sulfur mustard gas and chlorine gas exposure, and nerve agents.
- Potential dual use as an adjunct treatment for cancer patients receiving radiation therapy.

We believe that in order to file a NDA for ARS with the FDA, we will need to demonstrate efficacy in animal models and demonstrate product safety which is based upon the FDA's "Animal Rule". We also plan on pursuing Fast Track submission status for this indication, enabling rolling NDA submission process and a key step in achieving Priority Review, if accepted by the FDA. The FDA determines within 45 days of a company's request, made once the complete NDA is submitted, whether a Priority or Standard Review designation will be assigned.

The FDA's "Animal Rule" enumerates criteria whereby the FDA can rely on animal efficacy data when evidence is needed to demonstrate efficacy of new drugs against lethal or permanently disabling toxic substances when efficacy studies in humans cannot be ethically conducted. The criteria are as follows:

- Knowledge of the mechanism of radiation-induced damage to the lung and its amelioration by the candidate drug.
- Pharmacokinetic and pharmacodynamic analysis to provide information on relevant dose and administration schedule.
- Direct correlation of key study parameters (e.g., survival or major morbidity) with the desired clinical benefit in humans.
- Collection of efficacy data in two species relevant to the human radiation response and its treatment unless otherwise justified under GLP-compliant conditions.
- A Phase I safety trial using the same product and formulation as used in the pivotal trial(s) required.

Demonstrate Efficacy in Animal Models

Our efficacy plan is designed to accomplish two key goals: the validation of two animal models for acute radiation-induced lung injury and the generation of pivotal efficacy data in these species. The efficacy data produced in pivotal studies using these validated models will provide the data required to demonstrate efficacy of AEOL 10150 at the dose and schedule proposed for licensure. A second criterion of the "Animal Rule" is that the models must be reflective of "real world" conditions to which a human is likely to be exposed. The proposed models have been designed to reflect these real world conditions. Initial studies have been conducted with whole thorax exposure models to irradiate the total lung parenchym, and will be followed by studies with Total Body Irradiation with shielding of roughly 5 percent of bone marrow. This study design mimics real world conditions in which it is anticipated that many of those exposed to radiation will benefit from some shielding (e.g., from cars, buildings, etc.), which will protect

some bone marrow and allow for survival without a bone marrow transplant. This shielding approach has been used to develop both murine and NHP models for GI-ARS and in the NHP models for radiation-induced lung injury.

Demonstrate Product Safety

For product approval under the "Animal Rule", we will also demonstrate product safety using the same product and formulation used in the animal efficacy trials and proposed for use in humans. Demonstration of safety includes preclinical demonstration of safety via the standard pre-clinical studies and analyses methods and Phase I safety trials sufficient to demonstrate product safety in the target patient population. We believe our safety studies completed as a therapy for ALS may be utilized to demonstrate safety for this indication. We also plan to conduct two additional Phase I clinical safety studies, which are included in the BARDA Contract.

Competition

Currently there are no FDA-approved drugs for the treatment of Lung-ARS. We are also not aware of any other drug candidates that have demonstrated the ability to protect the lungs from radiation given post-exposure, which we believe is a critical aspect of the development of an MCM against the effects of acute radiation syndrome.

However, in general, we face significant competition for U.S. government funding for both development and procurements of an MCM for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. The U.S. federal government has currently allocated a significant amount of research funding to the development of countermeasures against the effects of radiation exposure. As a result, there are many drug candidates under development as a possible countermeasure against the various effects and sub-syndromes of radiation exposure.

Funding and Funding Options

In October 2010, we were notified that we had been awarded the maximum amount of about $244,000, under the Qualifying Therapeutic Discovery Grant Program ("QTDP") administered by the Internal Revenue Service ("IRS") and the HHS in support of our development of AEOL 10150 as an MCM for Lung-ARS.

On February 11, 2011, we signed an agreement with BARDA for the development of AEOL 10150 as a MCM against Lung-ARS (the "BARDA Contract"). Pursuant to the BARDA Contract we were awarded approximately $10.4 million in the base period of the contract. On April 16, 2012, we announced that BARDA had exercised two options under the BARDA Contract worth approximately $9.1 million, bringing the total exercised contract value to date to approximately $19.5 million. We may receive up to an additional $98.9 million in options exercisable over the years following the base period. If all of the options are exercised by BARDA, the total value of the contract would be approximately $118.4 million. Pursuant to the Statement of Work in the BARDA Contract, we expect to provide the data necessary for filing an EUA in the second half of 2013. Once the EUA is filed, it would be possible for BARDA to begin procuring AEOL 10150 for the strategic national stockpile. Procurements from BARDA may result in significant revenues, and profitability, for Aeolus

As of September 30, 2012, we were operating within the projected budget for the base period and exercised options. Further, stemming from operational efficiencies in the base and option periods, we have been able to add several additional program elements in each of the first two years of the contract and remain within the base period and two option contract amount.

Since we have been awarded the BARDA Contract, substantially all of the costs associated with the research and development of AEOL 10150 as a MCM for Lung-ARS have been covered by the BARDA Contract, and we expect such costs to continue to be covered by the BARDA Contract. We expect to have an internal program review meeting with BARDA in January 2012, at which time BARDA will review our execution under the contract to date, then decide on which, if any, options to exercise in order to continue the development of AEOL 10150 as an MCM for

Lung-ARS. The following are the key deliverables that will be reviewed and the status of these milestones and deliverables.

Milestones/Deliverables	Status
Hire Radiation Biologist	Completed
Hire Director Quality Assurance	Completed
Sign Quality Agreements	Completed
Submit Risk Management Plan	Completed
Submit Earned Value Management Plan	Completed
Complete Murine Radiation Dose Study	Completed
Initial Non-GMP Batch Production	Completed
Achieve Significant Improvement in API Production	Completed
File for Orphan Drug Designation	Completed
Complete 10150 GMP API Initial Production	Completed
Complete In-Vivo Comet Assay Study	Completed
Complete NHP Radiation Dose Study	Completed
Complete Media Fill Runs for Final Drug Product	Completed
Complete GMP API Method Validation	Completed
System Integration/Implementation	Completed
Complete Murine Radiation Dose Study Amendment (CBA)	Completed
Develop Impurity Profile for API	Completed
Complete Murine CBA 10150 Dose Escalation Study	Completed
Complete Final Product Process Development Work	Completed
Hold 2nd Pre-IND Meeting with FDA	Completed
Initiate NHP AEOL 10150 Dose Evaluation Study	Completed
Complete Final Drug Product Formulation Development	Completed
Initiate Murine (CBA) Duration of Treatment	Q2iti

Study	
Complete First Batch of Bulk Drug Substance under New Methods	Q2mpl
Complete First Lot of Final Drug Product under New Methods	Q2mpl
Initiate Phase 1 Human Safety Study	Q3mpl
Complete CBA AEOL 10150 Dose Evaluation Study	Q3mpl
Complete Murine Mechanism of Action Studies	Q3le
Complete CBA Duration of Treatment Study	Q4iti
Complete NHP AEOL 10150 Dose Evaluation Study	Q4le
Complete Phase 1 Human Safety Study	Q4mpl
File IND for Lung ARS Indication	Q1mpl
File for Fast Track with FDA	Q1mpl

AEOL 10150 as a potential medical countermeasure against the effects of radiation on the gastro-intestinal tract

Overview

GI-ARS is a massive, currently untreatable, problem following high-dose, potentially lethal radiation exposure. Agents that mitigate these effects would reduce sickness and hopefully prevent fatalities. The intestinal epithelium, a single layer of cells lining the surface of the GI lumen, is responsible for vital functions of nutrient absorption, maintaining fluid and electrolyte balance and protection of the body from bacteria, bacterial toxins and non-absorbed materials. The functional integrity of the GI system is maintained via incessant production of epithelial cells from specialized stem cells located in crypts at the base of the epithelium. High-dose, total-body irradiation can result in a lethal GI syndrome that results in significant morbidity and mortality within days consequent to killing of the crypt stem cells and loss of the protective and absorptive epithelial barrier. There are no FDA-approved drugs or biologics to treat GI-ARS.

Pre-clinical studies

The NIH-NIAID's Radiation/Nuclear Medical Countermeasures development program is currently testing AEOL 10150 as a countermeasure for GI-ARS through the Medical Countermeasures Against Chemical Threats ("MCART") program. The studies are being funded by the NIAID and are designed to test the efficacy of AEOL 10150 as a treatment for damage to the GI tract due to exposure to radiation. The study protocols call for the examination of both histological and survival endpoints in mice in a multi-armed vehicle-controlled trial. For the histological portion, crypt histology will be assessed with crypt number and crypt width being the primary endpoint. Animals receiving AEOL 10150 began dosing 24 hours after radiation exposure and receive one dose per day for the remainder of the study. Preliminary results have demonstrated that AEOL 10150 can effectively increase regeneration of GI stem cells, reduce the severity and duration of diarrhea and improve survival when administered at 24 hours after doses of total-body irradiation that produce the lethal GI syndrome. The studies are being conducted by Epistem, Ltd. in compliance with criteria of the FDA that are a pre-requisite for movement of our drug along the pathway for FDA licensure to treat lethally irradiated persons in the event of a terrorist nuclear act. Epistem, Ltd. operates a major contract research organization and provides services to identify novel drugs that can protect or improve the repair of the GI tract following exposure to irradiation and performs these studies as part of NIH's program for the screening of novel agents for bio-defense applications.

At a development meeting held in the fourth quarter of 2010, MCART reviewed the results of the two mouse studies that have been conducted with AEOL 10150 to date and concluded:

AEOL10150 is biologically active as a countermeasure (specifically for GI-ARS)

- Based on the fact that all of the animals in the control group died, the level of radiation exposure (13 Gy and 15 Gy) was too high for the study, and a lower level of exposure that generates a mortality rate of 50 to 70 percent would be more appropriate to examine efficacy.
- A radiation dose range study will be conducted in which they will look at exposing animals to radiation between 9 and 12 Gy.

Recently MCART completed the radiation dose range study work and determined the survival curve for GI-ARS in the C57LJ mouse at the LD30, LD50 and LD70 levels. Additionally, MCART completed radiation dose range work in NHPs and determined the survival curve at the LD30, LD50 and LD70 levels. The results supported the conclusion that radiation exposure of 13 Gy and 15 Gy was above the optimal exposure levels for an appropriate study to examine efficacy.

We are unaware of any published studies of agents that accomplish this enhanced stem cell regenerative effect while maintaining GI function and improving survival when administered post irradiation.

Future Development Plans

In collaboration with the NIH-NIAID, we are planning additional studies to confirm the efficacy results demonstrated in the study described above. NIH-NIAID initiated a confirmatory efficacy study of AEOL 10150 in mice during September 2012 and plans to initiate an efficacy study of AEOL 10150 in the NHP during fiscal year 2013. We also expect to perform additional studies which could be funded by NIH-NIAID to optimize dose and duration of delivery, and to evaluate the window of opportunity for treatment after exposure.

Upon completion of these studies we would need to demonstrate efficacy in animal models and demonstrate product safety based upon the FDA's "Animal Rule". We also plan on pursuing Fast Track submission status for this indication, enabling rolling NDA submission process and a key step in achieving Priority Review, if accepted by the FDA. The FDA determines within 45 days of a company's request, made once the complete NDA is submitted, whether a Priority

or Standard Review designation will be assigned. Under the “Animal Rule,” we would need to complete pivotal studies in two species relevant to the human radiation response and its treatment. We believe that these studies can be completed using existing validated models for both murine and NHP. This study design would also mimic real world conditions in which it is anticipated that many of those exposed to radiation will benefit from some shielding (e.g., from cars, buildings, etc.), which will protect some bone marrow and allow for survival without a bone marrow transplant.

We will also demonstrate product safety using the same product and formulation used in the animal efficacy trials and proposed for use in humans. Demonstration of safety includes preclinical demonstration of safety via the standard pre-clinical studies and analyses methods and Phase I safety trials sufficient to demonstrate product safety in the target patient population. We believe our safety studies completed as a therapy for ALS and those to be performed under our Lung-ARS contract with BARDA will be more than adequate to demonstrate safety for this indication.

Competition

We are unaware of any compounds that protect crypt cells and that increase survival when given to animals exposed to radiation at levels greater than 10 Gys and given after exposure. There are several companies developing drug candidates that have shown efficacy when given prior to exposure or at lower levels of radiation.

However, in general, we face significant competition for U.S. government funding for both development and procurements of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. The U.S. federal government has currently allocated a significant amount of research funding to the development of countermeasures against the effects of radiation exposure. As a result, there are many drug candidates under development as a possible countermeasure against the effects of radiation exposure.

Funding Options

AEOL 10150 as an MCM for GI-ARS is being tested by our research partners under funding from NIH-NIAID.

AEOL 10150 as a potential medical countermeasure against the effects of chlorine gas

Overview

Chlorine gas is a toxic gas that confers airway injury through primary oxidative stress and secondary inflammation. Chlorine inhalation was recently used in terrorist/insurgent attacks on military and civilian populations, and has caused numerous industrial, transportation, swimming pool, and household accidents, as well as deaths to members of the U.S. military in the past. Chlorine gas, also known as bertholite, was first used as a weapon in World War I. Chlorine gas was also used against the local population and coalition forces in the first Iraq War in the form of chlorine bombs.

The increased risk of a terrorist attack in the United States involving chemical agents has created new challenges for many departments and agencies across the federal government. Within the HHS, the NIH is taking a leadership role in pursuing the development of new and improved medical countermeasures designed to prevent, diagnose, and treat the conditions caused by potential and existing chemical agents of terrorism. In addition, many of the same chemicals posing a threat as terrorist agents may also be released from transportation and storage facilities by industrial accidents or during a natural disaster. The NIH has developed a comprehensive NIH-CounterACT Research Network that includes Research Centers of Excellence, individual research projects, small business innovation research, contracts and other programs. The NIH-CounterACT network is conducting basic, translational and clinical research aimed at the discovery and/or identification of better therapeutic and diagnostic medical countermeasures against chemical threat agents, and their movement through the regulatory process. The overarching goal of this research program is to enhance our diagnostic and treatment response capabilities during an emergency.

Another critical goal of the NIH-CounterACT program is to assist in the development of safe and effective medical countermeasures designed to prevent, diagnose, and treat the conditions caused by potential and existing chemical agents of terrorism which can be added to the Nation’s Strategic National Stockpile (“SNS”). The SNS is maintained by

the Centers for Disease Control and Prevention (“CDC”).The SNS now contains CHEMPACKS which are located in secure, environmentally controlled areas throughout the United States available for rapid distribution in case of emergency. The CDC has established a diagnostic response network for the detection of nerve agents, mustard, cyanide and toxic metals. The NIH will continue to research, develop and improve medical products that include chemical antidotes, drugs to reduce morbidity and mitigate injury, drugs to reduce secondary chemical exposure and diagnostic tests and assessment tools to be used in mass casualty situations.

Worldwide, independent of warfare and chemical terrorism, chlorine is the greatest single cause of major toxic release incidents (16.Davis DS, Dewolf GB, Ferland KA, et al. Accidental Release of Air Toxins. Park Ridge, New Jersey: NDC; 1989:6-9.). In the U.S., there are about 5-6,000 exposures per year resulting in, on average, about one death, 10 major, 400-500 moderate, and 3-4,000 minor adverse outcomes. Like mustard, chlorine causes damage to upper and lower respiratory tracts. While chlorine is an irritant, its intermediate water solubility may delay emergence of upper airway symptoms for several minutes. Aqueous decomposition of chlorine gas forms hydrochloric acid and hypochlorous acid, itself also a product of inflammation. Cell injury is thought to result from oxidation of functional groups in cell components, from tissue formation of hydrochloric acid and hypochlorous acid, and possibly from formation of other ROS. For treatment of acute exposures in humans, decontamination, supplemental oxygen, treatment of bronchospasm and/or laryngospasm, and supportive care are the only accepted therapies, while use of nebulized sodium bicarbonate and parenteral and/or inhaled steroids remain quite controversial. No specific beneficial therapies are available. We expect that AEOL 10150 will decrease airway injury, inflammation, oxidative damage, hyperreactivity and cell proliferation after acute chlorine gas inhalation in mice and therefore could be a possible beneficial therapy for chlorine gas inhalation injury to the airways.

Pre-clinical studies

Under a grant from NIH CounterACT, researchers from National Jewish Health and McGill University have completed a series of preliminary studies demonstrating that AEOL 10150 protects lungs from chlorine gas exposure in mice and rats. The primary objective of these studies was to determine whether administration of AEOL 10150, after exposure, reduces the severity of acute lung injury and asthma-like symptoms induced by chlorine gas. AEOL 10150 was given to mice at a 5 mg/kg subcutaneous dose one hour after chlorine gas exposure (100 ppm for 5 minutes) and repeated every 6 hours. Twenty-four hours after exposure, lung inflammation was assessed by changes in bronchoalveolar lavage (“BAL”) cellularity and neutrophil influx. AEOL 10150 significantly reduced ($p<0.05$, $n=6$/group) chlorine gas-induced lung inflammation as measured by BAL fluid cellularity levels by 40% that appeared to be due to limiting neutrophil influx. AEOL 10150 also significantly attenuated ($p<0.05$, $n=6$) the degree of asthma-like airway reactivity induced by chlorine gas exposure by 40%. These results indicate that AEOL 10150 can attenuate lung injury and asthma-like symptoms from chlorine gas exposure and may provide an effective countermeasure against chlorine gas-induced lung injury.

National Jewish Health replicated the mice studies previously conducted by McGill University in rats to determine whether AEOL 10150 mitigates lung damage due to chlorine gas exposure. In the study, 10150 significantly reduced protein, IgM, white blood cell, red blood cell, macrophage and neutrophil counts in Broncho-alveolar lavage fluid.

Future Development Plans

Under a new $12.5 million grant received from NIH CounterACT in September 2011, University of Colorado and National Jewish Health plan to conduct studies in 2012/2013 to determine whether the initiation of treatment with AEOL 10150 can be delayed to 24 hours or later for sulfur, mustard and chlorine gas-induced lung injury. Additionally, studies will be run to examine the longer term effect of chlorine gas-induced lung fibrosis and AEOL 10150’s ability to mitigate those effects. Upon completion of these studies, we plan to file an IND for Chlorine Gas exposure with the FDA.

Following these studies, and provided we received sufficient funding for the program, we seek to develop a second animal model and to launch the two pivotal efficacy studies required for approval by the FDA under the “Animal Rule.” We believe that the safety and CMC work being done under the BARDA Lung-ARS further described under the heading “AEOL 10150 as a potential medical countermeasure against the effects of Pulmonary Acute Radiation Syndrome – Future Development Plans” will be sufficient to satisfy the safety and CMC requirements for an NDA filing.

Competition

There are currently no effective treatments for chlorine gas exposure and AEOL 10150 is a major focus of the NIH-CounterACT program to identify an effective treatment.

However, in general, we face significant competition for U.S. government funding for both development and procurements of MCMs for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. The U.S. federal government has currently allocated a significant amount of research funding to the development of countermeasures against bioterrorism. As a result, there are many drug candidates under development as a possible countermeasure against chemical threat agents.

Funding Options

In October 2011, we announced that National Jewish Health was awarded a $12.5 million contract from NIH-CounterACT to continue the development of AEOL 10150 as a MCM against chlorine gas exposure. Also included in the grant is support of research looking at tissue plasminogen activator (TPA) and Silabilin as MCMs against sulfur mustard gas exposure. The ultimate objective of the sulfur mustard and chlorine gas work at National Jewish Health will be to complete all work necessary to initiate pivotal efficacy studies for both indications. This would include: running efficacy studies in the rat model for higher doses of sulfur mustard and chlorine gas; establishing endpoints, optimal dosing and duration of treatment for pivotal efficacy studies; and characterizing the natural history from sulfur mustard and chlorine gas damage.

AEOL 10150 as a potential medical countermeasure against the effects of mustard gas

Overview

Sulfur mustards, of which mustard gas is a member, are a class of related cytotoxic, vesicant chemical warfare agents with the ability to form large blisters on exposed skin and cause pneumonitis and fibrosis in the lungs. In their pure form most sulfur mustards are colorless, odorless, viscous liquids at room temperature. When used as warfare agents they are usually yellow-brown in color and have an odor resembling mustard plants, garlic or horseradish. Mustard agents, including sulfur mustard, are regulated under the 1993 Chemical Weapons Convention. Three classes of chemicals are monitored under this Convention, with sulfur and nitrogen mustard grouped in the highest risk class, “schedule 1.” However, concerns about its use in a terrorist attack have led to resurgence in research to develop a protectant against exposure.

Mustard gas is a strong vesicant (blister-causing agent). Due to its alkylating properties, it is also strongly mutagenic (causing damage to the DNA of exposed cells) and carcinogenic (cancer causing). Those exposed usually suffer no immediate symptoms. Within 4 to 24 hours the exposure develops into deep, itching or burning blisters wherever the mustard contacted the skin; the eyes (if exposed) become sore and the eyelids swollen, possibly leading to conjunctivitis and blindness. At very high concentrations, if inhaled, it causes bleeding and blistering within the respiratory system, damaging the mucous membrane and causing pulmonary edema. Blister agent exposure over more than 50% body surface area is usually fatal.

The NIH awarded a five-year, $7.8 million grant to National Jewish Health and the University of Colorado Health Sciences Center, both in Denver, Colorado. This Center of Excellence was developed to focus on sulfur mustard toxicity in the lung and skin with the long-term goal to develop an effective treatment for mustard gas induced injury in lung and skin. Members of the Center are establishing optimal compounds, route and mode of delivery. Research projects are ongoing to determine countermeasures that will help establish specific interventions needed to rescue mustard gas-induced injury. After three years of research, AEOL 10150 has been identified by the National Jewish Health Center of Excellence as a lead compound for its center, and research work there has been focused on further testing and studies of AEOL 10150.

Research in the area of mustard gas-mediated lung injury has provided experimental evidence that the mechanisms of these injuries are directly linked to the formation of reactive oxygen and nitrogen species and that superoxide dismutase and catalase can improve injury responses. This theory has led to the hypothesis that the administration of catalytic antioxidant therapy can protect against mustard gas-induced acute lung and dermal injury. AEOL 10150 has already been shown to be well tolerated in humans and could be rapidly developed as a drug candidate in this area pending animal efficacy data.

Researchers have found that the chemical warfare agent analog, 2-chloroethyl ethyl sulfide ("CEES")-induced lung injury could be improved by both exogenous superoxide dismutase and catalase. Both of these natural enzymes are important catalytic antioxidants and both of these reactions are exhibited by metalloporphyrins. CEES-induced lung injury is dependent in part upon blood neutrophils. Activated neutrophils are an important source of reactive oxygen species that are known to contribute to lung injury responses. Antioxidants have also been shown to protect against CEES-induced dermal injury. Mustard exposure is often associated with producing acute respiratory distress syndrome that requires supplemental oxygen therapy to maintain adequate tissue oxygenation.

Further studies revealed that AEOL 10150 was effective at diminishing life-threatening airway obstruction produced by high dose exposure of CEES in rats with AEOL 10150 rescue providing substantial improvements in blood gas oxygen saturation, decreased airway obstruction and inflammation.

Pre-clinical studies

A study performed by researchers from National Jewish Health demonstrated that AEOL 10150 showed statistically significant protection of lung tissue in animals exposed to CEES or half-mustard. In a study sponsored by the NIH-CounterACT program, AEOL 10150 was tested along with 19 other compounds to determine effectiveness in protecting lung tissue against edema and hemorrhage resulting from exposure to mustard gas.

AEOL 10150 was given to rats one hour after CEES exposure and again 6 hours later. Eighteen hours after exposure, lung edema and hemorrhage was assessed by changes in the bronchoalveolar lavage protein and red blood cell levels. AEOL 10150 significantly reduced ($p<0.05$) mustard gas-induced lung edema and hemorrhage. These results suggest that AEOL 10150 rescues the lung from mustard gas exposure and may provide a countermeasure against mustard gas-induced lung injury. Further studies at National Jewish Health and the University of Colorado showed that doses in the range of 5 to 30 mg/kg of AEOL 10150 given at one and eight hours after exposure mitigate both lung and skin injury in animal models. Doses in the range of 5 to 10 mg/kg/d showed the most potent effect including significant mitigation as assessed by histopathology and immunohistochemistry.

Non-clinical studies

In 2009, several studies were launched to test the efficacy of AEOL 10150 as a treatment for damage to the skin and lungs due to exposure to sulfur mustard gas and to examine potential effective doses, duration of delivery and the window of opportunity for treatment after exposure. The studies are being conducted using “whole” sulfur mustard gas at Lovelace Respiratory Research Institute, another NIH-CounterACT Center of Excellence, and using data obtained from CEES studies at National Jewish Health and build on results from previous studies using CEES conducted at National Jewish Health and the University of Colorado.

The first whole mustard gas study was completed in October 2009. The study demonstrated that AEOL 10150 protects lungs from whole mustard gas exposure in rats. The data affirmed our earlier studies where AEOL 10150 protected the lung against the half-mustard, CEES. The primary objective of the studies was to determine whether administration of AEOL 10150, after exposure, reduces the severity of acute lung injury induced by mustard gas. AEOL 10150 was given to rats one hour after sulfur mustard exposure and repeated every 6 hours. Twenty-four hours after exposure, lung edema was assessed by changes in the BAL protein levels. AEOL 10150 significantly reduced ($p<0.05$) mustard gas-induced lung edema as measured by BAL protein levels. In addition, AEOL 10150 decreased SM-induced increase in the numbers of BAL neutrophils. These results indicate that AEOL 10150 can attenuate lung injury from mustard gas exposure and may provide an effective countermeasure against mustard gas-induced lung injury.

In June 2010, National Jewish Health and Lovelace Respiratory Research Institute reported results from a second whole mustard study confirming that AEOL 10150 protects lungs from whole mustard gas exposure in rats. The primary objective of this study was to determine whether administration of AEOL 10150, after exposure, reduces the severity of acute lung injury induced by mustard gas. AEOL 10150 was given to rats one hour after sulfur mustard vapor exposure and repeated every 6 hours. Twenty-four hours after exposure, lung edema was assessed by changes in the BAL protein levels. AEOL 10150 significantly reduced ($p<0.05$) mustard gas-induced lung edema as measured by bronchoalveolar lavage protein levels. In addition, AEOL 10150 decreased SM-induced increases in macrophages ($p<0.05$) and epithelial cells in BAL fluid ($P<0.05$).In all three measurements AEOL 10150 provided approximately 100 percent protection – with levels approximating that of the control animals in the study. These results indicate that AEOL 10150 can attenuate lung injury from mustard gas exposure and may provide an effective countermeasure against mustard gas-induced lung injury.

Future Development Plans

Following these confirmatory studies, we seek to launch the two pivotal efficacy studies required for approval by the FDA under the "Animal Rule" as well as complete the necessary safety studies as further described under the heading "AEOL 10150 as a potential medical countermeasure against the effects of Pulmonary Acute Radiation Syndrome – Future Development Plans – Demonstrate Product Safety."

Competition

There are currently no effective treatments for mustard gas exposure and AEOL 10150 is a major focus of a sponsored research grant awarded by the NIH-CounterACT program to National Jewish Health to identify an effective treatment.

However, in general, we face significant competition for U.S. government funding for both development and procurements of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. The U.S. federal government has currently allocated a significant amount of research funding to the development of countermeasures against bioterrorism. As a result, there are many drug candidates under development as a possible countermeasure against chemical threat agents.

Funding Options

This development program to date has been funded under the NIH-CounterACT Program and we expect that future efficacy studies necessary for approval by the FDA will also be funded by the NIH-CounterACT program.

AEOL 10150 in Radiation Therapy

Overview

According to the American Cancer Society, cancer is the second leading cause of death by disease, representing one out of every four deaths in the United States. Approximately 572,000 Americans were expected to die of cancer in 2011. In 2011, about 1.6 million new cancer cases were expected to be diagnosed in the United States. According to the Radiological Society of North America, about 50 to 60 percent of cancer patients are treated with radiation at some time during their disease. The NIH estimated overall costs of cancer in 2008 in the United States at $228.1 billion, $93.2 billion for direct medical costs, $18.8 billion for indirect morbidity costs (costs of lost productivity due to illness) and $116.1 billion for indirect mortality costs (cost of lost productivity due to premature death).

Combinations of surgery, chemotherapy and radiation treatments are the mainstay of modern cancer therapy. Success is often determined by the ability of patients to tolerate the most aggressive, and most effective, treatment regimens. Radiation therapy-induced toxicity remains a major factor limiting radiation doses. The ability to deliver maximal radiation doses for treatment of tumors without injury to surrounding normal tissue has important implications in oncology therapeutic outcomes because higher doses of radiation therapy may improve both local tumor control and patient survival.

Advances in the tools of molecular and cellular biology have enabled researchers to develop a better understanding of the underlying mechanisms responsible for radiation therapy-induced normal tissue injury. For decades ionizing radiation has been known to increase production of free radicals, which is reflected by the accumulation of oxidatively damaged cellular macromolecules.

As one example of radiation-induced damage to adjacent normal tissue, radiation therapy may injure pulmonary tissue either directly via generation of ROS or indirectly via the action on parenchymal and inflammatory cells through biological mediators such as TGF- and pro-inflammatory cytokines. Since the discovery of SOD, it has become clear that these enzymes provide an essential line of defense against ROS. SODs and SOD mimics, such as AEOL 10150, act by catalyzing the degradation of superoxide radicals into oxygen and hydrogen peroxide. SODs are localized intra/extracellularly, are widely expressed throughout the body, and are important in maintenance of redox status (the balance between oxidation and reduction). Previous studies have demonstrated that treating irradiated animal models with SOD delivered by injection of the enzyme through liposome/viral-mediated gene therapy or insertion of human SOD gene can ameliorate radiation therapy-induced damage. For an illustrative example of the radiation therapy reaction see Figure 9.

Figure 9

Figure 9 above shows the dual mechanism of action of radiation therapy and the application of AEOL 10150 to the process.

In vitro studies have demonstrated that AEOL 10150 reduces the formation of lipid peroxides and that it inactivates biologically important ROS molecules such as superoxide, hydrogen peroxide and peroxynitrite. AEOL 10150 inactivates these ROS by one or two electron oxidation or reduction reactions in which the oxidation state of the manganese moiety in AEOL 10150 changes. AEOL 10150 is not consumed in the reaction and it continues to inactivate such ROS molecules as long as it is present at the target site. Preclinical models and human safety studies suggest AEOL 10150 is not metabolized in the body and is excreted in feces and urine.

Pre- clinical studies

Figure 10

Figure 10.Relative tumor volumes of human prostate tumor implants in nude mice: Implants of well-vascularized PC3 tumors were grown to substantial size prior to receiving fractionated radiation (5 Gy daily for three days).AEOL 10150 (7.5 mg/kg/bid) was administered subcutaneously commencing on the first day of irradiation and continued for 20 days. Other groups of mice received either no irradiation, irradiation only or AEOL 10150 without irradiation.

Due to the similar mechanisms of actions between radiation therapy (in oncology) and radiation exposure (from nuclear events), we believe that the pre-clinical studies performed for the development of AEOL 10150 as a potential medical countermeasure against the effects of Lung-ARS, as described below, also provide support for the development of AEOL 10150 in oncology, to be used in combination with radiation therapy.

We have performed several additional studies specifically for this indication to ensure the use of an antioxidant in radioprotection of normal adjacent tissue does not interfere with the efficacy of tumor radiotherapy. A number of preclinical, in vivo studies have addressed this issue and have demonstrated that AEOL 10150 does not negatively impact tumor radiotherapy.

In one study (Vujaskovic, et al. of Duke University), human prostate tumors (PC3) grown in nude mice to substantial size were fraction irradiated with 5 Gy per day for 3 days for a total of 15 Gy. AEOL 10150 at 7.5 mg/kg/bid was administered subcutaneously on the first day of radiation and continued for either of two time courses: when tumor volume reached 5 times the initial volume or for twenty days. The receding tumor volume curves for irradiation only and for irradiation plus AEOL 10150 were super-imposable. Therefore AEOL 10150 did not interfere with the radiation effect on xenogenic prostate tumor.

In another study of prostate cancer tumors (Gridley, et al of Loma Linda University), mouse prostate cancer cell line RM-9 was injected subcutaneously into C57/Bl6 mice, followed by up to 16 days of AEOL 10150 delivered intraperitonealy at 6 mg/kg/day. On day seven, a single non-fractionated dose of radiation (10 Gy) was delivered. Therefore, the mice received compound for seven days prior to radiation. The results of this study demonstrated that AEOL 10150 does not protect the prostate tumor against radiation, and, in fact, AEOL 10150 showed a trend towards increasing the effectiveness of the radiation treatment. The primary effect appears to be in down-regulation of radiation induced HIF-1 expression and VEGF and up-regulation of IL-4.Thus, AEOL 10150, through its down-regulation of VEGF, may inhibit formation of blood vessels (i.e., angiogenisis) required for tumor re-growth and protects normal tissues from damage induced by radiation and chemotherapy.

In another study (Vujaskovic, et al. of Duke University), mice were implanted with human NSCLC tumors and treated with all potential combinations of paclitaxel, radiation and AEOL 10150 to determine the impact on tumor growth. The results showed that AEOL 10150 did not impact the effects of either radiation therapy or paclitaxel. Further, the study indicated that the greatest impact in inhibiting tumor growth was with the regimen that included all three (radiation + paclitaxel + AEOL10150).

Figure 11

Figure 11 above measures tumor volume against time after implantation of RM-9 tumor cells and shows that AEOL 10150 treatment resulted in inhibition of tumor re-growth in a study performed by Dr. Gridley of Loma Linda University. Daily intraperitoneal injections of AEOL 10150 were initiated on day 1.At 12 days, approximately one half of each tumor-bearing group and control mice with no tumor were euthanized for in vitro analyses; remaining mice/group were followed for tumor growth and euthanized individually when maximum allowed tumor volume was attained. Each point represents the mean +/- standard error of the mean. Two-way analysis of the variance for days 8 to 14 revealed that group and time had highly significant main effects (Ps<0.001) and a group x time interaction was noted (P<0.001).

Figure 12

Figure 12 above shows the HIF-1 Expression in prostate tumors and the impact of the treatment of AEOL 10150 in a study by Dr. Gridley of Loma Linda University.

Figure 13

Figure 13 above shows impact on tumor growth in mice that were implanted with human NSCLC tumors and treated with all potential combinations of paclitaxel, Radiation and AEOL 10150.

In summary, the data obtained in these preclinical studies suggest that the post-irradiation, long-term delivery of AEOL 10150 may be protective against radiation-induced lung injury, as assessed by histopathology and immunohistochemistry. Oxidative stress, inflammation and hypoxia, which play important roles in the pathogenesis of radiation mediated fibrosis, were shown to be reduced in animals treated with higher doses of AEOL 10150. Studies have also shown that AEOL 10150 does not adversely impact tumor response to radiation therapy. Thus, treatment with AEOL 10150 does not significantly protect tumors from the cell killing effects of radiation therapy. This combined with other studies that have shown that AEOL 10150 significantly prevents radiation induced normal tissue injury suggests that AEOL 10150 has the potential to achieve normal tissue protection without protection of tumor tissue. Additionally, it appears the down-regulation of radiation induced HIF-1 expression and VEGF and up-regulation of IL-4 may provide additional anti-tumor effects. Thus, AEOL 10150, through its down-regulation of VEGF, may inhibit formation of blood vessels required for tumor re-growth, while protecting normal tissues from damage induced by radiation and chemotherapy.

Future Development Plans

We are leveraging the significant investment made by U.S. government agencies to develop this promising compound for use in oncology indications, where it would be used in combination with chemotherapy and radiation therapy, and is currently in development for use as both a therapeutic and prophylactic drug. Data has already been published showing that AEOL 10150 does not interfere with the therapeutic benefit of radiation therapy in prostate and lung cancer preclinical studies.

In 2013, we expect to initiate a safety study in healthy normal volunteers under the BARDA Contract. Upon the successful completion of the Phase I study and approval of its protocol by the FDA and the appropriate IRBs, we expect to begin a Phase II study in NSCLC patients.

Competition

There are currently three drugs approved for the treatment of the side effects of radiation therapy. We do not believe that any of these drugs directly competes with AEOL 10150 in terms of mechanism of action or targeted therapeutic benefit when used in combination with radiation therapy.

Amifostine (Ethyol®) is approved by the FDA as a radioprotector. Amifostine (Ethyol) is marketed by MedImmune, Inc. for use in reduction of chemotherapy-induced kidney toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer and radiation-induced xerostomia (damage to the salivary gland) in patients undergoing post-operative radiation treatment for head and neck cancer. MedImmune, Inc. is studying Amifostine in other indications of radiation therapy. KepivanceTM (palifermin) is marketed by Amgen, Inc. for use in the treatment of severe oral mucositis (mouth sores) in patients with hematologic (blood) cancers who are undergoing high-dose chemotherapy followed by bone transplant. Amgen, Inc. is also studying Kepivance as an antimucositis agent in patients with head and neck cancer, non-small cell lung cancer and colon cancer. Salagen Tablets (pilocarpine hydrochloride) is marketed by Eisai Pharmaceuticals in the United States as a treatment for the symptoms of xerostomia induced by radiation therapy in head and neck cancer patients. In addition, there are many drugs under development to treat the side effects of radiation therapy.

Funding Options

Substantially all of our costs associated with the CMC and toxicology necessary for the oncology indications, plus human safety studies in humans, have been, or we expect will be, covered by the BARDA Contract. We expect such costs to continue to be covered by the BARDA Contract. If BARDA chooses not to exercise its options under the BARDA Contract, then we would need to raise additional capital, or partner with another firm, in order to complete the non-clinical and safety programs noted above. We will need to internally fund the human efficacy programs in oncology, as well as any non-clinical studies that may be necessary for specific oncology indications. We may still seek to raise capital through other sources even if BARDA exercises additional options under the BARDA Contract.

AEOL 10150 in Amyotrophic Lateral Sclerosis

Overview

ALS, commonly referred to as “Lou Gehrig’s disease,” the most common motor neuron disease, results from progressive degeneration of both upper and lower motor neurons. Motor Neuron Disease (“MND”) is an all-embracing term used to cover a number of illnesses of the motor neuron. ALS, Progressive Muscular Atrophy (PMA), Progressive Bulbar Palsy (PBP), Primary Lateral Sclerosis (PLS) are all subtypes. MND is the generic term for this disease and is used more frequently in Europe, while ALS is used more frequently in the U.S.

According to the ALS Association ("ALSA"), the incidence of ALS is two per 100,000 people. ALS occurs more often in men than women, with typical onset between 40 and 70 years of age. ALS is a progressive disease and approximately 80% of ALS patients die within five years of diagnosis, with only 10% living more than 10 years. The average life expectancy is two to five years after diagnosis, with death from respiratory and/or bulbar muscle failure. The International Alliance of ALS/MND Associations reports there are over 350,000 patients with ALS/MND worldwide and 100,000 people die from the disease each year worldwide. In the United States, ALSA reports that there are approximately 30,000 patients with ALS with 5,600 new patients diagnosed each year.

Sporadic (i.e., of unknown origin) ALS is the most common form, accounting for approximately 90% of cases. The cause of sporadic ALS is unclear. Familial ALS comprises the remainder of cases and 5-10% of these patients have a mutated superoxide dismutase 1 ("SOD1") gene. More than 90 point mutations have been identified, all of which appear to associate with ALS, and result in motor neuron disease in corresponding transgenic mice. SOD mutations have been observed in both familial and sporadic ALS patients, although the nature of the dysfunction produced by the SOD1 mutations remains unclear. The clinical and pathological manifestations of familial ALS and sporadic ALS are indistinguishable suggesting common pathways in both types of disease.

In November 2003, the FDA granted orphan drug designation for our ALS drug candidate. Orphan drug designation qualifies a product for possible funding to support clinical trials, study design assistance from the FDA during development and for financial incentives, including seven years of marketing exclusivity upon FDA approval.

Pre-clinical studies

John P. Crow, Ph.D., and his colleagues at the University of Alabama at Birmingham tested AEOL 10150 in an animal model of ALS (SOD1 mutant G93A transgenic mice). The experiments conducted by Dr. Crow (now at the University of Arkansas College of Medicine) were designed to be clinically relevant by beginning treatment only after the onset of symptoms in the animals is observed. Twenty-four confirmed transgenic mice were alternately assigned to either a control group or AEOL 10150-treatment on the day of symptom onset, which was defined as a noticeable hind-limb weakness. Treatment began on the day of symptom onset. The initial dose of AEOL 10150 was 5 mg/kg, with continued treatment at a dose of 2.5 mg/kg once a day until death or near death.

Treatment	Age at Symptom onset mean days + SD(range)	Survival Interval mean days + SD(range)	P-value Log-rank (v. control)	P-value Wilcoxon (v. control)
Control	104.8 + 1.43 (100-112)	12.8 + 0.79 (9-16)		
AEOL 10150	106.1 + 1.5 (100-115)	32.2 + 2.73 (15-46)	< 0.0001	0.0002

Table 1.Effect of AEOL 10150 on survival of G93A transgenic mice

Figure 14.

Table 1 and Figure 14 above show that AEOL 10150 treatment resulted in a greater than 2.5 times mean survival interval, compared to control. AEOL 10150-treated mice were observed to remain mildly disabled until a day or two before death. In contrast, control mice experienced increased disability daily.

Dr. Crow has repeated the ALS preclinical experiment a total of four times, in each case with similar results. The efficacy of AEOL 10150 in the G93A mouse model of ALS has also been evaluated by two additional laboratories. One of these laboratories verified an effect of AEOL 10150 in prolonging survival of the G93A mouse, while no beneficial effect of the drug was identified in the other laboratory.

Future Development Plans

We do not currently have any plans to pursue the development of AEOL 10150 for the treatment of ALS unless we are able to obtain funding specifically for this purpose.

Competition

Rilutek® (riluzole), marketed by Sanofi-Aventis SA, is the only commercially approved treatment for ALS in the United States and the European Union. Administration of Rilutek prolongs survival of ALS patients by an average of 60-90 days, but has little or no effect on the progression of muscle weakness, or quality of life. Rilutek was approved in the United States in 1995, and in 2001 in the European Union. However, there are at least twenty drug candidates reported to be in clinical development for the treatment of ALS.

In addition, ALS belongs to a family of diseases called neurodegenerative diseases, which includes Alzheimer's, Parkinson's and Huntington's disease. Due to similarities between these diseases, a new treatment for one ailment potentially could be useful for treating others. There are many companies that are producing and developing drugs used to treat neurodegenerative diseases other than ALS.

AEOL 10150 Clinical Development Program

AEOL 10150 has been thoroughly tested for safety, tolerability and pharmacokinetics with no serious or clinically significant adverse effects observed. To date, 38 patients have received AEOL 10150 in three clinical trials designed to test the safety and tolerability of the drug candidate.

In September 2005, we completed a multi-center, double-blind, randomized, placebo-controlled, Phase I clinical trial. This escalating-dose study was conducted to evaluate the safety, tolerability and pharmacokinetics of AEOL 10150 administered by twice daily subcutaneous injections in patients with ALS.

In the Phase Ia study, 4-5 patients diagnosed with ALS were placed in a dosage cohort (3 or 4 receiving AEOL 10150 and 1 receiving placebo).Each dose cohort was evaluated at a separate clinical center. In total, seven separate cohorts were evaluated in the study, and 25 ALS patients received AEOL 10150.Based upon an analysis of the data, it was concluded that single doses of AEOL 10150 ranging from 3 mg to 75 mg were safe and well tolerated. In addition, no serious or clinically significant adverse clinical events were reported, nor were there any significant laboratory abnormalities. Based upon extensive cardiovascular monitoring (i.e., frequent electrocardiograms and continuous Holter recordings for up to 48 hours following dosing), there were no compound-related cardiovascular abnormalities.

The most frequently reported adverse events in this Phase I clinical trial were injection site reactions, followed by dizziness and headache. Adverse events were primarily mild in severity, and approximately one-half of the events

were considered to have a possible relationship to the study medication. In addition, no clinically meaningful findings were noted in the safety, laboratory, vital sign, the Unified Parkinson's Disease Rating Scale ("UPDRS"), functional ALS, or electro cardiogram ("ECG") data. All cohorts exhibited dose-related peak plasma drug concentrations and consistent disappearance half-lives.

In October 2006, we completed a multi-center, double-blind, randomized, placebo-controlled, Phase Ib clinical trial. This multiple dose study was conducted to evaluate the safety, tolerability and pharmacokinetics of AEOL 10150 administered by subcutaneous injection and infusion pump in patients with ALS. Under the multiple dose protocol, three groups of six ALS patients (four receiving AEOL 10150 and two receiving placebo) were enrolled, based upon patients who meet the El Escorial criteria for Clinically Definite ALS, Clinically Probable ALS, Clinically Probable-Laboratory Supported ALS, or Definite Familial-Laboratory Supported ALS (i.e., Clinically Possible ALS with an identified SOD gene mutation).

The first two cohorts of the Phase Ib multiple dose study received a fixed daily dose of AEOL 10150 twice a day by subcutaneous injection. In the first cohort, each patient received twice daily subcutaneous injections of 40 mg of AEOL 10150 or placebo, for six consecutive days, followed by a single subcutaneous injection on the seventh day, for a total of 13 injections. In the second cohort, each patient received twice daily subcutaneous injections of 60 mg of AEOL 10150 or placebo, for six consecutive days, followed by a single subcutaneous injection on the seventh day, for a total of 13 injections.

In contrast, the third cohort received a weight adjusted dose (i.e., mg per kilogram of body weight per day) delivered subcutaneously over twenty four hours by continuous infusion pump. In the third cohort, each patient received AEOL 10150 via continuous infusion pump for six and one half consecutive days for a total of 2.0 mg per patient kilogram per day. Each patient in all three cohorts completed the study and follow-up evaluation at 14 days.

The Phase Ib study was conducted at five academic clinical ALS centers. Male and female ALS patients, 18 to 70 years of age, who were ambulatory (with the use of a walker or cane, if needed) and capable of orthostatic blood pressure assessments were enrolled in the study. Clinical signs/symptoms, laboratory values, cardiac assessments and pharmacokinetics (PK) were performed.

Based upon an analysis of the data, it was concluded that multiple doses of AEOL 10150 for a period of six and one half consecutive days in the amount of 40 mg per day, 60 mg per day and 2 mg per kilogram per day were safe and well tolerated. No serious or clinically significant adverse events were reported or observed. The most frequent adverse events related to study compound were injection site observations related to compound delivery. There were no significant laboratory abnormalities. Based upon extensive cardiovascular monitoring (i.e., frequent electrocardiograms and continuous Holter recordings throughout the six and one half days of dosing), there were no compound-related cardiovascular abnormalities.

Pharmacokinetic findings from the Phase Ib study to data are as follows:

- Increases in Cmax and AUC (0-8) appear to correlate with increases in dose, but the correlation is not strong.
- The mean Cmax for the 40 mg cohort was 1,735 ng/mL; 2,315 ng/mL for the 60 mg cohort and 1,653 ng/mL for the 2 mg/kg cohort.
  - There were probable linear correlations between both Cmax and AUC(0-8) and dose based on body weight.
- The terminal half-life (a measurement of the time period for which a compound stays in the body) as determined from Day 7 data was approximately 8 to 9 hours.
- Steady-state occurs within three days of multiple dosing. There was no evidence for a third longer half-life that would be associated with long term accumulation. Thus, compound accumulation is not expected beyond the third day with multiple dosing.
- From 48 hours to the end of the infusion, the plasma concentrations of AEOL 10150 during the infusion showed little variability, indicating a smoother delivery of the drug than with twice-daily injections.

During 2008, we completed a follow-on Phase I open label compassionate use multiple dose study of AEOL 10150 in a patient diagnosed with progressive and debilitating amyotrophic ALS. The study was conducted at the University of California, Los Angeles by Martina Wiedau-Pazos, M.D., and was designed to evaluate the safety and efficacy of AEOL 10150 in an ALS patient over an extended period of time. The patient received a subcutaneous injection of 75mg of AEOL 10150 two times each day for 34 days. Efficacy and safety data was monitored for the duration of the study. The primary objective of this study was to assess the clinical efficacy of AEOL 10150 with respect to the patient's baseline assessment of functional status. Secondary objectives included the assessments of muscle strength, respiratory function, quality of life and safety. The patent's baseline efficacy results were an ALS Functional Rating Scale ("ALSFRS-R") rating of 19, Muscle strength Manual Muscle Testing Scale ("MMTS") of 68 and a forced vital capacity ("FVC") of 30%. The patient's results after 2 months were an ALSFRS-R rating of 22, a MMTS rating of 86

and an FVC of 28%. It should be noted that the subject began using breathing assistance (BiPAP) approximately two weeks after the study started. The patient discontinued treatment due to nausea and moderately increased liver transaminases. Other drug-associated adverse events included mild skin irritation at the injection site and mild urine discoloration.

AEOL 11207

Overview

We have selected AEOL 11207 as our second development candidate based upon results from data obtained from our pre-clinical testing of our pipeline drug candidates. Because of the wide-ranging therapeutic opportunities that the compound evidenced in diverse pre-clinical models of human diseases, we have not yet ascertained what the most robust therapeutic use of AEOL 11207 might be. However, data collected to date suggest that AEOL 11207 may be useful as a potential once-every-other-day oral therapeutic treatment option for central nervous system ("CNS") disorders, most likely Parkinson's disease.

Parkinson's disease is a common neurodegenerative disorder, second in occurrence among these disorders only to Alzheimer's disease. According to the National Parkinson Foundation, Parkinson's affects as many as one million people in the United States, with approximately 60,000 new cases diagnosed in the United States each year.

Parkinson's specifically involves the progressive destruction of the nerves that secrete dopamine and control the basal ganglia, an area of the brain involved in the regulation of movement. Dopamine turnover has been shown to elevate the levels of ROS in the brain. In addition, a street-drug contaminant has appeared that can cause parkinsonism in drug abusers. The compound N-methyl-4-phenyl-1, 2, 3, 6tetrahydropyridine ("MPTP") has been identified in underground laboratory preparations of a potent analog of meperidine (Demerol). MPTP-containing powder, sometimes sold as a new "synthetic heroin," can be dissolved in water and administered intravenously or taken by the intranasal route. MPTP has been documented to produce irreversible chronic Parkinson symptoms in drug abusers. Agents such as MPTP overproduce ROS in the basal ganglia. Therefore, ROS mediated neuronal dysfunction may play a key role in the development of Parkinson's disease. Symptoms of this disease include tremors, rigidity and bradykinesia (i.e., slowness of movement).In the more advanced stages, it can cause fluctuations in motor function, sleep problems and various neuro-psychiatric disorders. A biological hallmark of Parkinson's disease is a reduction in brain dopamine levels. Preventing or slowing the destruction of brain cells that lead to the depletion of dopamine levels in the brain is an important therapeutic approach for the treatment of this disease.

Pre-clinical studies

Data developed by our scientists and Dr. Manisha Patel at the University of Colorado Health Sciences Center and Department of Medicine, indicate that when administered orally, AEOL 11207 is greater than 80% bioavailable, meaning that it is readily absorbed and reaches both the circulatory system and the brain in sufficient amounts to demonstrate biological activity. Data developed with AEOL 11207 in a widely used animal model of Parkinson's disease (the "MPTP model") showed that when administered orally, AEOL 11207 crosses the blood brain barrier and protected dopamine neurons in a dose-dependent manner. Further data suggest that the compound has a half- life (a measurement of the time period for which a compound stays in the body) of about 3 days in both the circulatory system and the brain, and that prior to stopping administration of the compound, the levels of AEOL 11207 in both the circulatory system and brain reach a steady state (a valuable measurement of when the levels of the drug in the body remain substantially constant, neither increasing nor decreasing) after 2 days of dosing. Data have also been developed that indicate that when dosing of AEOL 11207 is stopped, the compound is excreted from the body.

In September 2010, Manisha Patel of the University of Colorado was informed by the Michael J. Fox Foundation that she had been awarded a supplement to her grant. The funds are for the synthesis of additional quantities of AEOL1114B and AEOL11203; for the completion of the evaluation of AEOL1114B and AEOL11203's effects on MPTP toxicity (TH+ cells in substantia nigra), and behavioral testing and accumulation of manganese after chronic dosing.

Prior to receiving the funding for this program, we filed a new composition of matter and use patent for AEOL 11114B and 11203.

Future Development Plans

For this and other reasons, we believe that the therapeutic rationale for developing AEOL 11207 as a neuroprotectant, may substantially change the course of therapeutic treatment options for Parkinson's disease if AEOL 11207 were to achieve regulatory approval for commercialization. However, we are unable to determine at this time that such regulatory approval for AEOL 11207 can be or will be secured and we will not be able to further develop AEOL 11207 unless funding for this purpose is obtained.

AEOL 11207 is patent-protected and has the same chemical core structure as AEOL 10150.Because of this common structural feature, it is anticipated that AEOL 11207 will evidence substantially the same safety profile in clinical evaluations as observed with AEOL 10150, making clinical trial design and testing of AEOL 11207 more robust and facile. Furthermore, all of our compounds evidence the ability to scavenge and decrease ROS and reactive nitrogen species (RNS), all of which are implicated in a variety of CNS diseases.

Funding Options

The University of Colorado, our research provider for the development of AEOL 11207 for the treatment of Parkinson's Disease, received a grant for funding from the Michael J. Fox Foundation to further test AEOL 11207 and several of our other compounds.

In November 2010, we received approximately $92,000 from the Qualifying Therapeutic Discovery Grant Program ("QTDP") administered by the Internal Revenue Service ("IRS") and HHS in support of our development of AEOL 11207 for Parkinson's Disease.

Background on Antioxidants

Oxygen Stress and Disease

Oxygen plays a pivotal role in supporting life by enabling energy stored in food to be converted to energy that living organisms can use. The ability of oxygen to participate in key metabolic processes derives from its highly reactive nature. This reactivity is necessary for life, but also generates different forms of oxygen that can react harmfully with living organisms. In the body, a small proportion of the oxygen we consume is converted to superoxide, a free radical species that gives rise to hydrogen peroxide, hydroxyl radical, peroxynitrite and various other oxidants.

Oxygen-derived free radicals can damage DNA, proteins and lipids resulting in inflammation and both acute and delayed cell death. The body protects itself from the harmful effects of free radicals and other oxidants through multiple antioxidant enzyme systems such as SOD. These natural antioxidants convert the reactive molecules into compounds suitable for normal metabolism. When too many free radicals are produced for the body's normal defenses to convert, "oxidative stress" occurs with a cumulative result of reduced cellular function and, ultimately, disease.

Data also suggests that oxygen-derived free radicals are an important factor in the pathogenesis of a large variety of diseases, including neurological disorders such as ALS, Parkinson's disease, Alzheimer's disease and stroke, and in non-neurological disorders such as cancer radiation therapy damage, emphysema, asthma and diabetes.

Antioxidants as Therapeutics

Because of the role that oxygen-derived free radicals play in disease, scientists are actively exploring the possible role of antioxidants as a treatment for related diseases. Preclinical and clinical studies involving treatment with SOD, the body's natural antioxidant enzyme, or more recently, studies involving over-expression of SOD in transgenic animals, have shown promise of therapeutic benefit in a broad range of disease therapies. Increased SOD function improves outcome in animal models of conditions including stroke, ischemia-reperfusion injury (a temporary cutoff of blood supply to tissue) to various organs, harmful effects of radiation and chemotherapy for the treatment of cancer, and in neurological and pulmonary diseases. Clinical studies with bovine SOD, under the brand Orgotein, or recombinant human SOD in several conditions including arthritis and protection from limiting side effects of cancer radiation or chemotherapy treatment, have also shown promise of benefit. The major limitations of enzymatic SOD as a therapeutic are those found with many proteins, most importantly limited cell penetration and allergic reactions.

Allergic reactions led to the withdrawal of Orgotein from almost every worldwide market.

Catalytic Antioxidants vs. Antioxidant Scavengers

From a functional perspective, antioxidant therapeutics can be divided into two broad categories, scavengers and catalysts. Antioxidant scavengers are compounds where one antioxidant molecule combines with one reactive oxygen molecule and both are consumed in the reaction. There is a one-to-one ratio of the antioxidant and the reactive molecule. With catalytic antioxidants, in contrast, the antioxidant molecule can repeatedly inactivate reactive oxygen molecules, which could result in multiple reactive oxygen molecules combining with each antioxidant molecule.

Vitamin derivatives that are antioxidants are scavengers. The SOD enzymes produced by the body are catalytic antioxidants. Catalytic antioxidants are typically much more potent than antioxidant scavengers, in some instances by a multiple of up to 10,000.

Use of antioxidant scavengers, such as thiols or vitamin derivatives, has shown promise of benefit in preclinical and clinical studies. Ethyol, a thiol-containing antioxidant, is approved for reducing radiation and chemotherapy toxicity during cancer treatment, and clinical studies have suggested benefit of other antioxidants in kidney and neurodegenerative diseases. However, large sustained doses of the compounds are required as each antioxidant scavenger molecule is consumed by its reaction with the free radical. Toxicities and the inefficiency of scavengers have limited the utility of antioxidant scavengers to very specific circumstances.

Contracts and Grants

We seek to advance development of our drug candidates through external funding arrangements. We may slow down development programs or place them on hold during periods that are not covered by external funding. We have received external funding awards for the development of AEOL 10150 as an MCM for Lung-ARS, GI-ARS, mustard gas and chlorine gas exposure from the NIH.

BARDA Contract

In December 2009, we were informed by BARDA that we had been chosen to submit a full proposal for funding of our Lung-ARS program from its current stage through FDA approval, based on a summary “white paper” submitted by us earlier in 2009. We submitted a full proposal in February 2010. We were notified in July 2010 that our proposal had been chosen by BARDA, and then entered into negotiations for a development contract with the agency.

On February 11, 2011, we signed an agreement with BARDA for the development of AEOL 10150 as a MCM against Lung-ARS (the “BARDA Contract”). Pursuant to the BARDA Contract we were awarded approximately $10.4 million in the base period of the contract. On April 16, 2012, we announced that BARDA had exercised two options under the BARDA Contract worth approximately $9.1 million, bringing the total exercised contract value to date to approximately $19.5 million. We may receive up to an additional $98.9 million in options exercisable over the years following the base period. If all of the options are exercised by BARDA, the total value of the contract would be approximately $118.4 million. Pursuant to the Statement of Work in the BARDA Contract, we expect to provide the data necessary for filing an EUA in the second half of 2013. Once the EUA is filed, it would be possible for BARDA to begin procuring AEOL 10150 for the strategic national stockpile. Procurements from BARDA may result in significant revenues, and profitability, for Aeolus

Activities conducted during the base period include developing animal models with radiation survival curve studies, dosing studies, bulk drug manufacturing, final drug product manufacturing, validation testing, compliance studies and the filing of IND, an orphan drug status application and a fast track designation application with the FDA. In the event BARDA exercises additional options to provide additional funding under the BARDA Contract, activities to be conducted would include, among other things, bulk drug and final drug product manufacturing, stability studies, animal pivotal efficacy studies, human clinical safety studies and Phase I, Phase II and pre-new drug application (“NDA”) meetings and applications with the FDA.

Following the commencement of the BARDA Contract, we entered into a series of agreements with various parties in furtherance of our efforts under the BARDA Contract, which are described in this paragraph. On February 18, 2011, we entered into a Research and Manufacturing Agreement with Johnson Matthey Pharmaceutical Materials, Inc. (d/b/a Johnson Matthey Pharma Services) (“JMPS”), pursuant to which we engaged JMPS to, among other things, assess and develop a reliable separations or manufacturing process for certain chemical compounds as required by us and to

perform such additional work as may be required or agreed upon by the parties and to manufacture compounds for us. Each project performed by JMPS under the agreement will have a detailed project description and separate fee agreement based on the nature and duration of the project and the specific services to be performed by JMPS. The term of the agreement with JMPS will continue until February 16, 2016 or the date on which all projects under the agreement have been completed or terminated. On February 23, 2011, we and Booz Allen Hamilton Inc. ("Booz Allen") entered into a General Management Consulting Assignment, pursuant to which we engaged Booz Allen to, among other things, provide us with evaluation, operational and transitional support during the establishment and enhancement of our quality assurance, document management, earned value management and program management systems. We have agreed to pay Booz Allen on a time-and-materials basis. On March 16, 2011, we and the Office of Research and Development of the University of Maryland, Baltimore ("UMB") entered into a Sub-award Agreement, pursuant to which we engaged UMB to, among other things, develop a whole thorax lung irradiation model for use in studies supporting the licensure of AEOL 10150. The Sub-award Agreement is a fixed fee agreement inclusive of all direct and indirect costs. As a result of the contract modification and no-cost extension with BARDA mentioned below, the term of the Sub-award Agreement will continue through at least September, 2013. On April 12, 2011, we and Duke University ("Duke") entered into a Sponsored Research Agreement (Non-Clinical), pursuant to which we engaged Duke to perform a program of scientific research entitled "Murine Studies for the Development of AEOL 10150 as a Medical Countermeasure Against ARS and DEARE" (Delayed Effects of Acute Radiation Exposure), which will include, among other things, studies and models of optimum dosing of AEOL 10150 in mice. We entered into the Sponsored Research Agreement in furtherance of our efforts under the BARDA Contract. The Sponsored Research Agreement is a cost plus fee agreement inclusive of all direct and indirect costs.

On February 14, 2012, the Aeolus team presented the results and deliverables that had been produced during the first twelve months under the base period of the BARDA Contract at an “In-Progress Review” meeting with BARDA, and requested the exercise of additional contract options, which contain additional key items required in the advanced development of AEOL 10150.

On February 15, 2012, we announced that we entered into a contract modification and no-cost extension with BARDA. The modification and extension allowed us to continue operating under the base period of the contract awarded in February 2011, and restructured the timing and components of the options that could be awarded under the remaining four years of the agreement. The changes did not impact the total potential value of the contract, which remains at approximately $118.4 million. The contract restructure was driven by our ability to generate cost savings in the base year contract, and to allow BARDA to better manage contract options to expedite development program.

On April 16, 2012, we announced that BARDA had exercised two contract options worth approximately $9.1 million. BARDA's exercise of the options was in response to the presentation of the deliverables and progress made under the contract at the meeting on February 14, 2012. Among the key items in the options BARDA exercised are animal efficacy studies, mechanism of action research and manufacturing and process validation work. All of these items build off of work successfully completed during the first twelve months of the contract base period. The contract is designed to produce the data necessary for an approval under the FDA “Animal Rule” and for a potential Emergency Use Authorization (EUA). An approval or EUA would allow the federal government to buy AEOL 10150 for the Strategic National Stockpile under Project Bioshield. Project Bioshield is designed to accelerate the research, development, purchase and availability of effective medical countermeasures for the Strategic National Stockpile

Since February 11, 2011, we have been actively developing AEOL 10150 under the BARDA Contract. Among the key deliverables accomplished in the program, we hired the necessary personnel required under the contract, completed the radiation dose studies in mice and NHPs, manufactured a GMP batch for use in human safety studies and a non-GMP batch of material for use in animal efficacy studies, developed significant improvements to the process for manufacturing compound which will reduce the cost of producing the drug; made several discoveries related to the mechanism of damage of radiation and mechanism of action of AEOL 10150; met twice with the FDA to discuss our IND filing for Lung-ARS; and designed and initiated quality, reporting, risk management and project management programs required under the BARDA Contract. We have also initiated a number of animal efficacy studies for which we expect to report data during 20123.

Under the BARDA Contract, we plan to deliver the data necessary for BARDA to file an Emergency Use Authorization (“EUA”) with the FDA in approximately the second half of 2013. An EUA is a legal means for the FDA to approve new drugs or new indications for previously approved drugs that may be stockpiled and used during a declared emergency. To date, about half of the procurements for the national stockpile for medical countermeasures against potential terrorist events have been made under EUAs, prior to approval by the FDA for the indication in question.

As of September 30, 2012, the total contract value exercised by BARDA under the BARDA Contract is $19.5 million.

NIH and HHS Grants

AEOL 10150 continues to be the subject of research sponsored by NIH-CounterACT as an MCM for chlorine gas and sulfur mustard gas exposure at National Jewish Health.

In November 2010, we received approximately $244,000 from the QTDP, administered by the IRS and HHS, in support of our development of AEOL 10150 as an MCM for Lung-ARS.

We, and our development partners, continue to actively pursue additional government or foundation sponsored development contracts and grants and to encourage both governmental, non-governmental agencies and philanthropic organizations to provide development funding or to conduct clinical studies of our drug candidates.

Collaborative and Licensing Arrangements

Duke Licenses

Pursuant to our license agreements with Duke, we have obtained exclusive worldwide rights from Duke to products using antioxidant technology and compounds developed by Dr. Irwin Fridovich and other scientists at Duke. We are obligated under the licenses to pay Duke royalties ranging in the low single digits of net product sales during the term of the Duke licenses, and we must make payments upon the occurrence of certain development milestones in an aggregate amount of up to $2,000,000. In addition, we are obligated under the Duke licenses to pay patent filing, prosecution, maintenance and defense costs. The Duke licenses are terminable by Duke in the event of breach by us and otherwise expire when the last licensed patent expires.

National Jewish Medical and Research Center and National Jewish Health

We have obtained an exclusive worldwide license from the National Jewish Medical and Research Center (“NJMRC”) to develop, make, use and sell products using proprietary information and technology developed under a previous Sponsored Research Agreement within the field of antioxidant compounds and related discoveries. We must make milestone payments to the NJMRC in an aggregate amount of up to $250,000 upon the occurrence of certain development milestones. Our royalty payment obligations to the NJMRC under this license agreement are in the low single digits of net product sales. We are also obligated to pay patent filing, prosecution, maintenance and defense costs. This NJMRC license agreement is terminable by the NJMRC in the event of breach and otherwise expires when the last licensed patent expires.

In 2009, we obtained an additional exclusive worldwide license from National Jewish Health to develop, make, use and sell products using proprietary information and technology developed at NJH related to certain compounds as an MCM against mustard gas exposure. Under this license agreement, we must make milestone payments to NJH in an aggregate amount of up to $500,000 upon the occurrence of certain development milestones. In addition, we must make royalty payments to NJH under this license agreement ranging in the low-single digits as a percentage of all sublicensing fees, milestone payments and sublicense royalties that we receive from sublicenses granted by us pursuant to this license agreement. We are also obligated to pay patent filing, prosecution, maintenance and defense costs. This NJH license agreement is terminable by NJH in the event of breach and otherwise expires when the last licensed patent expires.

Research and Development Expenditures

Expenditures for research and development activities were $6,468,000 and $5,055,000 during the years ended September 30, 2012 and 2011, respectively. Research and development expenses for fiscal 2012 and 2011 related primarily to the advancement of our lead compound, AEOL 10150.

Manufacturing

We currently do not have the capability to manufacture any of our drug candidates on a commercial scale. Materials for non-clinical and clinical studies are produced under contract with third parties. To date, we have partnered with Johnson Matthey for the manufacture of our active pharmaceutical ingredients. Johnson Matthey is an almost 200 year old company that is a global supplier of active pharmaceutical ingredients, fine chemicals and other specialty chemical products and services to a wide range of chemical and pharmaceutical industry customers and industrial and academic research organizations. Johnson Matthey is a leader in the manufacture of metal-based pharmaceutical products.

Commercialization

If BARDA elects to procure AEOL10150 pursuant to an EUA, as described above, or after FDA approval, it may be possible for us to generate significant sales revenue without the need of raising significant funds to build a commercial organization. Depending on the size of those procurements, and assuming the successful development and FDA approval of our compounds in other, non-biodefense indications, we may have sufficient financial resources to internally fund the building of a commercial organization. However, in the event procurements from BARDA are not made, and assuming successful development and FDA approval of one or more of our compounds, to successfully commercialize our catalytic antioxidant programs, we must seek corporate partners with expertise in commercialization or develop this expertise internally. However, we may not be able to successfully commercialize our catalytic antioxidant technology, either internally or through collaboration with others.

Marketing

Our potential catalytic antioxidant products are being developed for large therapeutic markets. We believe these markets are best approached by partnering with established biotechnology or pharmaceutical companies that have broad sales and marketing capabilities. We are pursuing collaborations of this type as part of our search for development partners. However, we may not be able to enter into any marketing arrangements for any of our products on satisfactory terms or at all.

Biodefense Industry

Market Overview

The market for biodefense countermeasures has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks. The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs is in the form of development funding from NIAID, BARDA and the Department of Defense ("DoD") and procurements of countermeasures by BARDA, the CDC and the DoD. The U.S. government is now the largest source of development and procurement funding for academic institutions and biotechnology companies conducting biodefense research or developing vaccines and immunotherapies directed at potential agents of bioterror or biowarfare.

We analyze the biodefense market in three segments; the United States military market, United States commercial market and non U.S. markets, with the U.S. government funding representing the vast majority of the worldwide market. According to the Center for Biosecurity at the University of Pittsburgh Medical Center the U.S. government's biodefense military and civilian spending approximated $8 billion in fiscal 2009 and has averaged around $5.5 billion from fiscal years 2001 to 2009.

- U.S. Civilian: The U.S. civilian market includes funds to protect the U.S. population from biological agents and is largely funded by the Project BioShield Act of 2004 ("Project BioShield"). Project BioShield is the U.S. government's largest biodefense initiative. It governs and funds with, $5.6 billion, procurements of biodefense countermeasures for the SNS for the period from July 2004 through 2013.

- U.S. Military: The DoD is responsible for the development and procurements of countermeasures for the military segment which focuses on providing protection for military personnel and civilians who are on active duty.

- Non-U.S. Markets: Non-U.S. markets address protection against biowarfare agents for both civilians and military personnel in foreign countries. We anticipate that foreign countries will want to procure biodefense products as they are developed and validated by procurements by the U.S. government.

Project BioShield and the Pandemic and All-Hazards Preparedness Act

Project BioShield became law in 2004 and authorizes procurements of countermeasures for chemical, biological, radiological and nuclear attacks for the SNS, which is a national repository of medical assets and countermeasures designed to provide federal, state and local public health agencies with medical supplies needed to treat those affected by terrorist attacks, natural disasters, industrial accidents and other public health emergencies. Project BioShield provided appropriations of $5.6 billion to be expended over ten years into a special reserve fund.

The Pandemic and All-Hazards Preparedness Act, passed in 2006, established BARDA as the agency responsible for awarding procurement contracts for biomedical countermeasures and providing development funding for advanced research and development in the biodefense arena, and supplements the funding available under Project BioShield for

chemical, biological, radiological and nuclear countermeasures, and provides funding for infectious disease pandemics. Funding for BARDA is provided by annual appropriations by Congress. Congress also appropriates annual funding for the CDC for procurements of medical assets and countermeasures for the SNS and for NIAID to conduct biodefense research. This appropriation funding supplements amounts available under Project BioShield.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 was signed into law on March 5, 2013 by the President. Previously, it passed the Senate by unanimous consent on February 28th, and the amended bill was passed by the House on March 4, 2013 by a vote of 370 to 28. Important terms of this reauthorization bill include:

- Emphasizes chemical, radiological, biological, and nuclear threats as part of an all-hazards approach to our National Preparedness Goals; promotes strategic initiatives to advance medical countermeasures (MCMs) development and procurement

- Enhances the Secretary's ability to make MCMs under review available in limited circumstances based on either a declared emergency or identified threat.

- BioShield– Encourages further development of MCMs to address chemical, biological, radiological, and nuclear threats by reauthorizing BioShield's Special Reserve Fund. Requires HHS to report to Congress when the Special Reserve Fund falls below a certain threshold and the potential impact of such a reduction on addressing MCM priorities.

- Advanced Research and Development– Enhances the Biomedical Advanced Research and Development Authority's (BARDA's) strategic focus on supporting the development of innovative and cutting-edge biodefense initiatives.

- MCM Acceleration– Charges the FDA with promoting MCM professional expertise and developing regulatory science tools to advance the review, approval, clearance, and licensure of MCMs within FDA as well as enhancing scientific exchange between FDA and MCM stakeholders.

- Regulatory Management Plan– Requires FDA to work with sponsors and applicants of certain eligible MCMs to develop individualized regulatory management plans to improve regulatory certainty

Currently, the U.S. government may, at its discretion, purchase critical biodefense products for the SNS prior to FDA approval based on Emergency Use Authorization enabled under the Project BioShield legislation. On an ongoing basis we monitor notices for requests for proposal, grants and other potential sources of government funding that could potentially support the development of our drug candidates. Nevertheless, changes in government budgets, priorities and agendas as well as political pressures could result in a reduction in overall government financial support for the biodefense sector in general and/or specifically the drug candidates we are developing. Due to the current economic downturn, the accompanying fall in tax revenues and the U.S. government's efforts to stabilize the economy, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government contract awards, the likelihood that the government will exercise its right to extend any of its existing contracts and/or the likelihood that the government would procure products from us.(For further information, see "Risk Factors — Risks Related to Our Dependence on U.S. Government Grants and Contracts — Most of our immediately foreseeable future revenues are contingent upon grants and contracts from the U.S. government and we may not achieve sufficient, if any, revenues from these agreements to attain profitability.") As a result, further development of our drug candidates and ultimate product sales to the government, if any, could be delayed or stopped altogether.

Competition

General

Competition in the pharmaceutical industry is intense and we expect it to increase. Technological developments in our field of research and development occur at a rapid rate and we expect competition to intensify as advances in this field are made. We will be required to continue to devote substantial resources and efforts to research and development

activities. Our most significant competitors, among others, are fully integrated pharmaceutical companies and more established biotechnology companies, which have substantially greater financial, technical, sales, marketing and human resources than we do. These companies may succeed in developing and obtaining regulatory approval for competitive products more rapidly than we can for our drug candidates. In addition, competitors may develop technologies and products that are, or are perceived as being, cheaper, safer or more effective than those being developed by us or that would render our technology obsolete.

We expect that important competitive factors in our potential product markets will be the relative speed with which we and other companies can develop products, complete the clinical testing and approval processes, and supply commercial quantities of a competitive product to the market. With respect to clinical testing, competition might result in a scarcity of clinical investigators and patients available to test our potential products, which could delay development.

We are aware of products in research or development by our competitors that address the diseases and therapies being targeted by us. In addition, there may be other competitors of whom we are unaware with products which might be more effective or have fewer side effects than our products and those of our known competitors.

Antioxidants

Several companies have explored the therapeutic potential of antioxidant compounds in numerous indications. Historically, most of these companies have focused on engineered versions of naturally occurring antioxidant enzymes, but with limited success, perhaps because the large size of these molecules makes delivery into the cells difficult. Antioxidant drug research continues at a rapid pace despite previous clinical setbacks.

Patents and Proprietary Rights

We currently license rights to our potential products from third parties. We generally seek patent protection in the United States and other jurisdictions for the potential products and proprietary technology licensed from these third parties. The process for preparing and prosecuting patents is lengthy, uncertain and costly. Patents may not issue on any of the pending patent applications owned by us or licensed by us from third parties. Even if patents issue, the claims allowed might not be sufficiently broad to protect our technology or provide us protection against competitive products or otherwise be commercially valuable. Patents issued to or licensed by us could be challenged, invalidated, infringed, circumvented or held unenforceable. Even if we successfully defend our patents for our products, the costs of defense can be significant.

As of December 1, 2011, our catalytic antioxidant small molecule technology base is described in 12 issued United States patents and four United States pending patent applications. These patents and patent applications belong in whole or in part to Duke or the NJH and are licensed to us. These patents and patent applications cover soluble manganic porphyrins as antioxidant molecules as well as targeted compounds obtained by coupling such antioxidant compounds to molecules that bind to specific extracellular elements. The pending U.S. patent applications and issued U.S. patents include composition of matter claims and method claims for several series of compounds. Corresponding international patent applications have been filed, 83 of which have issued, and one of which has been allowed as of December 1, 2011. Our 12 issued U.S. patents will expire between 2015 and 2023.

In addition to patent protection, we rely upon trade secrets, proprietary know-how and technological advances that we seek to protect, in part, through confidentiality agreements with our collaborative partners, employees and consultants. Our employees and consultants are required to enter into agreements providing for confidentiality and the assignment of rights to inventions made by them while in our service. We also enter into non-disclosure agreements to protect our confidential information furnished to third parties for research and other purposes.

Government Regulation

Our research and development activities and the manufacturing and marketing of our future products are subject to regulation by numerous governmental agencies in the United States and in other countries. The FDA and comparable agencies in other countries impose mandatory procedures and standards for the conduct of clinical trials and the production and marketing of products for diagnostic and human therapeutic use. Before obtaining regulatory

approvals for the commercial sale of any of our products under development, we must demonstrate through preclinical studies and clinical trials that the product is safe and efficacious for use in each target indication. The results from preclinical studies and early clinical trials might not be predictive of results that will be obtained in large-scale testing. Our clinical trials might not successfully demonstrate the safety and efficacy of any products or result in marketable products.

The United States system of drug approvals is considered to be the most rigorous in the world. It takes an average of 8.5 years for a drug candidate to move through the clinical and approval phases in the United States according to a November 2005 study by the Tufts Center for the Study of Drug Development. Only five in 5,000 drug candidates that enter preclinical testing make it to human testing and only one of those five is approved for commercialization. On average, it costs a company $897 million to get one new drug candidate from the laboratory to United States patients according to a May 2003 report by Tufts Center for the Study of Drug Development. A November 2006 study by Tufts Center for the Study of Drug Development reported that the average cost of developing a new biotechnology product was $1.2 billion and took on average slightly more than eight years to be approved by the FDA.

The steps required by the FDA before new drug products may be marketed in the United States include:

- completion of preclinical studies;
- the submission to the FDA of a request for authorization to conduct clinical trials on an IND, which must become effective before clinical trials may commence;
- adequate and well-controlled Phase I clinical trials which typically involves normal, healthy volunteers. The tests study a drug candidate's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized and excreted as well as the duration of its action;
- adequate and well-controlled Phase II clinical trials which typically involve treating patients with the targeted disease with the drug candidate to assess a drug's effectiveness;
- adequate and well-controlled Phase III clinical trials involving a larger population of patients with the targeted disease are treated with the drug candidate to confirm efficacy of the drug candidate in the treatment of the targeted indication and to identify adverse events;
- submission to the FDA of an NDA; and
- review and approval of the NDA by the FDA before the product may be shipped or sold commercially.

In addition to obtaining FDA approval for each product, each product manufacturing establishment must be registered with the FDA and undergo an inspection prior to the approval of an NDA. Each manufacturing facility and its quality control and manufacturing procedures must also conform and adhere at all times to the FDA's current good manufacturing practices ("cGMP") regulations. In addition to preapproval inspections, the FDA and other government agencies regularly inspect manufacturing facilities for compliance with these requirements. Manufacturers must expend substantial time, money and effort in the area of production and quality control to ensure full technical compliance with these standards.

Preclinical testing includes laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Preclinical testing results are submitted to the FDA as a part of an IND which must become effective prior to commencement of clinical trials. Clinical trials are typically conducted in three sequential phases following submission of an IND. Phase I represents the initial administration of the drug to a small group of humans, either patients or healthy volunteers, typically to test for safety (adverse effects), dosage tolerance, absorption, distribution, metabolism, excretion and clinical pharmacology, and, if possible, to gain early evidence of effectiveness. Phase II involves studies in a small sample of the actual intended patient population to assess the efficacy of the drug for a specific indication, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential adverse effects. Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, Phase III studies are initiated to further establish clinical safety and efficacy of the therapy in a broader sample of the general patient population, in order to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for any physician labeling. During all clinical studies, we must adhere to good clinical practices ("GCPs") standards. The results of the research and product development, manufacturing, preclinical studies, clinical studies and related information are submitted in an NDA to the FDA.

The process of completing clinical testing and obtaining FDA approval for a new drug is likely to take a number of years and require the expenditure of substantial resources. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA. Even after initial FDA approval has been obtained, further studies, including post-market studies, might be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested and approved. Also, the FDA will require post-market reporting and might require surveillance programs to monitor the side effects of the drug. Results of post-marketing programs might limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling or a change in manufacturing facility, an NDA supplement might be required to be submitted to the FDA.

The rate of completion of any clinical trials will be dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the size of the patient population, the nature of the trial, the availability of alternative therapies and drugs, the proximity of patients to clinical sites and the eligibility criteria for the study. Delays in planned patient enrollment might result in increased costs and delays, which could have a material adverse effect on us.

Failure to comply with applicable FDA requirements may result in a number of consequences that could materially and adversely affect us. Failure to adhere to approved trial standards and GCPs in conducting clinical trials could cause the FDA to place a clinical hold on one or more studies which would delay research and data collection necessary for product approval. Noncompliance with GCPs could also have a negative impact on the FDA's evaluation of an NDA. Failure to adhere to GMPs and other applicable requirements could result in FDA enforcement action and in civil and criminal sanctions, including but not limited to fines, seizure of product, refusal of the FDA to approve product approval applications, withdrawal of approved applications, and prosecution.

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The requirements governing the conduct of clinical trials and product approvals vary widely from country to country, and the time required for approval might be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for some European countries, in general, each country at this time has its own procedures and requirements. There can be no assurance that any foreign approvals would be obtained.

In addition to the regulatory framework for product approvals, we and our collaborative partners must comply with laws and regulations regarding occupational safety, laboratory practices, the use, handling and disposition of radioactive materials, environmental protection and hazardous substance control, and other local, state, federal and foreign regulation. The impact of such regulation upon us cannot be predicted and could be material and adverse.

Legislation and Regulation Related to Bioterrorism Counteragents

Because some of our drug candidates are intended for the treatment of diseases that may result from acts of bioterrorism, they may be subject to the specific legislation and regulation described below.

Project BioShield

Project BioShield provides expedited procedures for bioterrorism related procurements and awarding of research grants, making it easier for HHS to quickly commit funds to countermeasure projects. Project BioShield relaxes procedures under the Federal Acquisition Regulation for procuring property or services used in performing, administering or supporting biomedical countermeasure research and development. In addition, if the Secretary of HHS deems that there is a pressing need, Project BioShield authorizes the Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts and cooperative agreements related to biomedical countermeasure research and development activity.

Under Project BioShield, the Secretary of HHS, with the concurrence of the Secretary of the Department of Homeland Security ("DHS"), and upon the approval of the President, can contract to purchase unapproved countermeasures for the SNS in specified circumstances. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the SNS is paid on delivery of a substantial portion of the countermeasure. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there are sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. To exercise this authority, the Secretary of HHS must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- the product may reasonably be believed to be effective in detecting, diagnosing, treating or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks; and

- there is no adequate alternative to the product that is approved and available.

Although this provision permits the Secretary of HHS to circumvent the FDA approval process, its use would be limited to rare circumstances.

Safety Act

The Support Anti-Terrorism by Fostering Effective Technologies Act enacted by the U.S. Congress in 2002 (the "Safety Act") creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an "approved product" by the DHS and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. The government contractor defense, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act enacted by Congress in 2005 (the "PREP Act") provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products." For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. We cannot predict whether Congress will fund the relevant PREP Act compensation programs; or whether the necessary prerequisites for immunity would be triggered with respect to our drug candidates.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The actual time required to obtain clearance to market a product in a particular foreign jurisdiction may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product candidate and the specific requirements of that jurisdiction. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary from country to country.

Reimbursement and Pricing Controls

In many of the markets where we could commercialize a drug candidate following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to reimbursement programs with varying price control mechanisms.

In the United States, there is an increasing focus on drug pricing in recent years. There are currently no direct government price controls over private sector purchases in the United States. However, the Veterans Health Care Act establishes mandatory price discounts for certain federal purchasers, including the Veterans Administration, Department of Defense and the Public Health Service; the discounts are based on prices charged to other customers.

Under the Medicaid program (a joint federal/state program that provides medical coverage to certain low income families and individuals), pharmaceutical manufacturers must pay prescribed rebates on specified drugs to enable them to be eligible for reimbursement. Medicare (the federal program that provides medical coverage for the elderly and disabled) generally reimburses for physician-administered drugs and biologics on the basis of the product's

average sales price. Outpatient drugs may be reimbursed under Medicare Part D. Part D is administered through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. Various states have adopted further mechanisms that seek to control drug prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the marketplace and increases downward pressure on the prices of pharmaceutical products.

Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to particular products over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses that are either approved by the FDA or that are supported by other appropriate evidence, such as published medical literature, and appear in a recognized compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries cross-border imports from low-priced markets exert a commercial pressure on pricing within that country.

Regulations Regarding Government Contracting

We may become a government contractor in the United States and elsewhere which would mean that we would be subject to various statutes and regulations that govern procurements of goods and services by agencies of the United States and other countries, including the Federal Acquisition Regulation. These governing statutes and regulations can impose stricter penalties than those normally applicable to commercial contracts, such as criminal and civil damages liability and suspension and debarment from future government contracting. In addition, pursuant to various statutes and regulations, our government contracts may be subject to unilateral termination or modification by the government for convenience in the United States and elsewhere, detailed auditing requirements and accounting systems, statutorily controlled pricing, sourcing and subcontracting restrictions and statutorily mandated processes for adjudicating contract disputes.

Hazardous Materials and Select Agents

Our development and manufacturing processes involve the use of hazardous materials, including chemicals and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state and local laws and regulations governing the use, manufacturing, storage, handling and disposal of these materials. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

Other Regulations

In the United States and elsewhere, the research, manufacturing, distribution, sale and promotion of drug and biological products are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services; other divisions of HHS, such as the Office of Inspector General: the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice and state and local governments. For example, sales, marketing and scientific and educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

CPEC, LLC

We were previously developing bucindolol for the treatment of heart failure, but development was discontinued in 1999. Commercial rights to bucindolol are owned by CPEC, LLC, a limited liability company (“CPEC”), of which we own 35% and Endo Pharmaceuticals (formerly Indevus Pharmaceuticals), Inc. owns 65%.

During fiscal 2008, CPEC received a milestone payment from ARCA of $500,000.The milestone payment was triggered by the acceptance by the FDA of an NDA for bucindolol. Future milestone payments and royalty payments to us and CPEC, if any, while provided for under the agreement between CPEC and ARCA, cannot be assured or guaranteed. Also as a result of the filing of the NDA with the FDA, we were obligated to pay $413,000 in the form of cash or stock at our election to the majority owner of CPEC who in turn paid the original licensors of bucindolol per the terms of the 1994 Purchase Agreement of CPEC. On November 6, 2009, we issued 1,099,649 shares of common stock to the majority owner of CPEC to satisfy our obligation.

During fiscal 2009, we sold our holdings of ARCA, generating a gain of $133,000. In addition, during fiscal 2009, ARCA received a Complete Response letter from the FDA for its NDA for bucindolol for the treatment of patients with chronic heart failure. In the Complete Response letter, the FDA stated that it cannot approve the NDA in its current form and specifies additional actions and information required for approval of the bucindolol NDA.

Employees

At May 8, 2013, we had five full-time employees and no part time employees. None of our employees is represented by a labor union. In addition to our employees, we utilize several consultants to perform key functions for us.

MANAGEMENT

Information Regarding Directors

The following sets forth the names and ages (as of May 8, 2013) of our directors, and certain other information about them.

Name of Director	Age as of May 8, 2013	Director Since
David C. Cavalier	43	April 2004
John M. Farah, Jr., Ph.D.	60	October 2005
Amit Kumar, Ph.D.	48	June 2004
Chris A. Rallis	59	June 2004
John M. Clerici	42	May 2013
Mitchell D. Kaye, J.D.	44	May 2013
Jeffrey A. Scott, M.D.	55	May 2013

David C. Cavalier has been the Chairman of our Board since April 30, 2004, and an employee of the Company since November 2009. Since 2001, he has been a Principal and the Chief Operating Officer of Xmark Opportunity Partners, LLC, a manager of a family of private investment funds. From 1995 to 1996, Mr. Cavalier worked for Tiger Real Estate, a $785 million private investment fund sponsored by Tiger Management Corporation. Mr. Cavalier began his career in 1994 in the Investment Banking Division of Goldman, Sachs & Co. working on debt and equity offerings for public and private real estate companies. He received a B.A. from Yale University and an M. Phil. from Oxford University. We believe that Mr. Cavalier's experiences, qualifications, attributes and skills to serve as a director of our Company include his strong understanding of our Company and operations, having served as Chairman of the Board for over 7 years and as an employee for the past 2 years. In addition, Mr. Cavalier's past experience and expertise in investment banking and company financings are a valuable contribution to our Board.

John M. Farah, Jr., Ph.D. has been an independent director of ours since October 2005 and a member of our audit committee. He is founder and managing director of a private international consultancy serving branded biopharma clients in the US and abroad and currently serves as an independent director of the private biopharmaceutical company, Melior Discovery, Inc. From 2008 to 2010, Dr. Farah was an independent director of GenSpera, Inc. (GNSZ), a publicly-traded pharmaceutical development stage company. Dr. Farah was a vice president at Cephalon, Inc., a biopharmaceutical company, from October 1992 until December 2011 after the company was integrated into Teva Pharmaceuticals. At Cephalon, Dr. Farah led the headquarter team of an international business unit with oversight of strategic product registrations, operations and sales abroad; he was latterly responsible for key Asia Pacific markets coordinating corporate product support for third party distributors and licensees. Dr. Farah joined Cephalon in 1992 to manage scientific affairs in support of the company's R&D department. He gained increasing responsibilities in scientific affairs, and eventually, became a senior team member of worldwide business development promoting and negotiating R&D and commercial alliances with multinational and regional pharmaceutical firms. In 2003, Dr. Farah led worldwide product export with P&L responsibilities for third party product sales and support, and in 2006 focused on strategic growth and commercial success in Asia and the Americas ex-US. In addition to his responsibilities for business development and regional international revenues, Dr. Farah oversaw successful patent litigations in Europe and Latin America. From 2008 until the company's acquisition by Teva, he served as treasurer and a director of Cephalon's political action committee. Prior to joining Cephalon, Dr. Farah was a research investigator at GD Searle in nervous system and immunoinflammatory disease programs. His training included postdoctoral neuroscience research at the National Institutes of Health (NIH, NINCDS) following his doctorate in physiology from the Uniformed Services University. He holds a B.S. in Zoology from the University of Maryland and a B.H.A. from New College of California. We believe that Dr. Farah should serve as a director of our Company because of his extensive career in the pharmaceutical industry and international experience. Dr. Farah's past experience negotiating research partnerships, product licensing and academic collaborations are a valuable contribution to our Board and his experience allows him to provide additional insight to our Board in considering and approving hese types of partnerships for the Company.

Amit Kumar, Ph.D. is currently the Chairman of the Board of Ascent Solar Technologies, a publicly-held solar energy company. From September 2001 to June 2010, Dr. Kumar was President and Chief Executive Officer of CombiMatrix Corporation, a publicly-held biotechnology company. He has been a director of CombiMatrix since September 2000. Previously, Dr. Kumar was Vice President of Life Sciences of Acacia Research Corp. From January 1999 to February 2000, Dr. Kumar was the founding President and CEO of Signature BioSciences, Inc., a life science company developing technology for advanced research in genomics, proteomics and drug discovery. From January 1998 to December 1999, Dr. Kumar was an Entrepreneur in Residence with Oak Investment Partners, a venture capital firm. From October 1996 to January 1998, Dr. Kumar was a Senior Manager at Idexx Laboratories, Inc., a biotechnology company. From October 1993 to September 1996, he was Head of Research & Development for Idetek Corporation, which was later acquired by Idexx Laboratories, Inc. Dr. Kumar received his B.S. in Chemistry from Occidental College. After joint studies at Stanford University and the California Institute of Technology, he received his Ph.D. from the California Institute of Technology in 1991. He also completed a post-doctoral fellowship at Harvard University from 1991 to 1993. Dr. Kumar is also a member of the board of directors of Luechemix and Tacere Therapeutics, both private biotechnology companies. We believe that Dr. Kumar should serve as a director of our Company in light of his experience serving as an officer and on the board of directors of a number of publicly-held companies, as well as his past venture capital and capital-raising experience. Dr. Kumar's experience in scientific research and development is also a valuable contribution to our Board, particularly during deliberations and discussions relating to research and development matters.

Chris A. Rallis has been an executive-in-residence at Pappas Ventures, a life science venture capital firm since January 2008. Previously, Mr. Rallis was the President and Chief Executive Officer of ImmunoBiosciences, Inc. ("IBI"), a vaccine technology company located in Raleigh, North Carolina from April 2006 through June 2007. Prior to joining IBI, Mr. Rallis served as an executive in residence (part time) for Pappas Ventures, and as a consultant for Duke University and Panacos Pharmaceuticals, Inc. Mr. Rallis is the former President and Chief Operating Officer and director of Triangle Pharmaceuticals, Inc., which was acquired by Gilead Sciences in January 2003 for approximately $465 million. Prior to assuming the role of President and COO in March 2000, he was Executive Vice President, Business Development and General Counsel. While at Triangle, Mr. Rallis participated in 11 equity financings generating gross proceeds of approximately $500 million. He was also primarily responsible for all business development activities which included a worldwide alliance with Abbott Laboratories and the in-licensing of ten compounds. Before joining Triangle in 1995, Mr. Rallis served in various business development and legal management roles with Burroughs Wellcome Co. over a 13-year period, including Vice President of Strategic Planning and Business Development. Mr. Rallis also serves on the boards of Adherex Technologies, Inc., a publicly-held biopharmaceutical company located in Research Triangle Park, NC and Oxygen Biotherapeutics, Inc., a publicly-held biopharmaceutical company located in Morrisville, NC. Mr. Rallis serves on the audit committees of both boards and chairs the audit committee at Adherex. Mr. Rallis received his A.B. degree in economics from Harvard College and a J.D. from Duke University. We believe that Mr. Rallis should serve as a director of our Company in light of his experience serving as an executive officer of, and participating in a number of equity financings for, other pharmaceutical companies. Mr. Rallis' experiences in development activities and strategic alliances are valuable to Board deliberations. In addition, his venture capital consulting experience allows him to contribute additional insight to the Board in refining our Company's business strategies and commercial objectives.

John M. Clerici, age 42, is a founding Principal of Tiber Creek Partners, LLC, a company focused on providing scientific and business counseling to biotechnology companies seeking to use non-dilutive capital from the U.S. and foreign governments and from non-governmental organizations. Mr. Clerici is also a Partner in the government contracts practice at McKenna Long & Aldridge LLP. For over 14 years, Mr. Clerici has been at the forefront of the creation of the public health preparedness sector, including helping large pharmaceutical and emerging biotechnology companies develop creative approaches to access non-dilutive capital to fund the development of biotechnology for emerging disease and engineered threats. Since 1999, Mr. Clerici has assisted over three dozen companies in obtaining nearly $4 billion in funding for research, development and procurement of public health countermeasures from the Federal government, which includes the majority of the awards made under Project Bioshield, the U.S. Government's initiative for preparing the United States against a bioterrorist attack. Prior to joining McKenna Long & Aldridge LLP, Mr. Clerici was a judge advocate with the U.S. Air Force where, among other assignments, he advised the Air Force Research Laboratory on the procurement of technology from research institutions throughout the United States, Europe and Asia. Mr. Clerici earned his Juris Doctor from the University of North Carolina at Chapel Hill in 1995. He did his undergraduate work at the Catholic University of America, graduating summa cum laude. We believe that Mr. Clerici should serve as a director of our Company in light of his over 14 years of experience in working with the US Government in public health preparedness. We believe he will contribute significantly to our medical countermeasure development programs.

Mitchell D. Kaye, J.D., age 44, is the Founder of MedClaims Liaison, LLC and has served as its Chief Executive Officer since 2009. MedClaims is a consumer advocacy business which works on behalf of families in managing reimbursement disputes with medical providers and insurance companies. From 2008-2010, Mr. Kaye was a Managing Director with Navigant Capital Advisors, a financial and strategic advisory services firm, and Head of Navigant's Financial Institutions Restructuring Solutions Team (FIRST). While at Navigant, Mr. Kaye led numerous high profile engagements on behalf of investment funds and investors. Previously, as a successful entrepreneur in the asset management industry, Mr. Kaye launched two highly profitable asset management companies. Mr. Kaye was the founding member of Xmark Opportunity Partners, LLC, an investment fund exclusively focused on investments in publicly traded life sciences companies, and has served as a member of the management committee since 2001. Mr. Kaye established a venerable reputation as an activist investor, taking influential stakes in numerous companies, forcing changes at the boards of directors and management team levels, and guiding the sale of several of his portfolio companies to the benefit of shareholders. In 1996, Mr. Kaye began his career as a founding member of Brown Simpson Asset Management, LLC (Brown Simpson), an investment fund that was at the foreground of private placement investing in the public markets. Brown Simpson's life sciences investment unit produced a value weighted cash-on-cash return in excess of 100% during the life of the fund. During his career, Mr. Kaye has consummated over 100 transactions as a lead investor, structured over a billion dollars in debt and equity-linked transactions, and taken an active role in the management of numerous portfolio companies. Mr. Kaye has served on the boards of several private and public companies, and also served on the board of the New York Alzheimer's Association. From September 2007 until the company's unwinding in June 2009, Mr. Kaye served on the board of directors of Genaera Corporation, a biopharmaceutical company that was listed on the Nasdaq Capital Market. Mr. Kaye received his BA from Wesleyan University, and his Juris Doctorate from Northwestern University School of Law. We believe that Mr. Kaye should serve as a director of our Company in light of his experience in business development and financing biotech companies, which we believe will be invaluable as we begin to generate efficacy data from our animal efficacy and cancer studies.

Jeffrey A. Scott, M.D., age 55, whose specialty is oncology, currently is General Manager/Senior Vice President for P4 Healthcare, a division of Cardinal Health Specialty Solutions, which is a division of Cardinal Health. He is also a member of Cardinal Health's Operating Committee. Prior to the 2010 sale of P4 Healthcare to Cardinal Health, Dr. Scott was the Founder, President and Chief Executive Officer of P4 Healthcare, since its inception in 2006. P4 Healthcare was a multimedia Healthcare Marketing and Education Company with a focus in Oncology. From 1998 to 2002, Dr. Scott served as the National Medical Director and President of the International Oncology Network (ION), a network of more than 4,000 U.S. private practice oncologists headquartered in Baltimore, Maryland. In 2002, ION became a subsidiary of Amerisource Bergen Corporation upon its sale. Dr. Scott continued to serve as President and General Manager for ION until 2005. Dr. Scott was a practicing physician, Founding Partner and Chief Financial Officer of Georgia Cancer Specialists located in Atlanta, Georgia from 1990 to 2000. During Dr. Scott's tenure as Chief Financial Officer of Georgia Cancer Specialists, the physician practice had over $100 million in revenue and Dr. Scott was responsible for development of financial programs of practice after the merger and corporate buyout by Phymatrix. Also at the Georgia Cancer Specialists, Dr. Scott took responsibility for the development of an extensive clinical research program. From 1998 to 2000, he also served as Medical Chief of Staff at Emory Northlake Regional Medical Center in Atlanta, Georgia. Dr. Scott's biotechnology experience includes his role as a Consultant to NexStar Pharmaceuticals, Inc. ("NexStar") of Boulder, Colorado. Prior to NexStar's 1999 merger with Gilead Sciences, Inc., it was engaged in the discovery, development, manufacture and commercialization of products to treat serious and life-threatening illnesses. As a consultant to NexStar, Dr. Scott was responsible for assisting and educating the sales force in dealing with physician networks and consulting with investment advisors regarding potential investments in other biotechnology companies. Dr. Scott's educational background includes a B.S. degree in Microbiology from the University of Michigan, Ann Arbor, Michigan, a medical education at Wayne State University, Detroit, Michigan, and a fellowship in Oncology at University of Texas Health Sciences, San Antonio, Texas. Dr. Scott has Board Certifications from the American Board of Internal Medicine, Internal Medicine, September 1987, and the American Board of Internal Medicine, Medical Oncology, November 1989. Dr. Scott has served on the board of directors of

Biovest International, Inc. (OTCQB: BVTI) since March 2004. We believe that Dr. Scott should serve as a director of our Company in light of his experience as an oncologist, drug developer and senior executive in one of the leading pharmaceutical distribution companies, which we believe will be invaluable as we begin to move forward with our AEOL 10150 oncology development program and begin to formulate our strategies for making our compound available in the most efficient and effective way for biodefense purposes.

Executive Officers

Our executive officers and their ages as of May 8, 2013 were as follows:

Name	Age	Position(s)
David Cavalier	43	Chairman of the Board
John L. McManus	48	President and Chief Executive Officer
Russell Skibsted	53	Senior Vice President, Chief Financial Officer and Secretary

David C. Cavalier has been the Chairman of our Board since April 30, 2004, and an employee of the Company since November 2009. Since 2001, he has been a Principal and the Chief Operating Officer of Xmark Opportunity Partners, LLC, a manager of a family of private investment funds. From 1995 to 1996, Mr. Cavalier worked for Tiger Real Estate, a $785 million private investment fund sponsored by Tiger Management Corporation. Mr. Cavalier began his career in 1994 in the Investment Banking Division of Goldman, Sachs & Co. working on debt and equity offerings for public and private real estate companies. He received a B.A. from Yale University and an M. Phil. from Oxford University. We believe that Mr. Cavalier's experiences, qualifications, attributes and skills to serve as a director of our Company include his strong understanding of our Company and operations, having served as Chairman of the Board for over 7 years and as an employee for the past 2 years. In addition, Mr. Cavalier's past experience and expertise in investment banking and company financings are a valuable contribution to our Board.

John L. McManus . Mr. McManus began as a consultant to the Company in June 2005 as President. He became employed as our President and Chief Operating Officer in July 2006 and was appointed President and Chief Executive Officer in March 2007.Mr. McManus, who received his degree in business administration from the University of Southern California in 1986, is the founder and president of McManus Financial Consultants, Inc. ("MFC"), which provides strategic, financial and investor relations advice to senior managements and boards of directors of public companies, including advice on mergers and acquisitions. These companies have a combined value of over $25 billion. He has served as president of MFC since 1997.In addition, Mr. McManus previously served as Vice President, Finance and Strategic Planning to Spectrum Pharmaceuticals, Inc. (NASDAQ: SPPI), where he had primary responsibility for restructuring Spectrum's operations and finances, including the design of strategic and financial plans to enhance Spectrum's corporate focus, and leading the successful implementation of these plans. The implementation of these plans led to an increase in Spectrum's market value from $1 million to more than $125 million at the time of Mr. McManus' departure.

Russell R. Skibsted . Mr. Skibsted is a seasoned executive with over 25 years of experience in finance, acquisitions, partnering, marketing and operations with companies ranging from start-ups to a Fortune 5. He has significant private equity, public market, operations and transaction experience with both public and private companies. From May 2006 to September 2009, Mr. Skibsted was Senior Vice President and Chief Business Officer of Spectrum Pharmaceuticals (NASDAQ: SPPI), where he led global strategy, mergers and acquisitions, licensing, fund-raising and investor and public relations. At Spectrum, Mr. Skibsted completed a significant partnership and an asset sale generating over $62 million in non-dilutive funding to the Company in 2008. From October 2004 to January 2006, Mr. Skibsted was Chief Financial Officer at Talon Therapeutics, Inc. (OTC: TLON) (formerly Hana Biosciences, Inc.), where he led the process of bringing the Company public and completed two financings. Prior to that time, from May 2000 to July 2004, Mr. Skibsted was Partner and Chief Financial Officer of Asset Management Company, a venture capital firm, where he oversaw the financial and administrative functions, public and private portfolios and aviation operations. Mr. Skibsted holds a BA in Economics from Claremont McKenna College and an MBA from Stanford University.

Family Relationships and Orders, Judgments and Decrees

There is no family relationship between any of our officers or directors. There are no orders, judgments, or decrees of any governmental agency or administrator, or of any court of competent jurisdiction, revoking or suspending for cause any license, permit or other authority to engage in the securities business or in the sale of a particular security or temporarily or permanently restraining any of our officers or directors from engaging in or continuing any conduct, practice or employment in connection with the purchase or sale of securities, or convicting such person of any felony or misdemeanor involving a security, or any aspect of the securities business or of theft or of any felony. Nor are any of the officers or directors of any corporation or entity affiliated with us so enjoined.

Code of Ethics

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. We have posted the text of Code of Ethics on our Internet website at www.aeoluspharma.com. A copy of the Code of Ethics can also be obtained free of charge by writing to Russell Skibsted, Aeolus Pharmaceuticals, Inc., 26361 Crown Valley Parkway, Suite 150 Mission Viejo, CA 92691.

Audit Committee

The Board has established an Audit Committee in accordance with section 3(a)(58)(A) of the Exchange Act.

COMPENSATION OF DIRECTORS

The following table sets forth information for the fiscal year ended September 30, 2012 regarding the compensation of our directors.

Director Compensation

Name	Fees Earned or Paid in Cash	Option Awards(1)	All Other Compensation	Total
David C. Cavalier	—$	—	—$	—
John M. Farah, Jr., Ph.D.	—	22,141	—	22,141
Joseph J. Krivulka	—	13,902	—	13,902
Amit Kumar, Ph.D.	—	24,112	—	24,112
Michael E. Lewis, Ph.D.	—	11,641	—	11,641
Chris A. Rallis	—	24,112	—	24,112
Peter D. Suzdak, Ph.D.	—	15,272	—	15,272

(1) The amounts in the “Option Awards” column reflect the aggregate grant date fair value of awards for grants of options to each listed director in fiscal 2012, computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. These amounts do not represent the actual amounts paid to or realized by the directors during fiscal 2012. The fair value of the options was determined at the date of the grant using the Black-Scholes option pricing model with the following weighted average assumptions: (i) dividend yield: 0%; (ii) expected volatility: 147.02%; (iii) risk-free interest rate: 0.99%; and (v) expected option life after shares are vested: 5.5 years. We use a straight line method of amortization of stock-based compensation.

All directors are reimbursed for expenses incurred in connection with each board or committee meeting attended. In addition, the Board adopted the following compensation program for the outside members of the Board on December 11, 2008, effective beginning July 1, 2008:

- Each non-executive Board member shall be eligible to receive nonqualified stock options for up to an aggregate of 45,000 shares per year based upon the number of meetings attended by the non-executive Board member during the year. The option exercise prices shall be equal to the closing price of the Common Stock on the grant date. The options shall have 10-year terms and vest, as long as the director remains on the Board, on a monthly basis over a 12-month period beginning on the date of grant. Unvested options expire upon resignation or termination from the Board.

- In addition, each Audit Committee member shall be eligible to receive a nonqualified stock option for up to an aggregate of 15,000 shares per year based the number of Audit Committee meetings attended by the Audit Committee member during the year. The option exercise prices shall be equal to the closing price of the Common Stock on the grant date. The options shall have 10-year terms and vest, as long as the director remains on the Board, on a monthly basis over a 12-month period beginning on the date of grant. Unvested options expire upon resignation or termination from the Board.

Outstanding Equity Awards for Directors as of September 30, 2012

The following table sets forth information regarding unexercised stock options for each Director outstanding as of September 30, 2012. We have not awarded stock grants or other equity incentive awards and as such have not made any disclosures regarding such awards.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options
David C. Cavalier	172,750	—	—
John M. Farah, Jr., Ph.D.	248,780	25,311	—
Joseph J. Krivulka	230,375	16,875	—
Amit Kumar, Ph.D.	320,939	25,311	—
Michael E. Lewis, Ph.D.	222,500	11,250	—
Chris A. Rallis	320,939	25,311	—
Peter D. Suzdak, Ph.D.	239,375	16,875	—

EXECUTIVE COMPENSATION

The following table sets forth all compensation earned for the fiscal year ended September 30, 2012 and 2011, by its principal executive officer, principal financial officer, and its one other executive officer who served in such capacity as of the end of fiscal 2012, collectively referred to as the "Named Executive Officers".

Summary Compensation Table

Name and Principal Position(s)	Fiscal Year	Annual Compensation Salary ($)	Bonus ($)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
John L. McManus	2012	$ 409,000	—	$ 89,325	$ —	$ 498,325
President and	2011	$ 345,608	50,000	$ 91,600	—	$ 487,208
Chief Executive Officer						
Russell Skibsted (2)	2012	$ 255,625	—	$ 107,025	$ —	$ 362,650
Senior Vice President, Chief Financial Officer and	2011	$ 161,306	—	$ 149,835	$ —	$ 311,141
Secretary						
David C. Cavalier	2012	$ 332,313	—	$ —	$ —	$ 332,313
Chairman of the Board	2011	$ 261,458	—	$ —	$ —	$ 261,458

(1) The amounts in the "Option Awards" column reflect the aggregate grant date fair value of awards for grants of options to each listed Named Executive Officer, computed in accordance with FASB ASC Topic 718. These amounts do not represent the actual amounts paid to or realized by any of the Named Executive Officers during fiscal 2012 or fiscal 2011. The fair value of the options was determined at the date of the grant using the Black-Scholes option pricing model with the following weighted average assumptions: (i) dividend yield: 0%; (ii) expected volatility: 143.41%; (iii) risk-free interest rate: 0.68%; and (v) expected option life after shares are vested: 5.27 years. We use a straight line method of amortization of stock-based compensation.

(2) Mr. Skibsted became an employee of ours in February 2011.

Grants of Plan Based Awards During the Fiscal Year Ended September 30, 2012

The following table summarizes all option grants during the fiscal year ended September 30, 2012 to the Named Executive Officers. Each of these options was granted pursuant to the 2004 Plan.

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)(1)	Exercise or Base Price of Option Awards	Grant Date Fair Value of Option Awards (2)
John L. McManus	7/14/2012	250,000	$ 0.28	$ 63,150

(1) The option grant vests on a monthly basis for twelve months with a ten-year term, subject to earlier termination upon certain events.

(2) The amounts in the “Grant Date Fair Value of Option Awards” column reflect the aggregate grant date fair value of awards for grants of options to Mr. McManus in fiscal 2012, computed in accordance with FASB ASC Topic 718. These amounts do not represent the actual amounts paid to or realized by Mr. McManus during fiscal 2012.

Grants of Plan Based Awards During the Fiscal Year Ended September 30, 2012

The following table summarizes all option grants during the fiscal year ended September 30, 2012 to the Named Executive Officers. Each of these options was granted pursuant to the 2004 Plan.

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)(1)	Exercise or Base Price of Option Awards	Grant Date Fair Value of Option Awards (2)
John L. McManus	7/14/2012	250,000	$ 0.28	$ 63,150

(1) The option grant vests on a monthly basis for twelve months with a ten-year term, subject to earlier termination upon certain events.

(2) The amounts in the "Grant Date Fair Value of Option Awards" column reflect the aggregate grant date fair value of awards for grants of options to Mr. McManus in fiscal 2012, computed in accordance with FASB ASC Topic 718. These amounts do not represent the actual amounts paid to or realized by Mr. McManus during fiscal 2012.

Outstanding Equity Awards as of September 30, 2012

The following table sets forth information regarding unexercised stock options for each of the Named Executive Officers outstanding as of September 30, 2012. We have not awarded stock grants or other equity incentive awards and as such have not made any disclosures regarding such awards.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Awards Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
John L. McManus	10,000	—	—	$ 0.97	7/29/2015
	10,000	—	—	$ 0.91	8/31/2015
	10,000	—	—	$ 1.12	9/30/2015
	10,000	—	—	$ 1.15	10/31/2015
	10,000	—	—	$ 1.03	11/30/2015
	10,000	—	—	$ 0.95	12/30/2015
	10,000	—	—	$ 0.89	1/31/2016
	10,000	—	—	$ 0.90	2/28/2016
	10,000	—	—	$ 0.80	3/31/2016
	10,000	—	—	$ 0.75	4/28/2016
	10,000	—	—	$ 0.60	5/31/2016
	10,000	—	—	$ 0.81	6/30/2016
	250,000	—	—	$ 0.75	7/14/2016
	250,000	—	—	$ 0.90	7/13/2017
	250,000	—	—	$ 0.32	7/14/2018
	1,000,000	—	—	$ 0.30	5/6/2019
	250,000	—	—	$ 0.39	7/30/2019
	250,000	—	—	$ 0.40	7/14/2020
	1,500,000	—	—	$ 0.40	7/29/2020
	250,000	—	—	$ 0.40	7/14/2021
	41,666	208,334 (1)	—	$ 0.28	7/14/2022
Russell Skibsted	360,000	—	—	$ 0.60	12/15/2020
David Cavalier	20,000	—	—	$ 1.85	9/22/2014
	20,000	—	—	$ 0.90	9/7/2015
	30,000	—	—	$ 0.85	9/12/2016
	30,000	—	—	$ 0.55	7/27/2017
	27,750	—	—	$ 0.40	12/11/2018

3,750	—	—$	0.29	2/5/2019
11,250	—	—$	0.33	3/26/2019
3,750	—	—$	0.38	4/30/2019
11,250	—	—$	0.35	6/4/2019
15,000	—	—$	0.39	7/30/2019

(1) Options vest at a rate of approximately 20,833 per month from the grant date for twelve months, provided that John McManus is an employee or consultant of the Company on the applicable vesting date. In the event of a sale of the Company, through a merger or otherwise, all of the options shall be fully vested and immediately exercisable.

Option Exercises and Stock Vested During the Fiscal Year Ended September 30, 2012

No stock options were exercised by any Named Executive Officer during the fiscal year ended September 30, 2012.

We had no stock awards outstanding as of or for the year ended September 30, 2012.

Employment Agreement with John McManus

On March 4, 2013, we and John McManus entered into an amended and restated employment agreement (the "Restated Agreement"). Under the Amended Employment Agreement, Mr. McManus continues to serve as President, Chief Executive Officer and Chief Operating Officer of the Company. Pursuant to the agreement, Mr. McManus is paid $ 35,363 per month.

Under the Amended Employment Agreement, Mr. McManus will be entitled to receive an option to purchase at least 250,000 shares of the Company's common stock with an exercise price equal to the closing price of the Company's common stock on the date of grant. In addition, the Amended Employment Agreement provides that, on the date of the agreement, Mr. McManus shall be granted an option to purchase 2,000,000 shares of the Company's common stock with an exercise price equal to the closing price of the Company's common stock on the date of grant. In each case, the options shall vest at a monthly rate of 8.33% following the date of grant, subject to Mr. McManus remaining employed with the Company. The Amended Employment Agreement also provides that, upon a Change in Control of the Company (as defined in the Amended Employment Agreement), all of the stock options granted to Mr. McManus will fully vest and become immediately exercisable.

The current term of the Amended Employment Agreement is through March 4, 2014 unless terminated earlier. Pursuant to the Amended Employment Agreement, if (A) the Company terminates Mr. McManus' employment without "Cause" (as defined in the Amended Employment Agreement), and the Company has not provided Mr. McManus with a Non-Renewal Notice, or (B) Mr. McManus terminates his employment for "Good Reason" (as defined in the Amended Employment Agreement), in either case subject to Mr. McManus' agreement to release any claims against the Company, Mr. McManus will be entitled to receive a cash severance, payable over12 months, equal to: (i) Mr. McManus' effective base salary at the time of termination, plus (ii) the average of the annual bonus(es) paid to Mr. McManus, if any, during the two full years immediately preceding the year in which the termination occurs. If the Company provides Mr. McManus with a Non-Renewal Notice, other than as a result of Mr. McManus' death, disability or termination for "Cause", subject to Mr. McManus' agreement to release any claims against the Company, Mr. McManus will be entitled to receive a cash severance equal to: (x) Mr. McManus' effective base salary at the time of termination, plus (y) the average of the annual bonus(es) paid to Mr. McManus, if any, during the two full years immediately preceding the year in which the termination occurs, less (z) the salary payable to Mr. McManus under the Amended Employment Agreement for the remainder of his employment term, which amount will be payable in equal monthly installments following the end of the employment term until the one-year anniversary of the date of the Non-Renewal Notice

Letter Agreement and Consulting Agreement with Russell Skibsted

On September 1, 2010, we and Russell Skibsted entered into an offer letter agreement, pursuant to which we offered Mr. Skibsted full-time employment as our Senior Vice President, Chief Financial Officer and Secretary commencing upon the announcement of a contract for the development of AEOL 10150 as a medical countermeasure with the Biomedical Advanced Research and Development Authority ("BARDA"). On February 15, 2011, we announced a contract with BARDA for the development of AEOL 10150 (the "BARDA Contract") and concurrently appointed Mr. Skibsted to the position of Senior Vice President, Chief Financial Officer and Secretary in accordance with the terms of the Offer Letter. The Offer Letter provides that Mr. Skibsted will be entitled to a monthly salary of $20,833.33 and that Mr. Skibsted will be entitled to participate in all of our current customary employee benefit plans and programs, subject to eligibility requirements, enrollment criteria and the other terms and conditions of such plans and programs. In addition, pursuant to the Offer Letter, Mr. Skibsted was granted a stock option to purchase 360,000 shares of the Common Stock under the 2004 Plan. The stock option has an exercise price of $0.60 per share, the closing stock price of our Common Stock on the date of grant, and vested at a rate of 30,000 shares per month over a period of twelve months from the date of grant.

For the period from September 1, 2010 through immediately prior to our announcement of the BARDA Contract, Mr. Skibsted had been providing consulting services to us pursuant to a Consulting Agreement, dated as of September 1, 2010, between us and Mr. Skibsted (the "Skibsted Consulting Agreement"). Pursuant to the Skibsted Consulting Agreement, Mr. Skibsted received a monthly consulting fee of $15,000 per month. The Skibsted Consulting Agreement was terminated on February 15, 2011 concurrent with our appointment of Mr. Skibsted as our Senior Vice President, Chief Financial Officer and Secretary pursuant to the Offer Letter.

Consulting Arrangements

Prior to June 30, 2011, McManus & Company, Inc. ("M&C"), which is owned by Mr. John McManus, provided us with administrative, accounting and financial consulting services. In addition, M&C also provided us with our corporate headquarters, facilities management and the outsourcing of the administrative, accounting, finance and accounting functions. Pursuant to an agreement with M&C, we paid M&C a monthly consulting payment of $25,000. During fiscal 2012 and 2011, we paid M&C $0 and $180,000, respectively, in consulting fees pursuant to services rendered by M&C under the agreement. The agreement terminated on June 30, 2011.

Separation Agreements

We did not enter into any separation agreements during fiscal 2012.

Payments Upon Termination or Change of Control

We have an employment with Mr. John McManus, which provides for payments to Mr. McManus upon termination of employment or a change of control of Aeolus under specified circumstances. For information regarding the specific circumstances that would trigger payments and the provision of benefits, the manner in which payments and benefits would be provided and conditions applicable to the receipt of payments and benefits, see "—Employment Agreement with John McManus."

The following tables set forth information regarding potential payments and benefits that each Named Executive Officer who was serving as an executive officer on September 30, 2012 would receive upon termination of employment or consulting arrangement or a change of control of Aeolus under specified circumstances, assuming that the triggering event occurred on September 30, 2012.

Summary of Potential Payments Upon Termination or Change of Control

	Termination without Cause			Voluntary Resignation
Name	Cash Payments(1)	Value of Benefits(2)	Value of Options with Accelerated Vesting	Cash Payments
John L. McManus	$ 299,997	$ 18,117	$ 18,750(3)	—

(1) This amount reflects a lump sum payment equal to the remaining term of the Named Executive Officer's employment agreement with the Company, from October 1, 2012 through June 30, 2013, assuming notice of termination was given on September 30, 2012.

(2) The amounts in this column reflect the estimated value of health, dental, life and disability insurance that would be provided to the Named Executive Officer pursuant to his employment agreement with the Company for the period from October 1, 2012 through June 30, 2013.

(3) Pursuant to the Named Executive Officer's employment agreement with the Company, in the event the Named Executive Officer was terminated without cause on September 30, 2012, options to purchase 208,334 shares would have vested. The amounts in this column are calculated based on the difference between $0.37, the closing market price per share of the Common Stock on September 28, 2012, the last trading day of fiscal year 2012, and the exercise price per share of $0.28 for the options subject to accelerated vesting.

	Immediately upon a Change of Control		Termination without Cause in Connection with a Change of Control		
Name	Cash Payments(4)	Value of Options with Accelerated Vesting	Cash Payments(6)	Value of Benefits(7)	Value of Options with Accelerated Vesting

John L. McManus	$ 100,000	$ 18,750(5)	$ 399,997	$ 18,117	$ 18,750(5)

(4) The amounts in this column reflect the lump sum payment payable upon a change of control pursuant to the Named Executive Officer's employment agreement with the Company in effect on September 30, 2012 assuming a change of control of the Company occurred on September 30, 2012.

(5) Pursuant to the 2004 Plan, all outstanding options shall vest in connection with a change of control of the Company. The amounts in this column are calculated based on the difference between $0.37, the closing market price per share of the Common Stock on September 28, 2012, the last trading day of fiscal year 2012, and the $0.28 exercise price per share of the 208,334 options subject to accelerated vesting.

(6) The amounts in this column reflect the lump sum payment payable pursuant to a termination upon a change of control pursuant to the Named Executive Officer's employment agreement with the Company in effect on September 30, 2012 assuming a change of control of the Company occurred on September 30, 2012.

(7) The amounts in this column reflect the estimated value of health, dental, life and disability insurance that would be provided to the Named Executive Officer pursuant to his employment agreement with the Company for the period from October 1, 2011 through June 30, 2012.

Summary of Actual Payments Upon Termination of Employment

No payments were made to any Named Executive Officer in connection with a termination of employment during fiscal 2012.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Aeolus has adopted a policy that all transactions between Aeolus and its executive officers, directors and other affiliates must be approved by a majority of the members of the Board and by a majority of the disinterested members of the Board, and must be on terms no less favorable to Aeolus than could be obtained from unaffiliated third parties.

Consulting Agreement

Through June 2011, M&C, which is owned by Mr. John McManus, provided us with administrative, accounting and financial consulting services. In addition, M&C provided us with our corporate headquarters, facilities management and the outsourcing of the administrative, accounting, finance and accounting functions. Pursuant to an agreement with M&C, we paid M&C a monthly consulting payment of $25,000. During fiscal 2012 and 2011, we paid M&C $0 and $180,000, respectively, in consulting fees pursuant to services rendered by M&C under the agreement. The agreement terminated on June 30, 2011.

March and April 2012 Financing

On March 30, 2012 and April 4, 2012, we entered into a Securities Purchase Agreement with certain accredited investors (the "2012 Purchasers") to sell and issue to the 2012 Purchasers an aggregate of approximately 2,200,166 units (the "2012 Units") at a purchase price of $0.30 per unit, resulting in aggregate gross proceeds to us of approximately $660,049.90 (the "2012 Private Placement"). Each 2012 Unit consisted of (i) one share of Common Stock and (ii) a five year warrant to purchase 0.75 shares of Common Stock. The warrants have an initial exercise price of $0.40 per share. One of the purchasers in the April 4, 2012 closing was Joseph Krivulka, who served as a member of our Board from 2004 to May 8, 2013, who purchased 333,333 2012 Units, resulting in aggregate proceeds to us of $99,999.90. In connection with the 2012 Private Placement, we also entered into a Registration Rights Agreement with the 2012 Purchasers, pursuant to which we agreed, among other things, to file a registration statement with the SEC to register the resale of: (1) the shares of Common Stock issued pursuant to the 2012 Private Placement, and (2) the shares of Common Stock issuable upon exercise of the warrants that comprised the 2012 Units.

2013 Private Placement

One of the investors who participated in the February 19, 2013 closing of the 2013 private placement was JAK Investments, LLC whose manager is Joseph Krivulka, who served as a member of our Board from 2004 to May 8, 2013. JAK Investments, LLC purchased 400,000 of the 2013 Units, resulting in aggregate proceeds of $100,000 to us. In connection with the 2013 Private Placement, we also entered into a Registration Rights Agreement with the purchasers in the 2013 private placement, pursuant to which we agreed, among other things, to file a registration statement with the SEC to register the resale of: (1) the shares of Common Stock issued pursuant to the 2013 private placement, and (2) the shares of common stock issuable upon exercise of the warrants issued pursuant to the 2013 private placement.

Director Independence

After review of all relevant transactions or relationships between each director, or any of his family members, and the Company, our senior management and its independent registered public accounting firm, the Board of Directors has affirmatively determined that all of our directors are independent directors within the meaning of the applicable Nasdaq Stock Market, LLC ("Nasdaq") listing standards, as currently in effect, excluding Mr. Cavalier.

88

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Security Ownership of Certain Beneficial Owners and Management

The following tables set forth certain information regarding the ownership of shares of Aeolus' Common Stock and Series B Preferred as of the close of business on May 8, 2013, by:

- each person known by Aeolus to beneficially own more than 5% of the outstanding shares of each class of our stock;
- each of our directors;
- each of our Named Executive Officers (as defined under "Executive Compensation" below); and
- all of our directors and executive officers as a group.

	Preferred Stock		Common Stock	
Identity of Owner or Group (1)(2)	Beneficially Owned	Percentage Owned	Beneficially Owned(4)	Percentage Owned(5)
Directors:				
David C. Cavalier	-	-	97,104,694 (6)	72.1%
John M. Farah, Jr., Ph.D. (7)	-	-	283,988	*
Mitchell D. Kaye, J.D. (8)	-	-	96,944,444	72.0%
Amit Kumar, Ph.D. (7)	-	-	356,147	*
John M. Clerici (7)	-	-	12,500	*
Chris A. Rallis (7)	-	-	356,147	*
Jeffrey A. Scott, M.D. (7)	-	-	12,500	*
Named Executive Officers:				
John L. McManus (9)	-	-	4,721,133	3.4%
Russell Skibsted (10)	-	-	392,500	*
All directors and executive officers as a group (9 persons)	-	-	103,252,109 (11)	73.3%
Greater than 5% Stockholders:				
Elan Corporation, plc	526,080	100.0%(3)	526,080 (12)	*
Lincoln House				
Lincoln Place				
Dublin 2, Ireland				
BVF Partners, L.P. and its affiliates			17,440,552 (13)	9.98% (14)
900 N. Michigan Avenue,				
Suite 1100				
Chicago, IL 60611				

Xmark Opportunity Partners, LLC and its affiliates	-	-	97,104,694 (6)	72.1%
90 Grove Street				
Ridgefield, CT 06877				

* Less than one percent

(1) Unless otherwise indicated, the address of all the owners is: c/o Aeolus Pharmaceuticals, Inc., 26361 Crown Valley Parkway, Suite 150, Mission Viejo, California 92691.

(2) This table is based upon information supplied by our executive officers, directors and principal stockholders and Schedule 13Ds and 13Gs, as amended, filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

(3) Percent of shares beneficially owned by any person is calculated by dividing the number of shares of preferred stock beneficially owned by that person by 526,080, the number of shares of preferred stock outstanding as of the close of business on the Record Date, and the number of shares of preferred stock as to which that person has the right to acquire voting or investment power within 60 days of the Record Date.

(4) The number of shares of common stock beneficially owned includes any shares issuable pursuant to stock options or warrants that are currently exercisable or may be exercised within 60 days after May 8, 2013 as well as shares of preferred stock convertible into common stock. Shares issuable pursuant to such options or warrants and shares issuable upon conversion of such preferred stock are deemed outstanding for computing the ownership percentage of the person holding such options but are not deemed to be outstanding for computing the ownership percentage of any other person.

(5) Applicable percentages are based on 134,550,068 shares outstanding on May 8, 2013, plus the number of shares such stockholder can acquire within 60 days after May 8, 2013. All percentages are rounded.

(6) Consists of 172,750 shares of Common Stock issuable upon exercise of options held by David C. Cavalier; 29,095,831 shares of Common Stock owned by Xmark Opportunity Fund, L.P., a Delaware limited partnership ("Opportunity LP"); 63,680,083 shares of Common Stock owned by Xmark Opportunity Fund, Ltd., a Cayman Islands exempted company ("Opportunity Ltd"); 1,508,567 shares of Common Stock owned by Xmark JV Investment Partners, LLC, a Delaware limited liability company ("JV Partners"); and 2,647,463 shares of Common Stock owned by Goodnow Capital, L.L.C. ("Goodnow"), a Delaware limited liability company. Mr. Cavalier shares voting and dispositive power over these shares with Mr. Kaye.

(7) Consists solely of shares of Common Stock issuable upon exercise of options.

(8) Consists of 12,500 shares of Common Stock issuable upon exercise of options held by Mitchell D. Kaye; 29,095,831 shares of Common Stock owned by Opportunity LP; 63,680,083 shares of Common Stock owned by Opportunity Ltd; 1,508,567 shares of Common Stock owned by JV Partners; and 2,647,463 shares of Common Stock owned by Goodnow. Mr. Kaye shares voting and dispositive power over these shares with Mr. Cavalier.

(9) Consists of 70,300 shares owned directly, 10,000 shares owned directly by Mr. McManus' spouse and 4,640,833 shares issuable upon exercise of options.

(10) Consists of 10,000 shares owned directly, 10,000 shares owned directly by Mr. Skibsted's spouse and 372,500 shares issuable upon exercise of options.

(11) Consists of shares of Common Stock beneficially owned by our directors and the following executive officers: Mr. McManus and Mr. Skibsted. See footnotes (5), (6), (7), (9) and (10) above, the shares held by Opportunity LP, Opportunity Ltd, JV Partners and Goodnow, which are deemed to be beneficially owned by Mssrs. Cavalier and Kaye have been counted only once for purposes of this calculation. Consists of 6,219,865 shares subject to options.

(12) Consists of 526,080 shares of Common Stock which were issuable upon conversion of an aggregate of 526,080 shares of Series B Preferred Stock as of the close of business on the Record Date.

(13) Consists of (i) 8,912,219 shares of Common Stock, including 4,241,308 shares of Common Stock issuable upon the exercise of certain warrants held by Biotechnology Value Fund, L.P ("BVF"), (ii) 5,036,834 shares of Common Stock, including 2,371,924 shares of Common Stock issuable upon the exercise of certain warrants held by Biotechnology Value Fund II, L.P ("BVF2"), (iii) 646,354 shares of Common Stock held by BVF Investments, L.L.C. ("BVLLC"), and (iv) 2,845,145 shares of Common Stock, including 1,386,768 shares of Common Stock issuable upon the exercise of certain warrants held by Investment 10, L.L.C. ("ILL10").

BVF Partners L.P. ("Partners"), as the general partner of BVF and BVF2, the manager of BVLLC and the investment adviser of ILL10, may be deemed to beneficially own 17,440,552 shares of Common Stock, including 8,000,000 shares of Common Stock currently issuable upon the exercise of certain warrants, beneficially owned in the aggregate by BVF, BVF2, BVLLC and ILL10. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 17,440,552 shares of Common Stock, including 8,000,000 shares of Common Stock currently issuable upon the exercise of certain warrants, beneficially owned by Partners. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 17,440,552 shares of Common Stock, including 8,000,000 shares of Common Stock currently issuable upon the exercise of certain warrants, beneficially owned by BVF Inc.

The foregoing should not be construed in and of itself as an admission by any of Partners, BVF Inc. or Mark N. Lampert as to beneficial ownership of any shares of Common Stock owned by BVF, BVF2, BVLLC and ILL10. Each of Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the shares of Common Stock beneficially owned by BVF, BVF2, BVLLC and ILL10 and this filing shall not be construed as an admission that any such person or entity is the beneficial owner of any such securities.

(14) The terms of the warrants held by BVF, BVF2 and ILL10 each contain an issuance limitation prohibiting the holder from exercising such warrants to the extent that, after giving effect to such exercise of the warrants, the holder would beneficially own more than 9.98% of the Common Stock of the Company then issued and outstanding, which prohibition cannot be modified by the holder before the sixty-first day after such holder's notice to the Company of its election to modify such prohibition.

SELLING STOCKHOLDERS

We are registering the shares of common stock identified in the table below in order to permit the selling stockholders to offer the shares for resale from time to time. Of the 30,591,501 shares listed, 29,289,000 shares were issued in the 2013 private placement. In total we issued to the Selling Stockholders 14,462,000 shares of common stock and warrants to purchase 16,129,501 shares of our common stock. The shares and warrants were issued in reliance on Section 4(2) of the Securities Act, and Rule 506 promulgated thereunder. For additional information regarding the shares offered pursuant to this prospectus, please see "Description of the Shares Included in the Prospectus" beginning on page 21 of this prospectus.

Except for the ownership of our common stock, the selling stockholders, other than JAK Investments LLC, have not had any material relationship with us within the past three years JAK Investments LLC's managing partner is Joseph Krivulka who served as a member of our Board of Directors from 2004 to to May 2013.

Each of Noble Financial Capital Markets, Ladenburg Thalmann & Co., Inc., Monarch Bay Securities, LLC, Roth Capital Partners, LLC and Roberts Mitani, LLC are broker-dealers registered with the Financial Industry Regulatory Authority or FINRA, and also selling stockholders in this offering. Noble Financial Capital Markets, Monarch Bay Securities, LLC and Roberts Mitani, LLC received some or all of their warrants to purchase common stock as compensation for services other than underwriting activities and are therefore deemed to be underwriters in this offering. All other selling stockholders who are broker-dealers received their warrants to purchase common stock as underwriting compensation for their services as placement agents in either the 2013 private placement or the 2012 private placement.

The following table sets forth, as of the date of this prospectus: (1) the name of the stockholder for whom we are registering shares under this registration statement; (2) the number of shares of our common stock owned by the stockholder prior to this offering; (3) the number of shares of our common stock being offered pursuant to this prospectus; and (4) the amount and the percentage (if 1% or more) of the class to be owned by such stockholder after completion of the offering. The percentage of outstanding common stock owned upon completion of the offering is calculated based on 134,550,068 shares of common stock issued and outstanding as of May 8, 2013. We prepared this table based on the information supplied to us by the selling stockholders named in the table and we have not sought to verify such information.

Name and Address of Selling Stockholder	Common Stock Owned Prior to Offering(1)	Common Stock Being Offered Pursuant to this Prospectus	Common Stock Owned Upon Completion of Offering (1)(2)	Percentage of Common Stock Owned Upon Completion of Offering
Michael S. Barish 2401 E. 2nd Avenue, #500 Denver, CO 80206	1,200,000(3)	1,200,000	0	*
Biotechnology Value Fund, L.P. 900 N. Michigan Avenue, Suite 1100 Chicago, IL 60611	8,912,219(4)(37)(38)	8,482,616	429,603	*
Biotechnology Value Fund II, L.P	5,036,834(5)(37)(38)	4,743,848	292,986	*

900 N. Michigan Avenue, Suite 1100 Chicago, IL 60611				
Brio Capital Master Fund, Ltd. c/o Brio Capital Management, LLC 100 Merrick Road, Suite 401W Rockville Centre, NY 11570-4800	2,400,000(6)	2,400,000	0	*
Stevan F. Bruehl Box 1832 Bellingham, WA 98227	60,000(7)	60,000	0	*

Capital Ventures International c/o Heights Capital Management 101 California Street, Suite 3250 San Francisco, CA 94111	2,000,000(8)	2,000,000	0	*
CEOcast, Inc 317 Madison Avenue Suite 1621 New York, NY 10017	250,000(9)	250,000	0	*
Dan Delmonico 31 Bell Canyon Dove Canyon, CA 92679	50,000(10)	50,000	0	*
Michael Donahue 1100 Glendon Avenue Suite 850 Los Angeles, CA 90024	10,500(11)	10,500	0	*
Gary A. Cross 212-6631 Minory Blvd. Richmond, British Columbia V6Y-121	24,000(12)	24,000	0	*
Investment 10, L.L.C. 900 N. Michigan Avenue, Suite 1100 Chicago, IL 60611	2,845,145(13)(37) (38)	2,773,536	71,609	*
JALAA Equities 34 Sumner Road Greenwich, CT 06831	800,000(14)	800,000	0	*
JAK Investments LLC 3 Bucks Mill Lane Holmdel, NJ 07733	1,653,084 (15)	800,000	849,711	*
Arthur Klausner 136 East 55th Street, Apt. PH-E New York, NY 10022	274,275(16)	200,000	74,275	*
Hiroko Komatsu 805 Leavenworth St., #509 San Francisco, CA 94109	50,000(17)	40,000	10,000	*
Ladenburg Thalmann & Co. Inc.	239,167(18)	239,167	0	*

520 Madison Avenue, 9TH
Floor
New York, NY 10022

Edward Larkin 9540 South Maroon Circle Suite 250 Englewood, CO 80112	64,350(19)	64,350	0	*
Lincoln Park Capital Fund, LLC C/O Lincoln Park Capital 440 N. Wells Street, Suite 410 Chicago, IL 60654	911,495(20)	400,000	511,495	*
Market Pathways 17595 Harvard Ave. Suite C-519 Irvine, CA 92614	250,000(21)	250,000	0	*
Dennis McCarthy 898 N. Sepulveda Blvd. Suite 400 El Segundo, CA 90245	49,000(22)	49,000	0	*
Monarch Bay Securities, LLC 898 N. Sepulveda Blvd. Suite 400 El Segundo, CA 90245	21,000(23)	21,000	0	*
Michael J. Morgan 9540 South Maroon Circle Suite 250 Englewood, CO 80112	16,392(24)	16,392	0	*
Eugene L. Neidiger & Regina L. Roesener JTWROS 9540 South Maroon Circle, Suite 250 Englewood, Colorado 80112	18,286(25)	18,286	0	*
Nextview Capital, LP 180 Crestview Dr. Deerfield, IL 60015	2,112,400(26)	2,000,000	112,400	*
Noble Financial Capital Markets 951 Yamato Road Boca Raton, FL 33431	304,167(27)	304,167	0	*

Robert L. Parrish 9540 South Maroon Circle Suite 250 Englewood, CO 80112	7,430(28)	7,430	0	*
Anthony B. Petrelli 9540 South Maroon Circle Suite 250 Englewood, CO 80112	19,967(29)	19,967	0	*

Roberts Mitani, LLC 145 West 57th Street 21st floor New York, NY 10019	300,000(30)	300,000	0	*
Regina L. Roesener 9540 South Maroon Circle Suite 250 Englewood, CO 80112	3,575(31)	3,575	0	*
Roth Capital Partners, LLC 888 San Clemente Drive Newport Beach, CA 92660	4,167(32)	4,167	0	*
H. Leigh Severance 14282 E. Caley Avenue Aurora, CO 80016	1,200,000(33)	1,200,000	0	*
Alva Terry Staples 6705 E. Dorado Place Greenwood Village, CO 80111	240,000 (34)	200,000	40,000	*
Stonepine Capital, L.P. PO Box 250 Bend, OR 97709	1,600,000(35)	1,600,000	0	*
Roger Zickfeld 1100 Glendon Avenue Suite 850 Los Angeles, CA 90024	59,500(36)	59,500	0	*
TOTAL		30,591,501		

* Less than one percent

(1) Includes shares of common stock issuable upon exercise of warrants. For the purposes hereof, we assume the issuance of all shares issuable upon exercise of warrants and disregard any limitations on the exercise of warrants.

(2) Assumes the sale by the selling stockholders of all of the shares of common stock available for resale under this prospectus and disregards any limitations on the exercise of warrants.

(3) Consists of 1,200,000 shares of common stock and 1,200,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(4) Consists of 429,603 shares held directly by Biotechnology Value Fund, L.P and 4,241,308 shares of common stock and 4,241,308 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(5) Consists of 292,986 shares held directly by Biotechnology Value Fund II, L.P and 2,371,924 shares of common stock and 2,371,924 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(6) Consists of 2,400,000 shares of common stock and 2,400,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(7) Consists of 600,000 shares of common stock and 600,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(8) Consists of 2,000,000 shares of common stock and 2,000,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement. We have been advised that Heights Capital Management, Inc. is the investment manager to Capital Ventures International and, as such, has discretionary authority to vote and dispose of the shares held by Capital Ventures International and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by Capital Ventures International. Mr. Kobinger expressly disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest in such securities. The address for each of Mr. Kobinger and Heights Capital Management, Inc. is 101 California Street, Suite 3250, San Francisco, California 94111, and the address for Capital Ventures International is One Capitol Place, P.O. Box 1787 GT, Grand Cayman, Cayman Islands, British West Indies. Capital Ventures International is affiliated with one or more FINRA members. Capital Ventures International has represented to us that the securities held by it were purchased in the ordinary course of business and that at the time of such purchase, it did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by it.

(9) Consists of 250,000 shares of common stock issuable upon exercise of warrants issued for consulting services.

(10) Consists of 50,000 shares of common stock issuable upon exercise of warrants issued for consulting services.

(11) Consists of 10,500 shares of common stock issuable upon exercise of warrants issued for consulting services. Michael Donahue is an affiliate of a broker-dealer and has represented to us that the securities held by him were acquired in the ordinary course of business and that at the time of such purchase, he did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by him.

(12) Consists of 24,000 shares of common stock and 24,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(13) Consists of 71,609 shares held directly by Investment 10, L.L.C. and 1,386,768 shares of common stock and 1,386,768 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(14) Consists of 800,000 shares of common stock and 800,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(15) Consists of (1) 269,751 shares of common stock issuable upon exercise of options exercisable within 60 days of May 8, 2013 held by Joseph Krivulka, (2) 333,333 shares of common stock and 250,000 shares of common stock issuable upon exercise of warrants held directly by JJK Partners, LLC and (3) 400,000 shares of common stock and 400,000 shares of common stock issuable upon exercise of warrants purchased by JAK Investments LLC in the 2013 Private Placement. Joseph Krivulka is Managing Director for JJK Partners, LLC and Manager for JAK Investments, LLC and may be deemed to have voting and investment power with respect to such shares.

(16) Consists of 74,275 shares held directly by Mr. Klausner and 100,000 shares of common stock and 100,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(17) Consists of 10,000 shares held directly by Mr. Komatsu and 40,000 shares of common stock and 40,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(18) Consists of 235,000 shares of common stock issuable upon exercise of warrants issued as 2013 Placement Agent Warrants and 4,167 shares of common stock issuable upon exercise of warrants issued as 2012 Placement

Agent Warrants. Ladenburg Thalmann & Co. Inc. is s FINRA registered broker-dealer, however, all of the shares offered by it were received as underwriting compensation for its services as placement agent in connection with the 2013 Private Placement and 2012 Private Placement.

(19) Consists of 64,350 shares of common stock issuable upon exercise of warrants issued as 2013 Placement Agent Warrants to the selling stockholder, an employee of Neidiger, Tucker, Bruner, Inc., a registered broker-dealer and a co-placement agent in the 2013 Private Placement. Mr. Larkin is an affiliate of a Neidiger, Tucker, Bruner, Inc. and has represented to us that the securities held by him were acquired in the ordinary course of business and that at the time of such purchase, he did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by him.

(20) Consists of (1) 333,334 shares of common stock held directly and 250,001 shares of common stock Issuable upon warrants and (2) 200,000 shares of common stock and 200,000 shares of common stock issuable upon exercise of warrants issued in the 2013 Private Placement. Josh Scheinfeld and Jonathan Cope, the principals of Lincoln Park Capital Fund, LLC, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park Capital Fund, LLC. Messrs. Scheinfeld and Cope have shared voting and disposition power over the shares being offered.

(21) Consists of 250,000 shares of common stock issuable upon exercise of warrants issued for consulting services.

(22) Consists of 49,000 shares of common stock issuable upon exercise of warrants issued for consulting services. Mr. McCarthy is an affiliate of a broker-dealer and has represented to us that the securities held by him were acquired in the ordinary course of business and that at the time of such purchase, he did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by him..

(23) Consists of 21,000 shares of common stock issuable upon exercise of warrants issued for consulting services. Monarch Bay Securities, LLC is a FINRA registered broker-dealer and is deemed an underwriter in this offering.

(24) Consists of 16,392 shares of common stock issuable upon exercise of warrants issued as 2013 Placement Agent Warrants to the selling stockholder, an employee of Neidiger, Tucker, Bruner, Inc., a registered broker-dealer and a co-placement agent in the 2013 Private Placement. Mr. Morgan is an affiliate of a Neidiger, Tucker, Bruner, Inc. and has represented to us that the securities held by him were acquired in the ordinary course of business and that at the time of such purchase, he did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by him.

(25) Consists of 18,286 shares of common stock issuable upon exercise of warrants issued as 2013 Placement Agent Warrants to the selling stockholder, a trust controlled by Eugene L. Neidiger and Regina Roesener, each employees of Neidiger, Tucker, Bruner, Inc., a registered broker-dealer and a co-placement agent in the 2013 Private Placement. Each of Mr. Neidiger and Ms. Roesener are affiliates of Neidiger, Tucker, Bruner, Inc. and each has represented to us that the securities held by them were acquired in the ordinary course of business and that at the time of such purchase, they did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by them.

(26) Consists of 112,400 shares held directly by Nextview Capital, LP and 2,000,000 shares of common stock and 2,000,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(27) Consists of 300,000 shares of common stock issuable upon exercise of warrants issued for consulting services and 4,167 shares of common stock issuable upon exercise of warrants issued as 2012 Placement Agent Warrants. Noble Financial Capital Markets is a FINRA registered broker-dealer and is deemed an underwriter in this offering.

(28) Consists of 7,430 shares of common stock issuable upon exercise of warrants issued as 2013 Placement Agent Warrants to the selling stockholder, an employee of Neidiger, Tucker, Bruner, Inc., a registered broker-dealer and a co-placement agent in the 2013 Private Placement. Mr. Parrish is an affiliate of a Neidiger, Tucker, Bruner, Inc. and has represented to us that the securities held by him were acquired in the ordinary course of business and that at the time of such purchase, he did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by him.

(29) Consists of 19,967 shares of common stock issuable upon exercise of warrants issued as 2013 Placement Agent Warrants to the selling stockholder, an employee of Neidiger, Tucker, Bruner, Inc., a registered broker-dealer and a co-placement agent in the 2013 Private Placement. Mr. Petrelli is an affiliate of a Neidiger, Tucker, Bruner, Inc. and has represented to us that the securities held by him were acquired in the ordinary course of business and that at the time of such purchase, he did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by him.

(30) Consists of 300,000 shares of common stock issuable upon exercise of warrants issued for consulting services. Roberts Mitani, LLC is a FINRA registered broker-dealer and is deemed an underwriter in this offering.

(31) Consists of 3,575 shares of common stock issuable upon exercise of warrants issued as 2013 Placement Agent Warrants to the selling stockholder, an employee of Neidiger, Tucker, Bruner, Inc., a registered broker-dealer and a co-placement agent in the 2013 Private Placement. Ms. Roesener is an affiliate of Neidiger, Tucker, Bruner, Inc. and has represented to us that the securities held by her were acquired in the ordinary course of business and that at the time of such purchase, she did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by her.

(32) Consists of 4,167 shares of common stock issuable upon exercise of warrants issued as 2012 Placement Agent Warrants to Roth Capital Partners, LLC. Roth Capital Partners, LLC. is s FINRA registered broker-dealer, however, all of the shares offered by it were received as underwriting compensation for its services as placement agent in connection with the 2012 Private Placement.

(33) Consists of 1,200,000 shares of common stock and 1,200,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(34) Consists of 40,000 shares held directly by Mr. Staples and 100,000 shares of common stock and 100,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement to Mr. Staples.

(35) Consists of 1,600,000 shares of common stock and 1,600,000 shares of common stock issuable upon exercise of warrants issued in the 2013 private placement.

(36) Consists of 59,500 shares of common stock issuable upon exercise of warrants issued for consulting services. Mr. Zickfeld is an affiliate of a broker-dealer and has represented to us that the securities held by him were acquired in the ordinary course of business and that at the time of such purchase, he did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by him.

(37) On February 19, 2013, the Reporting Persons acquired warrants exercisable for an aggregate of 8,000,000 shares of Common Stock. Such warrants have an initial exercise price of $0.25 per Share, subject to adjustment pursuant to the terms of the warrants, and expire on February 19, 2018. The warrants may not be exercised if, after such exercise, the Reporting Persons would beneficially own, as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, more than 9.98% of the number of shares of Common Stock then issued and outstanding.

As of February 19, 2013, (i) Biotechnology Value Fund, L.P (“BVF”) beneficially owned 8,912,219 shares of Common Stock, including 4,241,308 shares of Common Stock issuable upon the exercise of certain warrants held by it, (ii) Biotechnology Value Fund II, L.P (“BVF2”) beneficially owned 5,036,834 shares of Common Stock, including 2,371,924 shares of Common Stock issuable upon the exercise of certain warrants held by it, (iii) BVF Investments, L.L.C. (“BVLLC”) beneficially owned 646,354 shares of Common Stock, and (iv) Investment 10, L.L.C. (“ILL10”) beneficially owned 2,845,145 shares of Common Stock, including 1,386,768 shares of Common Stock issuable upon the exercise of certain warrants held by it.

BVF Partners L.P. (“Partners”), as the general partner of BVF and BVF2, the manager of BVLLC and the investment adviser of ILL10, may be deemed to beneficially own 17,440,552 shares of Common Stock, including 8,000,000 shares of Common Stock currently issuable upon the exercise of certain warrants, beneficially owned in the aggregate by BVF, BVF2, BVLLC and ILL10.

BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 17,440,552 shares of Common Stock, including 8,000,000 shares of Common Stock currently issuable upon the exercise of certain warrants, beneficially owned by Partners.

Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 17,440,552 shares of Common Stock, including 8,000,000 shares of Common Stock currently issuable upon the exercise of certain warrants, beneficially owned by BVF Inc.

The foregoing should not be construed in and of itself as an admission by any of Partners, BVF Inc. or Mark N. Lampert as to beneficial ownership of any shares of Common Stock owned by BVF, BVF2, BVLLC and

ILL10. Each of Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the shares of Common Stock beneficially owned by BVF, BVF2, BVLLC and ILL10 and this filing shall not be construed as an admission that any such person or entity is the beneficial owner of any such securities.

(38) The warrants issued in the 2013 private placement each contain an issuance limitation prohibiting the holder from exercising such warrants to the extent that, after giving effect to such exercise of the warrants, the holder would beneficially own more than 9.98% of the Common Stock of the Company then issued and outstanding, which prohibition cannot be modified by the holder before the sixty-first day after such holder's notice to the Company of its election to modify such prohibition.

DESCRIPTION OF CAPITAL STOCK

As of May 8, 2013, we were authorized to issue up to 200,000,000 shares of common stock and 10,000,000 shares of preferred stock under our Amended and Restated Certificate of Incorporation. The preferred stock is divided into two series: 1,250,000 shares of preferred stock are designated "Series A Convertible Preferred Stock," and 1,600,000 shares of preferred stock are designated "Series B Convertible Preferred Stock."

Common Stock

As of May 8, 2013, we had 134,550,068 shares of common stock outstanding. As of May 8, 2013, there were 12,245,917 shares of common stock issuable upon the exercise of outstanding stock options and 17,879,627 shares of common stock issuable upon the exercise of warrants to purchase common stock.

Holders of shares of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders and are not entitled to cumulate votes for the election of directors. Subject to preferences that may be applicable to any outstanding shares of preferred stock, including our Series B Convertible Preferred Stock, holders of shares of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up of our company, the holders of shares of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distributions rights applicable to any outstanding shares of preferred stock. Shares of common stock have no preemptive, conversion or other subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

As of May 8, 2013, there were issued and outstanding 526,080 shares of Series B Convertible Preferred Stock and 896,037 shares of Series B Convertible Preferred stock issuable upon the exercise of warrants to purchase Series B Convertible Preferred Stock. As of May 8, 2013, no shares of Series A Convertible Preferred Stock were issued and outstanding.

Under our Amended and Restated Certificate of Incorporation, our board of directors has the authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions, including the dividend, conversion, voting, redemption (including sinking fund provisions), and other rights, liquidation preferences, and the number of shares constituting any series and the designations of such series, without any further vote or action by our stockholders.

Because the terms of the preferred stock may be fixed by our board of directors without stockholder action, the preferred stock could be issued quickly with terms calculated to defeat a proposed takeover of our company or to make the removal of our management more difficult. Under certain circumstances this could have the effect of decreasing the market price of our common stock.

Series B Convertible Preferred Stock

All shares of Series B Convertible Preferred Stock and warrants to purchase shares of Series B Convertible Preferred Stock currently are owned by Elan Corporation plc. The Series B Convertible Preferred Stock is non-voting stock. Each share of Series B Convertible Preferred Stock is convertible into one shares of our common stock, provided that no conversion may be effected that would result in the holders of Series B Convertible Preferred Stock owning more than 9.9% of our common stock on a fully converted to common stock basis. If we pay a cash dividend on our common stock, we also must pay the same dividend on an as converted basis on the Series B Convertible Preferred

Stock.

Warrants

Effective February 15, 2013, the Company and each of Xmark JV Investment Partners, LLC, Xmark Opportunity Fund, Ltd. and Xmark Opportunity Fund, L.P. (collectively, the "Xmark Entities") entered into a Warrant Repricing, Exercise and Lockup Agreement (the "Xmark Warrant Agreement") pursuant to which the Company agreed to reduce the exercise price of outstanding warrants to purchase an aggregate of up to 59,149,999 shares of Common Stock held by the Xmark Entities (the "Xmark Warrants") to $0.01 per share. In consideration for the reduction of the exercise price of the Xmark Warrants, each of the Xmark Entities agreed to immediately exercise all of the Xmark Warrants. The Xmark Warrant Agreement also provides that the Xmark Entities will not transfer the shares issuable upon exercise of the Xmark Warrants (the "Xmark Warrant Shares") until the Company either (i) declares a cash dividend on its common stock or otherwise makes a cash distribution or (ii) effects a Change of Control, subject in each case to the terms of the Xmark Warrant Agreement.

As of May 8, 2013, warrants to purchase an aggregate of 17,879,627 shares of common stock were outstanding with a weighted average exercise price of $0.29 per share. Details of the warrants for common stock outstanding at May 8, 2013 are as follows:

Number of Shares	Exercise Price	Expiration Date
100,000	$ 0.50	May 2014
100,000	$ 1.00	May 2014
100,000	$ 1.50	May 2014
125,000	$ 0.65	June 2014
125,000	$ 1.00	June 2014
20,000	$ 0.39	September 2014
15,000	$ 0.50	September 2014
15,000	$ 0.60	September 2014
50,000	$ 0.38	April 2015
50,000	$ 0.50	May 2016
50,000	$ 0.50	July 2016
50,000	$ 1.00	July 2016
50,000	$ 1.50	July 2016
50,000	$ 2.00	July 2016
50,000	$ 2.50	July 2016
1,337,627	$ 0.40	March 2017
325,000	$ 0.40	April 2017
300,000	$ 0.258	June 2017
140,000	$ 0.35	October 2017
13,085,000	$ 0.25	February 2018
1,742,000	$ 0.44	March 2018
17,879,627		

As of March 31, 2013, one warrant to purchase an aggregate of 896,037 shares of preferred stock was outstanding. The warrant has an exercise price of $0.01 per share and expires in February 2016.

Section 203 of the Delaware Corporation Law

Section 203 of the General Corporation Law of the State of Delaware (the “DGCL”) prevents an “interested stockholder” (defined in Section 203 of the DGCL, generally, as a person owning 15% or more of a corporation’s outstanding voting stock), from engaging in a “business combination” (as defined in Section 203 of the DGCL) with a publicly-held Delaware corporation for three years following the date such person became an interested stockholder, unless:

- before such person became an interested stockholder, the board of directors of the corporation approved the transaction in which the interested stockholder became an interested stockholder or approved the business combination;

- upon consummation of the transaction that resulted in the interested stockholder's becoming an interested stockholder, the interested stockholder owns at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (excluding stock held by directors who are also officers of the corporation and by employee stock plans that do not provide employees with the rights to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer); or

- following the transaction in which such person became an interested stockholder, the business combination is approved by the board of directors of the corporation and authorized at a meeting of stockholders by the affirmative vote of the holders of two-thirds of the outstanding voting stock of the corporation not owned by the interested stockholder.

Our certificate of incorporation expressly provides that the provisions of Section 203 of the DGCL do not apply. Consequently, a person or entity wishing to acquire control of our company would not have to comply with the director or stockholder approvals required by Section 203. This could make a takeover of our company easier even if the takeover were not approved by the board of directors or opposed by the stockholders as not being in their best interests.

Limitation of Liability

Section 145 of the DGCL provides a detailed statutory framework covering indemnification of officers and directors against liabilities and expenses arising out of legal proceedings brought against them by reason of their being or having been directors or officers. Section 145 generally provides that a director or officer of a corporation:

- shall be indemnified by the corporation for all expenses of such legal proceedings when he is successful on the merits;

- may be indemnified by the corporation for the expenses, judgments, fines and amounts paid in settlement of such proceedings (other than a derivative suit), even if he is not successful on the merits, if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful; and

- may be indemnified by the corporation for the expenses of a derivative suit (a suit by a stockholder alleging a breach by a director or officer of a duty owed to the corporation), even if he is not successful on the merits, if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation.

The indemnification discussed in clauses two and three above may be made only upon a determination that indemnification is proper because the applicable standard of conduct has been met. Such a determination may be made by a majority of a quorum of disinterested directors, independent legal counsel, the stockholders or a court of competent jurisdiction. The indemnification discussed in clause three above may not apply, however, if the director or officer is adjudged liable for negligence or misconduct in the performance of his duties to the corporation, unless a corporation determines that despite such adjudication, but in view of all the circumstances, he is entitled to indemnification.

Article Sixth of our certificate of incorporation provides in substance that, to the fullest extent permitted by the DGCL as it now exists or as amended, each director and officer shall be indemnified against reasonable costs and expenses, including attorney's fees, and any liabilities which he may incur in connection with any action to which he may be made a party by reason of his being or having been a director or officer of our company. The indemnification provided by our certificate of incorporation is not deemed exclusive of or intended in any way to limit any other rights to which any person seeking indemnification may be entitled. Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability

- for any breach of the director's duty of loyalty to the corporation or its stockholders,

- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law,

- under Section 174 of the DGCL, or

- for any transaction from which the director derived an improper personal benefit.

Article Eighth of our certificate of incorporation provides for the elimination of personal liability of a director for breach of fiduciary duty, as permitted by Section 102(b)(7) of the DGCL. We maintain liability insurance on our officers and directors against liabilities that they may incur in such capacities. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Anti-Takeover Effects

Bylaws

Our Bylaws are designed to make it difficult for a third party to acquire control of us, even if a change of control would be beneficial to stockholders. Our Bylaws do not permit any person other than the board of directors or certain executive officers to call special meetings of the stockholders. In addition, we must receive a stockholders' proposal for an annual meeting within a specified period for that proposal to be included on the agenda. Because stockholders do not have the power to call meetings and are subject to timing requirements in submitting stockholder proposals for consideration at an annual or special meeting, any third-party takeover not supported by the board of directors would be subject to significant delays and difficulties.

No Cumulative Voting

The DGCL provides that stockholders are denied the right to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation does not provide for cumulative voting.

Undesignated Preferred Stock

The authority that is possessed by our Board of Directors to issue preferred stock could potentially be used to discourage attempts by third parties to obtain control of our company through a merger, tender offer, proxy contest or otherwise by making such attempts more difficult or more costly. Our Board of Directors may issue preferred stock with voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of common stock.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

The combination of the provisions summarized above will make it more difficult for our stockholders to replace our Board of Directors as well as for another party to obtain control of us by replacing our Board of Directors. Therefore, these provisions may have the effect of deterring hostile takeovers or delaying changes in our control or management. These provisions are intended to enhance the likelihood of continued stability in the composition of our Board of Directors and in the policies they implement, and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in our management.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company.

102

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- 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;

- short sales effected after the date the registration statement of which this Prospectus is a part is declared effective by the Commission;

- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

- a combination of any such methods of sale; and

- any other method permitted by applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, 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 common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our

common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. 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 such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

Each selling stockholder has advised us that they have not entered into any written or oral agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which the shares may be sold without volume restrictions pursuant to Rule 144 of the Securities Act.

LEGAL MATTERS

K&L Gates LLP, Irvine, California, passed upon certain legal matters for us in connection with the offered securities.

EXPERTS

Grant Thornton LLP, an independent registered public accounting firm, has audited our consolidated financial statements for the fiscal years ended September 30, 2012 and September 30, 2011, as stated in its report, and such financial statements have been included in this prospectus in reliance upon the report of Grant Thornton given upon their authority as experts in accounting and auditing.

ADDITIONAL INFORMATION

We have filed with the SEC a Registration Statement on Form S-1 under the Securities Act with respect to the securities offered in this prospectus. This prospectus does not contain all of the information set forth in the registration statement or the exhibits and schedules filed with it. You should refer to the registration statement and its exhibits and schedules for additional information. When we make references in this prospectus to any of our agreements or other documents, the references are not necessarily complete and you should refer to the exhibits filed with the registration statement for copies of the actual agreements or other documents.

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934 and in accordance therewith file reports, proxy statements and other information with the SEC. Such reports, proxy statements, other information, and a copy of the registration statement and its exhibits may be inspected by anyone without charge and copies of these materials may be obtained upon the payment of the fees prescribed by the SEC, at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10 a.m. to 3 p.m. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The registration statement and the reports, proxy statements and other information filed by us are also available through the SEC’s website on the World Wide Web at www.sec.gov, as well as on our website at www.aeoluspharma.com.

INDEX TO FINANCIAL STATEMENTS

AEOLUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except per share data)

	March 31, 2013	September 30, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$1,926	$281
Accounts receivable	1,620	882
Deferred subcontractor cost	1,005	—
Prepaids and other current assets	92	61
Total current assets	4,643	1,224
Investment in CPEC LLC	32	32
Total assets	$4,675	$1,256
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$2,023	$2,272
Deferred revenue	1,046	—
Total current liabilities	3,069	2,272
Warrant liability	—	19,319
Total liabilities	3,069	21,591
Commitments and Contingencies (Note H)		
Stockholders' equity (deficit):		
Preferred stock, $.01 par value per share, 10,000,000 shares authorized:		
Series B nonredeemable convertible preferred stock, 1,600,000 and 1,600,000 shares authorized as of March 31, 2013 and September 30, 2012, respectively; 526,080 and 526,080 shares issued and outstanding as of March 31, 2013 and September 30, 2012, respectively	5	5
Common stock, $.01 par value per share, 200,000,000 shares authorized; 134,550,068 and 62,731,963 shares issued and outstanding as of March 31, 2013 and September 30, 2012, respectively	1,346	627
Additional paid-in capital	182,724	159,747
Accumulated deficit	(182,469)	(180,714)
Total stockholders' equity (deficit)	1,606	(20,335)
Total liabilities and stockholders' equity (deficit)	$4,675	$1,256

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

AEOLUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
Revenue:				
Contract Revenue	$859	$2,231	$2,201	$4,446
Costs and expenses:				
Research and development	618	1,927	1,787	3,998
General and administrative	1,003	865	1,659	1,720
Total costs and expenses	1,621	2,792	3,446	5,718
Loss from operations	(762)	(561)	(1,245)	(1,272)
Non-cash financing charges and change in fair value of warrants (Notes D, E and F)	(5,020)	3,324	(510)	7,012
Net income (loss)	$(5,782)	$2,763	$(1,755)	$5,740
Net income (loss) per weighted share attributable to common stockholders:				
Basic (Note G)	$(0.06)	$0.02	$(0.03)	$0.05
Diluted (Note G)	$(0.06)	$0.00	$(0.03)	$(0.01)
Weighted average common shares outstanding:				
Basic	94,425	60,490	69,664	60,480
Diluted	94,425	71,858	69,664	76,334

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

AEOLUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six Months Ended March 31,	
	2013	2012
Cash flows from operating activities:		
Net income (loss)	$(1,755)	$5,740
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	309	347
Change in fair value of warrants	510	(7,012)
Change in assets and liabilities:		
Accounts receivable	(738)	(803)
Deferred subcontractor cost	(1,005)	—
Prepaid and other assets	(31)	(17)
Accounts payable and accrued expenses	(249)	1,232
Deferred revenue	1,046	—
Net cash used in operating activities	(1,913)	(513)
Cash flows provided by financing activities:		
Proceeds from issuance of common stock and warrants	3,616	400
Costs related to the issuance of common stock and warrants	(58)	(15)
Net cash provided by financing activities	3,558	385
Net decrease in cash and cash equivalents	1,645	(128)
Cash and cash equivalents at beginning of period	281	518
Cash and cash equivalents at end of period	$1,926	$390
Supplemental disclosure of non-cash financing activities:		
Common stock issued for short-term receivable	$—	$130

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

AEOLUS PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

A. Organization, Business and Summary of Significant Accounting Policies

Organization

The accompanying unaudited condensed consolidated financial statements include the accounts of Aeolus Pharmaceuticals, Inc. and its wholly-owned subsidiary, Aeolus Sciences, Inc. (collectively, "we," "us," "Company" or "Aeolus"). All significant intercompany accounts and transactions have been eliminated in consolidation. Aeolus is a Delaware corporation. The Company's primary operations are located in Mission Viejo, California.

Business

Aeolus is a biopharmaceutical company developing a platform of a new class of broad-spectrum, catalytic antioxidant compounds that protect healthy tissue from the damaging effects of radiation. Its first compound, AEOL 10150, is being developed for oncology indications, where it is used in combination with radiation and chemotherapy. Aeolus is also developing AEOL 10150 as a medical countermeasure against the pulmonary effects of radiation exposure under a contract ("BARDA Contract") valued at up to $118.4 million with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Department of Health and Human Services ("HHS"). Aeolus is in its third year under the BARDA Contract. Additionally, Aeolus receives development support from the National Institutes of Health ("NIH") for development of the compound as a medical countermeasure against radiation and chemical exposure. Aeolus' strategy is to leverage the substantial investment in toxicology, manufacturing, and preclinical and clinical studies made by U.S. government agencies in AEOL 10150, including the BARDA Contract, to efficiently develop the compound for use in oncology. Additionally, Aeolus receives development support from the NIH for development of the compound as a medical countermeasure against radiation and chemical exposure.

Basis of Presentation

All significant intercompany activity has been eliminated in the preparation of the condensed consolidated financial statements. The unaudited condensed consolidated financial statements have been prepared in accordance with the requirements of Form 10-Q and Rule 10-01 of Regulation S-X. Some information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to those rules and regulations. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations and cash flows of the Company. The condensed balance sheet at September 30, 2012 was derived from the Company's audited financial statements included in the Company's Annual Report on Form 10-K/A for the fiscal year ended September 30, 2012, filed with the Securities and Exchange Commission (the "SEC") on May 14, 2013. As disclosed in the Company's Current Report on Form 8-K filed with the SEC on February 19, 2013, in connection with the preparation of the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2012, the Company determined that its basic and diluted net income (loss) per share calculations should have been prepared using the "two-class method." Under the two-class method, securities that participate in dividends are considered "participating securities." The Company's preferred shares, preferred warrants and most of its common stock warrants are considered "participating securities" because they include non-forfeitable rights to dividends. Additionally, the Company determined that the

diluted net income (loss) per share calculations did not include the net income effect of changes in fair value related to dilutive, liability classified warrants. On February 12, 2013, the Audit Committee of the Company's Board of Directors concluded, based on the recommendation of management, that the consolidated statements of operations for the fiscal years ended September 30, 2012 and 2011, and the consolidated statements of operations for the quarterly periods in the years ended September 30, 2012 and 2011, should no longer be relied upon because of the incorrect calculation of earnings per share. The Company's management and the Audit Committee discussed the matters relating to the restatements with Grant Thornton LLP, the Company's independent registered public accountants. On May 14, 2013, the Company filed an amendment to its Annual Report on Form 10-K for the year ended September 30, 2012 to reflect the revisions set forth above, and also reflected these revisions in the financial statements included in the Company's Post-Effective Amendment No. 1 to Form S-1 (Registration No. 333-181409) that was filed with the SEC on February 19, 2013. The unaudited condensed consolidated financial statements included herein should therefore be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K/A and in the Company's other SEC filings. Results for the interim period are not necessarily indicative of the results for any other period.

Use of Estimates

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

Cash and Cash Equivalents

The Company invests available cash in short-term bank deposits. Cash and cash equivalents include investments with maturities of three months or less at the date of purchase. The carrying value of cash and cash equivalents approximate their fair market value at March 31, 2013 and 2012 due to their short-term nature.

Significant customers and accounts receivable

For the six months ended March 31, 2013 and 2012, the Company's primary customer was BARDA. For the six months ended March 31, 2013 and 2012, revenues from BARDA comprised 100% of total revenues. As of March 31, 2013 and 2012, the Company's receivable balances were comprised 100% from this customer. Unbilled accounts receivable, included in accounts receivable, totaling $418,000 and $882,000 as of March 31, 2013 and September 30, 2012, respectively, relate to work that has been performed, though invoicing has not yet occurred. All of the unbilled receivables are expected to be billed and collected within the next 12 months. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from BARDA. If necessary, the Company records a provision for doubtful receivables to allow for any amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends. As of March 31, 2013 and September 30, 2012, an allowance for doubtful accounts was not recorded as the collection history from the Company's customers indicated that collection was probable.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company places its cash and cash equivalents with high quality financial institutions. Management believes that the financial risks associated with its cash and cash equivalents and investments are minimal. Because accounts receivable consist primarily of amounts due from the U.S. federal government agencies, management deems there to be minimal credit risk.

Revenue Recognition

Aeolus recognizes revenue in accordance with the authoritative guidance for revenue recognition. Revenue is recognized when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

The BARDA Contract is classified as a "cost-plus-fixed-fee" contract. Aeolus recognizes government contract revenue in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contracts. Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and indirect costs. In addition, we receive a fixed fee under the BARDA Contract, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under the BARDA Contract, including the fixed fee, are generally recognized as revenue in the period the reimbursable costs are incurred and become billable.

Fair Value of Financial Instruments

The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their fair values due to their short maturities.

Fair Value Measurements

The Company adopted Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures, for financial and non-financial assets and liabilities.

ASC Topic 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

The warrant liability is measured at fair market value on a recurring basis as of March 31, 2013 and September 31, 2012 and is summarized below (in thousands):

Fair value at March 31, 2013			Fair value at September 30, 2012		
Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
$ —	$ —	$ —	$ —	$ —	$ 19,319

Fair value measurements of warrants using significant unobservable inputs (Level 3)	
Balance at September 30, 2012	$ 19,319
Change in fair value of warrant liability	(1,574)
Warrant repricing modification charge	2,084
Exercised	(19,829)
Balance at March 31, 2013	$ —

Research and Development
Research and development costs are expensed in the period incurred.

Leases
The Company leases office space and office equipment under month to month operating lease agreements. For the six months ended March 31, 2013 and 2012, total rent expense was approximately $20,000 and $16,000, respectively.

Income Taxes
The Company recognizes liabilities or assets for the deferred tax consequences of temporary differences between the tax bases of assets or liabilities and their reported amounts in the financial statements. These temporary differences will result in taxable or deductible amounts in future years when the reported amounts of the assets or liabilities are recovered or settled. A valuation allowance is established when management determines that it is more likely than not that all or a portion of a deferred tax asset will not be realized. Management evaluates the Company's ability to realize its net deferred tax assets on a quarterly basis and valuation allowances are provided, as necessary. During this evaluation, management reviews its forecasts of income in conjunction with other positive and negative evidence surrounding the Company's ability to realize its deferred tax assets to determine if a valuation allowance is required. Adjustments to the valuation allowance will increase or decrease the Company's income tax provision or benefit. Management also applies the relevant guidance to determine the amount of income tax expense or benefit to be allocated among continuing operations, discontinued operations, and items charged or credited directly to stockholders' equity (deficit).

A tax position must meet a minimum probability threshold before a financial statement benefit is recognized. The minimum threshold is a tax position that is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation process, based on the technical merits of the position. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Net Income (Loss) Per Common Share

The Company computes net income attributable to common stockholders using the two-class method required for participating securities. Under the two-class method, securities that participate in dividends, such as the Company's outstanding preferred shares, preferred warrants, and most common stock warrants, are considered "participating securities." The Company's preferred shares, preferred warrants and common stock warrants are considered "participating securities" because they include non-forfeitable rights to dividends.

In applying the two-class method, (i) basic net income (loss) per share is computed by dividing net income (less any dividends paid on participating securities) by the weighted average number of shares of common stock and participating securities outstanding for the period and (ii) diluted earnings per share may include the additional effect of other securities, if dilutive, in which case the dilutive effect of such securities is calculated using the treasury stock method. The Company may have other securities with a dilutive effect outstanding, so the Company's basic net income (loss) per share uses the two-class method and diluted net income (loss) per share uses the treasury stock method.

Accounting for Stock-Based Compensation
The Company recognizes stock based compensation expense in the statement of operations based upon the fair value of the equity award amortized over the vesting period.

Segment Reporting
The Company currently operates in one segment.

Warrant Liability
The Company had warrants with an embedded feature that met the requirements of derivative accounting per ASC Topic 815, Derivatives and Hedging. The Company recorded these warrants at their fair value in accordance with ASC Topic 820. All the warrants subject to this accounting treatment were exercised in full on February 19, 2013 in connection with the financing. See Note D below for additional information.

The Company had warrants with an embedded feature that met the requirements of derivative accounting per ASC Topic 815, Derivatives and Hedging. The Company recorded these warrants at their fair value in accordance with ASC Topic 820. All the warrants subject to this accounting treatment were exercised in full on February 19, 2013 in connection with the financing. See Note D below for additional information.
Deferred Subcontractor Cost and Deferred Revenue
The Company has subcontracts that require advance payment prior to commencement of work under the BARDA Contract. The Company submits these advance billings from subcontractors to BARDA upon receipt. In the event that the Company has billings to BARDA in excess of earned revenue from BARDA activity, deferred revenue and accounts receivable are recorded to reflect advance billings submitted to BARDA. At the same time, the deferred subcontractor cost asset and accounts payable are recorded to reflect the payments that are owed to the subcontractors.

B. Liquidity

The Company had cash and cash equivalents of $1,926,000 on March 31, 2013, and $281,000 on September 30, 2012. The increase in cash was primarily due to the net impact of cash used in operations and cash raised in financings in February 2013 and March 2013. The Company had accounts receivable of $1,620,000 on March 31, 2013, and $882,000 on September 30, 2012, and accounts payable of $2,023,000 on March 31, 2013, and $2,272,000 on September 30, 2012.

The Company has incurred significant losses since its inception. At March 31, 2013, the Company's accumulated deficit was $182,469,000. This raises substantial doubt about Aeolus' ability to continue as a going concern, which will be dependent on the Company's ability to generate sufficient cash flows to meet the Company's obligations on a timely basis, obtain additional financing and, ultimately, achieve operating profits through product sales or BARDA procurements. The Company intends to explore strategic and financial alternatives, which may include a merger or acquisition with or by another company, the sale of shares of stock and/or convertible debentures, the establishment of new collaborations for current research programs that include initial cash payments and on-going research support and the out-licensing of the Company's compounds for development by a third party. The Company believes that without additional investment capital it will not have sufficient cash to fund its activities in the near future, and will not be

able to continue operating. As such, the Company's continuation as a going concern is dependent upon its ability to raise additional financing. If the Company is unable to obtain additional financing to fund operations, it will need to eliminate some or all of its activities, merge with another company, sell some or all of its assets to another company, or cease operations entirely. There can be no assurance that the Company will be able to obtain additional financing on acceptable terms or at all, or that the Company will be able to merge with another Company or sell any or all of its assets.

In its audit opinion issued in connection with the Company's consolidated balance sheets as of September 30, 2012 and 2011 and the Company's consolidated statements of operations, stockholder's equity and cash flows for the years ended September 30, 2012 and 2011, the Company's independent registered public accounting firm expressed substantial doubt about the Company's ability to continue as a going concern given the Company's recurring net losses, negative cash flows from operations and working capital. The Company recently completed a financing (see Note D below) that provided additional cash to the Company, after expenses, in the amount of approximately $3,558,000.

C. Warrant Liability

Increases or decreases in fair value of the warrants are included as a component of other income (expenses) in the accompanying statement of operations for the respective period. As of March 31, 2013, the aggregate liability for warrants decreased to $0, resulting in a loss to the statements of operations for the three and six months ended March 31, 2013 of $5,020,000 and $510,000, respectively. The warrant liability and revaluations have not had any impact on the Company's working capital, liquidity or business operations due to the non-cash nature of the liability. The Company previously had warrants with an embedded feature that met the requirements of derivative accounting per ASC Topic 815, Derivatives and Hedging. The Company recorded these warrants at their fair value in accordance with ASC Topic 820 and was required to revalue its liability for these warrants on a quarterly basis. All the warrants subject to this accounting treatment were exercised in full on February 19, 2013 in connection with the financing. See Note D below for additional information.

D. Stockholders' Deficit

Preferred Stock

The Certificate of Incorporation of Aeolus authorizes the issuance of up to 10,000,000 shares of Preferred Stock, at a par value of $.01 per share. The Board of Directors has the authority to issue Preferred Stock in one or more series, to fix the designation and number of shares of each such series, and to determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock, without any further vote or action by the stockholders of the Company.

Of the 10,000,000 shares of total authorized shares of Preferred Stock, 1,250,000 shares are designated as Series A Convertible Preferred Stock and 1,600,000 shares are designated as Series B Stock. The Series B Stock is not entitled to vote on any matter submitted to the vote of holders of the common stock except that the Company must obtain the approval of a majority of the outstanding shares of Series B Stock to either amend the Company's Certificate of Incorporation in a manner that would adversely affect the Series B Stock (including by creating an additional class or series of stock with rights that are senior or *pari passu* to the Series B Stock) or change the rights of the holders of the Series B Stock in any other respect. Each share of Series B Stock is convertible at any time by the holder thereof into one share of the Company's common stock, provided that no conversion may be effected that would result in the holders of Series B Stock owning more than 9.9% of the Company's common stock on a fully converted to common stock basis. If the Company pays a cash dividend on its common stock, it must also pay the same dividend on an as converted basis on the Series B Stock. Upon a liquidation, dissolution, bankruptcy or winding up of the Company or the sale of all or substantially all of the Company's assets, the holders of Series B Stock will be entitled to receive, together with the holders of common stock, the assets of the Company in proportion to the number of shares of common stock held (assuming conversion of the Series B Stock into shares of common stock).

As of March 31, 2013 and September 30, 2012, 526,080 shares of Series B Stock were outstanding, all of which were held by Elan. Each share of Series B Stock was convertible into one share of common stock as of March 31, 2013.

There were no shares of Series A Convertible Preferred Stock issued or outstanding as of March 31, 2013.

Common Stock

February/March 2013 Financing

On February 19, 2013 and March 4, 2013, the Company entered into Securities Purchase Agreements (the "Purchase Agreements") with certain accredited investors (the "Purchasers"). Under the terms of the agreements, the Company received $3,616,000 in gross proceeds in exchange for the issuance of an aggregate of approximately 14,462,000 units (the "Units"), consisting of 14,462,000 shares of common stock and 14,462,000 warrants, at a purchase price of $0.25 per unit. Each Unit consists of (i) one share of common stock (the "Common Shares") and (ii) a five year warrant to purchase one share of the Company's common stock (the "Warrants"). The Warrants have an initial exercise price of $0.25 per share.

On February 19, 2013, the Company received $3,225,000 in gross proceeds in exchange for the issuance of an aggregate of 12,900,000 Units, which consisted of 12,900,000 shares of common stock and 12,900,000 warrants.

On March 4, 2013, the Company received $390,000 in gross proceeds in exchange for the issuance of an aggregate of approximately 1,562,000 Units, which consisted of 1,562,000 shares of common stock and 1,562,000 warrants.

Net cash proceeds from the February/March 2013 Financing, after deducting for expenses, were approximately $3,558,000. The Company also incurred non-cash expenses in the form of 365,000 warrants issued to consultants, at similar terms as the financing Warrants, for services provided. The Company issued a total of 14,827,000 warrants as of March 31, 2013 in connection with the February/March 2013 Financing.

The fair value of the February/March 2013 Financing warrants was estimated to be $4,791,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 154.84%, risk free interest rate of 0.87% and an expected life of five years. The proceeds from the February/March 2013 Financing were allocated based upon the relative fair values of the February/March 2013 Financing Warrants and the February/March 2013 Common Shares.

The February/March 2013 Financing contains a registration rights agreement with an arrangement for liquidated damages in the event of a failure to file with the SEC a registration statement covering the February/March 2013 Financing Units. The Company has until May 16, 2013 to file the registration statement. In the event the registration statement is not timely filed, the Company will be required to make a cash payment of 0.5% of the aggregate amount invested to the Purchasers of the February/March 2013 Financing Units. The 0.5% payment equaling $18,000 would be due after each 30 day period following the closing date for a maximum of 6 months. The maximum liability would be $108,000. As of March 31, 2013, no liability was recorded as the Company expects to timely file the registration statement.

Modification to rights of Security Holders

Effective February 19, 2013, the Company and each of Xmark JV Investment Partners, LLC, Xmark Opportunity Fund, Ltd. and Xmark Opportunity Fund, L.P. (collectively, the “Xmark Entities”) entered into a Warrant Repricing, Exercise and Lockup Agreement (the “Xmark Warrant Agreement”) pursuant to which the Company agreed to reduce the exercise price of outstanding warrants to purchase an aggregate of up to 59,149,999 shares of Common Stock held by the Xmark Entities (the “Xmark Warrants”) to $0.01 per share. In consideration for the reduction of the exercise price of the Xmark Warrants, each of the Xmark Entities agreed to immediately exercise all of the Xmark Warrants by cashless exercise. The Xmark Warrant Agreement also provides that the Xmark Entities will not transfer the shares issuable upon exercise of the Xmark Warrants (the “Xmark Warrant Shares”) until the Company either (i) declares a cash dividend on its common stock or otherwise makes a cash distribution or (ii) effects a Change of Control, subject in each case to the terms of the Xmark Warrant Agreement.

Modifying the exercise price of the warrants to a fixed amount of $0.01 eliminated the requirement for warrant liability accounting treatment and resulted in a charge of $2,084,000, as described under “Warrant Liability” in Note A above.

March 2012 Financing

On March 30, 2012 and April 4, 2012, the Company entered into Securities Purchase Agreements (the “Purchase Agreements”) with certain accredited investors (the “Purchasers”) and completed a financing (the “March 2012 Financing”). Under the terms of the Purchase Agreements, the Company received $660,000 in gross proceeds in exchange for the issuance of an aggregate of 2,200,166 units (the “March 2012 Units”), consisting of 2,200,166 shares of common stock and 1,650,126 warrants, at a purchase price of $0.30 per Unit. Each Unit consisted of (i) one share of common stock (the “March 2012 Common Shares”) and (ii) a five year warrant to purchase 0.75 of a share of the Company’s common stock (the “March 2012 Warrants”). The March 2012 Warrants have an initial exercise price of

$0.40 per share.

On March 30, 2012, the Company received $530,000 in gross proceeds in exchange for the issuance of an aggregate of 1,766,833 March 2012 Units, which consisted of 1,766,833 shares of common stock and 1,325,126 warrants.

On April 4, 2012, the Company received $130,000 in gross proceeds in exchange for the issuance of an aggregate of approximately 433,333 March 2012 Units, which consisted of 433,333 shares of common stock and 325,000 warrants.

Net cash proceeds from the March 2012 Financing, after deducting for expenses, were $642,000. The Company also incurred non-cash expenses in the form of 12,501 warrants issued to consultants, at similar terms as the March 2012 Warrants, for services provided. Pursuant to the warrants, the Company is obligated to issue up to a total of 1,662,627 shares of common stock as of September 30, 2012 in connection with the March 2012 Financing.

The fair value of the March 2012 Warrants issued on March 30, 2012 was estimated to be $363,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 150.74%, risk free interest rate of 1.04% and an expected life of five years. The proceeds from the March 2012 Financing were allocated based upon the relative fair values of the March 2012 Warrants and the March 2012 Common Shares.

The fair value of the March 2012 Warrants issued on April 4, 2012 was estimated to be $84,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 149.36%, risk free interest rate of 1.05% and an expected life of five years. The proceeds from the March 2012 Financing were allocated based upon the relative fair values of the March 2012 Warrants and the March 2012 Common Shares.

Dividends

The Company has never paid a cash dividend on its common stock and does not anticipate paying cash dividends on its common stock in the foreseeable future. If the Company pays a cash dividend on its common stock, it also must pay the same dividend on an as converted basis on its outstanding Series B Stock.

Warrants

As of March 31, 2013, warrants to purchase an aggregate of 17,879,627 shares of common stock were outstanding with a weighted average exercise price of $0.29 per share. Details of the warrants for common stock outstanding at March 31, 2013 are as follows:

Number of Shares	Exercise Price	Expiration Date
100,000	$ 0.50	May 2014
100,000	$ 1.00	May 2014
100,000	$ 1.50	May 2014
125,000	$ 0.65	June 2014
125,000	$ 1.00	June 2014
20,000	$ 0.39	September 2014
15,000	$ 0.50	September 2014
15,000	$ 0.60	September 2014
50,000	$ 0.38	April 2015
50,000	$ 0.50	May 2016
50,000	$ 0.50	July 2016
50,000	$ 1.00	July 2016
50,000	$ 1.50	July 2016
50,000	$ 2.00	July 2016
50,000	$ 2.50	July 2016
1,337,627	$ 0.40	March 2017
325,000	$ 0.40	April 2017

300,000	$ 0.258	June 2017
140,000	$ 0.35	October 2017
13,085,000	$ 0.25	February 2018
1,742,000	$ 0.25	March 2018
17,879,627	$ 0.29	

As of March 31, 2013, one warrant to purchase an aggregate of 896,037 shares of preferred stock was outstanding. The warrant has an exercise price of $0.01 per share and expires in February 2016.

Below is a summary of warrant activity (“common and preferred”) for the six months ended March 31, 2013:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at 9/30/2012	62,993,663	$0.30	4.2	$5,344,623
Granted	14,932,000	$0.25	4.89	$1,039,373
Exercised	(59,149,999)	$0.01	3.75	$19,519,500
Expired or Canceled	-	$-	-	$-
Forfeited	-	$-	-	$-
Vested	-	$-	-	$-
Outstanding at 3/31/2013	18,775,664	$0.29	4.55	$1,335,864

Below is a summary of warrant activity (“common and preferred”) for the six months ended March 31, 2012:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at 9/30/2011	61,936,036	$0.30	5.13	$8,257,575
Granted	1,337,627	$0.40	5.00	$-
Exercised	-	$-	-	$-
Expired or Canceled	-	$-	-	$-
Forfeited	-	$-	-	$-
Vested	-	$-	-	$-
Outstanding at 3/31/2012	63,273,663	$0.30	4.64	$1,672,831

E. Stock-Based Compensation

Below is a summary of stock option activity for the six months ended March 31, 2013:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at 9/30/2012	9,473,661	$0.70	5.81	$153,850
Granted	2,745,000	$0.39	9.92	$901
Exercised	-	$-	-	$-
Expired or Canceled	(72,744)	$0.85	-	$-
Forfeited	-	$-	-	$-
Vested (RSAs)	-	$-	-	$-
Outstanding at 3/31/2013	12,145,917	$0.63	6.38	$45,084

For the six months ended March 31, 2013, all stock options were granted with an exercise price at or above the fair market value of the Company’s common stock on the date of grant.

Below is a summary of stock option activity for the six months ended March 31, 2012:

	Number of Shares	Weighted Average Exercise Price	Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at 9/30/2011	8,942,628	$0.82	6.48	$258,555
Granted	351,250	$0.33	9.89	$-
Exercised	-	$-	-	$-
Expired or Canceled	(65,645)	$12.47	-	$-
Forfeited	-	$-	-	$-
Vested (RSAs)	-	$-	-	$-
Outstanding at 3/31/2012	9,228,233	$0.72	6.17	$6,419

For the six months ended March 31, 2012, all stock options were granted with an exercise price at or above the fair market value of the Company's common stock on the date of grant.

The details of stock options for the six months ended March 31, 2013 were as follows:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding at March 31, 2013	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Number Exercisable at December 31, 2012	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
$0.23-$0.30	1,612,500	$ 0.29	6.81	1,491,670	$ 0.30	6.60
$0.31-$0.40	6,501,500	$ 0.39	8.32	3,796,817	$ 0.38	7.19
$0.41-$0.50	177,000	$ 0.46	6.25	177,000	$ 0.46	6.25
$0.51-$0.60	963,750	$ 0.59	6.14	963,750	$ 0.59	6.14
$0.61-$0.70	66,500	$ 0.68	3.38	66,500	$ 0.68	3.38
$0.71-$0.80	382,250	$ 0.75	4.17	382,250	$ 0.75	4.17
$0.81-$0.90	697,091	$ 0.88	3.51	697,091	$ 0.88	3.51
$0.91-$1.00	44,500	$ 0.94	2.49	44,500	$ 0.94	2.49
$1.01-$1.50	1,337,519	$ 1.48	0.43	1,337,519	$ 1.48	0.43
$1.51-$5.00	363,307	$ 2.77	1.26	363,307	$ 2.77	1.26

Stock-based compensation expense recognized in the statement of operations is as follows (in thousands):

	For the three months ended March 31,		For the six months ended March 31,	
	2013	2012	2013	2012
Research and Development Expenses	$5	$-	$9	$7
General and Administrative Expenses	232	148	300	340
	$237	$148	$309	$347

The total unrecognized compensation expense for outstanding and unvested stock options for the six months ended March 31, 2013 was $942,000. The weighted average remaining recognition period for the total deferred compensation expense is approximately nine months. The fair value of the options associated with the above compensation expense was determined at the date of the grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	For the six months ended March 31,	
	2013	2012
Dividend yield	0 %	0 %
Expected volatility	154.6%	151 %
Risk-free interest rate	0.86 %	1.08 %
Expected term	5.27 years	5.06 years

F-12

F. Net Income (Loss) Per Common Share

	For the three months ended March 31,		For the six months ended March 31,	
	2013	2012	2013	2012
	(in thousands, except per share data)			
Numerator:				
Net income (loss)	$ (5,782)	$ 2,763	$ (1,755)	$ 5,740
Less net income (loss) attributable to participating securities	-	1,382	-	(2,851)
Net income (loss) attributable to common stockholders – basic	$ (5,782)	$ 1,381	$ (1,755)	$ 2,889
Net income (loss)	$ (5,782)	$ 2,763	$ (1,755)	$ 5,740
Less gain (loss) on warrant liability for participating				
common warrants	-	3,046	-	6,868
Net loss attributable to common stockholders – diluted	$ (5,782)	$ (283)	$ (1,755)	$ (1,127)
Denominator:				
Weighted-average shares used in computing net income per				
share attributable to common stockholders – basic	94,425	60,490	69,664	61,359
Effect of potentially dilutive securities:				
Common stock warrants**	-	10,494	-	14,743
Convertible preferred warrants**	-	-	-	-
Convertible preferred stock**	-	-	-	-
Common stock options**	-	-	-	-
Non-participating common stock warrants**	-	-	-	-
Weighted-average shares used in computing net income				
(loss) per share attributable to common stockholders - diluted	94,425	70,984	69,664	76,102
Basic net income per common share	$ (0.06)	$ 0.02	$ (0.03)	$ 0.05
Diluted net income (loss) per common share	$ (0.06)	$ 0.00	$ (0.03)	$ (0.01)
* Prior period amounts have been restated, see note G below.				

** Amounts do not apply due to net loss per treasury method

Diluted weighted average common shares excluded incremental shares of approximately 6,261,000 and 5,069,000, respectively, for the three and six months ended March 31, 2013, due to their anti-dilutive effect. Diluted weighted average common shares excluded incremental shares of approximately 62,534,000 and 58,285,000, respectively, for the three and six months ended March 31, 2012, due to their anti-dilutive effect.

G. Restated Net Income (Loss) Per Common Share

As referenced in note A “Basis of Presentation”, the Company identified an error in the calculation of net income (loss) per common share since the filing of the 10-K on December 31, 2012. All references or presentations of net income (loss) per common share have been restated from the original filing of the 10-Q on May 4, 2012.

Basic net income (loss) per share

The Company computes basic net income (loss) per weighted average share attributable to common stockholders using the two-class method. Previously the Company used the weighted average number of shares of common stock outstanding during the period.

The restatement to our calculation relates to an unaccounted term in our preferred shares, preferred warrants and the majority of our common warrants (59,149,999 warrants). Each of these shares and warrants would participate in any potential common stock dividends declared by the Company. Dividend participation by these shares and warrants requires the two-class method of net income (loss) per share calculation in accordance with ASC 260-10-45-60.

Our previous basic income (loss) per share calculation was as follows:

	Period ended March 31, 2012	
	Three months ended	Six months ended
Numerator:		
Net income	$2,763	$5,740
Denominator:		
Weighted-average number of shares – basic	60,490	60,480
Net income (loss) per share – basic	$0.05	$0.10

Our restated basic income (loss) per share calculation is as follows:

	Period ended March 31, 2012			
	Three months ended		Six months ended	
Net income		$ 2,763		$ 5,740
	Weighted-average		Weighted-average	
Common stock and participating shares	Number of shares	Net income	Number of shares	Net income
Common stock	60,490	$ 1,381	60,480	$ 2,868
Participating common stock warrants	59,150	$ 1,350	59,150	$ 2,805
Participating series B preferred stock	526	$ 12	526	$ 25
Participating series B preferred warrants	896	$ 20	896	$ 42
	121,062	$ 2,763	121,052	$ 5,740
Numerator:				
Weighted-average net income (loss)		$ 1,381		$ 2,868
Denominator:				
Weighted-average number of basic shares	60,490		60,480	
Basic net income (loss) per share		$ 0.02		$ 0.05

Diluted net income (loss) per share

The Company computes diluted net income (loss) per weighted average share attributable to common stockholders using the two-class method, and when appropriate, the treasury method. Previously the Company used the weighted average number of shares of common and dilutive potential common shares outstanding during the applicable period. Potential common shares outstanding consist of stock options, warrants and convertible preferred stock using the treasury stock method and are excluded if their effect is anti-dilutive.

The restatement to our calculation relates to the required removal of fair value adjustments relating to our common stock warrants subject to warrant liability accounting from our calculation of net income (loss) available to diluted shareholders. Each of these warrants would participate in any potential common stock dividends in the future. The Company did not account for the removal of any non-cash gain (loss) from the fluctuation of the warrant liability associated with the incremental warrants in our calculation of net income (loss) per common share.

Our previous diluted income (loss) per share calculation was as follows:

	Period ended March 31, 2012	
	Three months ended	Six months ended
Numerator:		
Net income)	$ 2,763	$ 5,740
Denominator:		
Weighted-average number of shares – basic	60,490	60,480
Dilutive securities – equity awards	11,204	36,864
Weighted-average number of shares – diluted	71,694	97,344
Net income (loss) per share – diluted	$ 0.04	$ 0.08

Our restated diluted income (loss) per share calculation is as follows:

	Period ended March 31, 2012					
	Three months ended			Six months ended		
Net income (loss)	$2,763			$5,740		
Less gain (loss) on warrant liability:						
Participating common warrants	3,046			6,867		
Undistributed net income (loss)	$(283)			$(1,127)		
Common stock and common stock equivalents in order of dilutive effect	Outstanding	Incremental Dilutive shares *	Diluted shares	Outstanding	Incremental Dilutive shares *	Diluted shares
Common stock	60,490		60,490	60,480		60,480
Participating common warrants	59,150	10,494	10,494	59,150	14,743	14,743
Participating preferred warrants**	896	870	-	896	872	-
Series B preferred shares**	526	526	-	526	526	-
Common stock options**	9,228	184	-	9,228	349	-
Non-participating common stock warrants**	3,228	163	-	3,228	235	-
			70,984			75,223
Numerator:						
Weighted-average net income (loss)		$(283)			$(1,127)	
Denominator:						
Weighted-average number of basic shares		70,984			75,223	
Diluted net income (loss) per share		$0.00			$(0.01)	

* Treasury method applied

** Excluded as the effect is anti-dilutive

H. Commitments

The Company acquires assets still in development and enters into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the arrangement, the Company may have to make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these payments, they are not included in the table of contractual obligations. No milestones have been met, nor have any payments been paid, as of March 31, 2013.

The Company is also obligated to pay patent filing, prosecution, maintenance and defense costs, if any, for the intellectual property it has licensed from National Jewish Health, National Jewish Medical and Research Center and Duke University.

These arrangements may be material individually, and in the unlikely event that milestones for multiple products covered by these arrangements were reached in the same period, the aggregate charge to expense could be material to the results of operations in any one period. In addition, these arrangements often give Aeolus the discretion to unilaterally terminate development of the product, which would allow Aeolus to avoid making the contingent payments; however, Aeolus is unlikely to cease development if the compound successfully achieves clinical testing objectives.

I. Subsequent Event

The Company has evaluated subsequent events through the issuance of these condensed consolidated financial statements and determined that no material subsequent events have occurred.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Aeolus Pharmaceuticals Inc.

We have audited the accompanying consolidated balance sheets of Aeolus Pharmaceuticals Inc. (the "Company") as of September 30, 2012 and 2011, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for each of the two years in the period ended September 30, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Aeolus Pharmaceutical Inc. and its subsidiary as of September 30, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the two years in the period ended September 30, 2012, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note K, net income (loss) per share in the accompanying financial statements has been restated.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note C to the financial statements, the Company has incurred recurring losses and negative cash flows from operations, and management believes the Company does not currently possess sufficient working capital to fund its operations through fiscal 2013. These conditions, along with other matters as set forth in Note C, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note C. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GRANT THORNTON LLP
San Diego, CA
December 28, 2012 (except for Note K and the related effects thereof as to which the date is February 19, 2013)

AEOLUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(DOLLARS IN THOUSANDS)

	September 30, 2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 281	$ 518
Accounts receivable	882	1,677
Prepaids and other current assets	61	63
Total current assets	1,224	2,258
Investment in CPEC LLC	32	32
Total assets	$ 1,256	$ 2,290
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,272	$ 2,144
Total current liabilities	2,272	2,144
Warrant liability	19,319	23,405
Total liabilities	21,591	25,549
Commitments and Contingencies (Notes E and I)		
Stockholders' deficit:		
Preferred stock, $.01 par value per share, 10,000,000 shares authorized:		
Series A nonredeemable convertible preferred stock, 1,250,000 shares authorized as of September 30, 2012 and 2011, respectively; no shares issued and outstanding as of September 30, 2012 and 2011, respectively	—	—
Series B nonredeemable convertible preferred stock, 1,600,000 and 1,600,000 shares authorized as of September 30, 2012 and 2011, respectively; 526,080 and 526,080 shares issued and outstanding as of September 30, 2012 and 2011, respectively	5	5
Common stock, $.01 par value per share, 200,000,000 shares authorized; 62,731,963 and 60,470,718 shares issued and outstanding at September 30, 2012 and 2011, respectively	627	605
Additional paid-in capital	159,747	158,543
Accumulated deficit	(180,714)	(182,412)
Total stockholders' deficit	(20,335)	(23,259)
Total liabilities and stockholders' deficit	$ 1,256	$ 2,290

The accompanying notes are an integral part of these consolidated financial statements.

AEOLUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Fiscal Year Ended September 30,	
	2012	2011
Revenue:		
Contract revenue	$ 7,293	$ 4,821
Costs and expenses:		
Research and development	6,468	5,055
General and administrative	3,196	3,668
Total costs and expenses	9,664	8,723
Loss from operations	(2,371)	(3,902)
Interest expense	—	(21)
Warrant liability gain (charges)	4,069	3,887
Other income, net	—	335
Net income (loss)	$ 1,698	$ 299
Restated Net income (loss) attributable to common stockholders – basic	$ 856	$ 149
Restated Net income (loss) attributable to common stockholders – diluted	$ (2,161)	$ (3,253)
Restated Basic net income (loss) per common share (Note K)	$ 0.01	$ 0.00
Restated Diluted net income (loss) per common share (Note K)	$ (0.03)	$ (0.04)
Weighted average common shares outstanding:		
Basic (Note K)	61,593	59,474
Restated Diluted (Note K)	71,041	85,862

The accompanying notes are an integral part of these consolidated financial statements.

AEOLUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(Dollars in thousands)

	Series B Preferred Stock		Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Deficit	Deficit
Balance at September 30, 2010	475,087	$ 5	56,817,177	$ 568	$ 155,402	$ (182,711)	$ (26,736)
Common stock sales, net of issuance costs of $13,000	—	—	2,500,000	25	585	—	610
Note payable conversion	50,993	1	—	—	211	—	212
Issuance of warrant for note payable conversion	—	—	—	—	452	—	452
Exercise of warrants	—	—	1,153,541	12	900	—	913
Issuance of warrants to a consultant	—	—	—	—	88	—	88
Stock-based compensation	—	—	—	—	905	—	905
Net income for the fiscal year ended September 30, 2011	—	—	—	—	—	299	299
Balance at September 30, 2011	526,080	5	60,470,718	605	158,543	(182,412)	(23,259)
Common stock sales, net of issuance costs of $18,000	—	—	2,200,166	22	620	—	642
Exercise of warrants	—	—	61,079	—	16	—	16
Issuance of warrants to consultants	—	—	—	—	199	—	199
Stock-based compensation	—	—	—	—	369	—	369
Net income for the fiscal year ended September 30, 2012	—	—	—	—	—	1,698	1,698
Balance at September 30, 2012	526,080	$ 5	62,731,963	$ 627	$ 159,747	$ (180,714)	$ (20,335)

The accompanying notes are an integral part of these consolidated financial statements.

AEOLUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Fiscal Year Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income (loss)	$ 1,698	$ 299
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	7	5
Noncash compensation	568	993
Noncash interest and financing costs	17	—
Change in fair value of warrants	(4,086)	(3,887)
Change in assets and liabilities:		
Accounts receivable	795	(1,677)
Prepaid expenses and other assets	(6)	(22)
Accounts payable and accrued expenses	128	1,187
Net cash used in operating activities	(879)	(3,102)
Cash flows from investing activities:		
Purchase of equipment	—	—
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants	660	1,000
Proceeds from the exercise of warrants	—	276
Costs related to the issuance of common stock and warrants	(18)	(11)
Net cash provided by financing activities	642	1,265
Net increase (decrease) in cash and cash equivalents	(237)	(1,839)
Cash and cash equivalents at beginning of year	518	2,355
Cash and cash equivalents at end of year	$ 281	$ 518
Supplemental disclosure of cash flow information:		
Non-cash payments of interest	$ —	$ 21
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock and warrants issued for payment of note payable	$ —	$ 453
Preferred stock and warrants issued for payment of interest on note payable	$ —	$ 210

The accompanying notes are an integral part of these consolidated financial statements.

AEOLUS PHARMACEUTICALS, INC.
Notes to Condensed Consolidated Financial Statements
SEPTEMBER 30, 2012

A. Organization, Business and Summary of Significant Accounting Policies

Organization

The accompanying audited consolidated financial statements include the accounts of Aeolus Pharmaceuticals, Inc. and its wholly-owned subsidiary, Aeolus Sciences, Inc. (collectively "we," "us," "Company" or "Aeolus"). All significan intercompany accounts and transactions have been eliminated in consolidation. Aeolus is a Delaware corporation. The Company's primary operations are located in Mission Viejo, California.

Business

Aeolus is developing a new class of broad-spectrum, catalytic antioxidant compounds based on technology discovered at Duke University and National Jewish Health. The Company's lead compound, AEOL 10150, is a metalloporphyrin specifically designed to neutralize reactive oxygen and nitrogen species. The Company is developing AEOL 10150 as a medical countermeasure against the pulmonary effects of radiation exposure under a contract ("BARDA Contract") valued at up to $118.4 million with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Department of Health and Human Services ("HHS"). Additionally, Aeolus receives development support from the National Institutes of Health ("NIH") for development of the compound as a medical countermeasure against radiation and chemical exposure.

Restatement of Net Income (Loss) Per Common Share

As discussed in Note K, the Company has restated Net Income (Loss) Per Common Share for the years ended September 30, 2012 and 2011 and for the unaudited quarterly periods included in Note J.

B. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Aeolus and its wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated. The Company uses the equity method to account for its 35.0% ownership interest in CPEC.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Such estimates include revenue recognition, warrant liability, allowance for doubtful accounts, stock-based compensation and warrant expense. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company invests available cash in short-term bank deposits. Cash and cash equivalents include investments with maturities of three months or less at the date of purchase. The carrying value of cash and cash equivalents approximate their fair market value at September 30, 2012 and 2011 due to their short-term nature.

Significant customers and accounts receivable

For the year ended September 30, 2012, the Company's primary customer was BARDA. For the year ended September 30, 2012, revenues from BARDA comprised 100% of total revenues. As of September 30, 2012, the Company's receivable balances were comprised 100% from this customer. Unbilled accounts receivable, included in accounts receivable, totaling $558,000 as of September 30, 2012 relate to work that has been performed, though invoicing has not yet occurred. All of the unbilled receivables are expected to be billed and collected within the next 12 months. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. If necessary, the Company records a provision for doubtful receivables to allow for any amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends. As of September 30, 2012 and 2011, an allowance for doubtful accounts was not recorded as the collection history from the Company's customers indicated that collection was probable.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company places its cash and cash equivalents with high quality financial institutions. Management believes that the financial risks associated with its cash and cash equivalents and investments are minimal. Because accounts receivable consist primarily of amounts due from the U.S. federal government agencies, management deems there to be minimal credit risk.

Revenue Recognition

Aeolus recognizes revenue in accordance with the authoritative guidance for revenue recognition. Revenue is recognized when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

The BARDA Contract is classified as a "cost-plus-fixed-fee" contract. Aeolus recognizes government contract revenue in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contracts. Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and indirect costs. In addition, we receive a fixed fee under the BARDA Contract, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under this BARDA Contract, including the fixed fee, are generally recognized as revenue in the period the reimbursable costs are incurred and become billable.

Fair Value of Financial Instruments

The carrying amounts of our short-term financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their fair values due to their short maturities.

Fair Value Measurements

The Company adopted Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures, for financial and non-financial assets and liabilities.

ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). The Company utilizes the market approach. The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

The warrant liability is measured at fair market value on a recurring basis as of September 30, 2012 and 2011 and is summarized below (in thousands):

Fair value at September 30, 2012			Fair value at September 30, 2011		
Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
$ —	$ —	$ 19,319	$ —	$ —	$ 23,405

The following table summarizes, as of September 30, 2012, the warrant activity subject to Level 3 inputs which are measured on a recurring basis:

	Fair value measurements of warrants using significant unobservable inputs (Level 3)
Balance at September 30, 2011	$ 23,405
Warrants exercised	(17)
Change in fair value of warrant liability	(4,069)
Balance at September 30, 2012	$ 19,319

Research and Development

Research and development costs are expensed in the period incurred.

Leases

The Company leases office space and office equipment under month to month operating lease agreements. For the years ended September 30, 2012 and 2011, total rent expense was approximately $36,000 and $18,000, respectively.

Income Taxes

The Company recognizes liabilities or assets for the deferred tax consequences of temporary differences between the tax bases of assets or liabilities and their reported amounts in the financial statements. These temporary differences will result in taxable or deductible amounts in future years when the reported amounts of the assets or liabilities are recovered or settled. A valuation allowance is established when management determines that is more likely than not that all or a portion of a deferred tax asset will not be realized. Management evaluates the Company's ability to realize its net deferred tax assets on a quarterly basis and valuation allowances are provided, as necessary. During this evaluation, management reviews its forecasts of income in conjunction with other positive and negative evidence surrounding the Company's ability to realize its deferred tax assets to determine if a valuation allowance is required. Adjustments to the valuation allowance will increase or decrease the Company's income tax provision or benefit. Management also applies the relevant guidance to determine the amount of income tax expense or benefit to be allocated among continuing operations, discontinued operations, and items charged or credited directly to stockholders' equity (deficit).

A tax position must meet a minimum probability threshold before a financial statement benefit is recognized. The minimum threshold is a tax position that is more likely than not be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation process, based on the technical merits of the position. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Net Income (Loss) Per Common Share (as restated)

The Company computes net income attributable to common stockholders using the two-class method required for participating securities. Under the two-class method, securities that participate in dividends, such as the Company's outstanding preferred shares, preferred warrants, and most common stock warrants, are considered "participating securities." Our preferred shares, preferred warrants and common stock warrants are considered "participating securities" because they include non-forfeitable rights to dividends.

In applying the two-class method, (i) basic net income (loss) per share is computed by dividing net income (less any dividends paid on participating securities) by the weighted average number of shares of common stock and participating securities outstanding for the period and (ii) diluted earnings per share may include the additional effect of other securities, if dilutive, in which case the dilutive effect of such securities is calculated using the treasury stock method. The Company does have other securities with a dilutive effect outstanding, so the Company's basic net income (loss) per share uses the two-class method and diluted net income (loss) per share uses the treasury stock method.

	Fiscal Year Ended September 30,	
	2012	2011
Numerator:		
Net income (loss)	$ 1,698	$ 299
Net income attributable to participating securities (1)	(842)	(151)
Net income (loss) attributable to common stockholders – basic (1)	$ 856	$ 148
Net income (loss)	$ 1,698	$ 299
Less gain (loss) on warrant liability for participating common warrants (1)	3,859	3,553
Net income (loss) attributable to common stockholders – diluted (1)	$ (2,161)	$ (3,253)
Denominator:		
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders – basic	61,593	59,474
Effect of potentially dilutive securities:		
Common stock warrants (1)	9,448	26,388
Convertible preferred warrants	—	—
Convertible preferred stock	—	—
Common stock options	—	—
Non-participating common stock warrants	—	—
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders – diluted (1)	71,041	85,862
Basic net income (loss) per common share (1)	$ 0.01	$ 0.00
Diluted net income (loss) per common share (1)	$ (0.03)	$ (0.04)

Diluted weighted average common shares excluded incremental shares of approximately 51,364,000 (1) and 35,680,000 (1), respectively, for the fiscal year 2012 and 2011, due to their anti-dilutive effect.

(1) Amounts changed from the Company's Form 10-K filing on December 31, 2012. See note K.

Accounting for Stock-Based Compensation

The Company recognizes stock based compensation expense in the statement of operations based upon the fair value of the equity award amortized over the vesting period.

Segment Reporting

The Company currently operates in one segment.

Warrant Liability

The Company has warrants with an embedded feature that meet the requirements of derivative accounting per Accounting Standards Codification ("ASC") Topic 815. The Company records these warrants at their fair value in accordance with Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures.

Increases or decreases in fair value of the warrants are included as a component of other income (expense) in the accompanying statement of operations for the respective period. As of September 30, 2012, the liability for warrants decreased to approximately $19,319,000 from approximately $23,405,000 as of September 30, 2011, as a result of warrant exercises of $17,000 and a gain to the statements of operations for the fiscal year ended September 30, 2012 of approximately $4,069,000. The warrant liability and revaluations have not and will not have any impact on the Company's working capital, liquidity or business operations. Some of the Company's warrants contain terms that limit the number of shares the Company would be required to issue thereunder unless the warrant holder agrees to increase the limit prior to exercise. If the warrants outstanding as of September 30, 2012 were exercised in full without regard to any current exercise limits contained therein, the Company would be required to issue a maximum of 59,149,999 shares of common stock.

C. Liquidity

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, assuming the Company will continue as a going concern, which contemplates the realization of assets and the liquidation of liabilities in the normal course of business.

The Company has incurred significant cash outflows from operations of approximately $879,000 and $3,102,000 for the fiscal years ended September 30, 2012 and 2011, respectively. The Company had net income of approximately $1,698,000 (including a non-cash gain for decreases in valuation of warrants of approximately $4,069,000) for the year ended September 30, 2012. In 2011 the Company had net income from operations of approximately $299,000 (including a non-cash gain for decreases in valuation of warrants of $3,887,000). The Company expects to incur additional losses and cash outflows from operations for several more years.

The Company has historically raised capital through the sale of its common shares and preferred shares; said financing transactions are more thoroughly discussed at note F – Stockholders' Equity. Management expects they will need to continue to finance the Company's operations through equity financing for several more years. Subsequent to September 30, 2012, the Company's management has been engaged in discussions with various investors to raise additional capital through the sale of common shares. However, there is no assurance that this contemplated financing will be consummated on acceptable terms or at all.

If the Company is unable to obtain additional funding for its operations, it will need to eliminate or substantially limit some or all of its activities, merge with another company, sell, lease or license some or all of its assets, or cease operations entirely. There is no assurance that the Company will be able to obtain additional financing on acceptable terms, or at all, or that the Company will be able to merge with another Company or sell, lease or license any or all of its assets. This raises substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classifications of liabilities that might result from this uncertainty.

D. Investments

Investment in CPEC LLC

The Company uses the equity method to account for its 35.0% ownership interest in CPEC. CPEC had $91,000 of net assets at each of September 30, 2012 and 2011. Aeolus' share of CPEC's net assets is included in other assets and the Company has no operations or activities unrelated to the out licensing of bucindolol.

E. Commitments

The Company acquires assets still in development and enters into license and research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the arrangement, the Company may also be required to make royalty payments based upon a percentage of the net sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these payments, they are not included in the table of contractual obligations. No milestones have been met, nor have any payments been made, as of September 30, 2012.

We are also obligated to pay patent filing, prosecution, maintenance and defense costs, if any, for the intellectual property the Company has licensed from National Jewish Health ("NJH"), National Jewish Medical and Research Center (the "NJMRC") and Duke University.

These arrangements may be material individually, and in the unlikely event that milestones for multiple products covered by these arrangements were reached in the same period, the aggregate charge to expense could be material to the results of operations in any one period. In addition, these arrangements often give Aeolus the discretion to unilaterally terminate development of the product, which would allow Aeolus to avoid making the contingent payments; however, Aeolus is unlikely to cease development if the compound successfully achieves clinical testing objectives.

F. Stockholders' Deficit

Basis of Presentation

Preferred Stock

The Certificate of Incorporation of the Company authorizes the issuance of up to 10,000,000 shares of Preferred Stock, at a par value of $0.01 per share, of which 1,250,000 shares are designated Series A Convertible Preferred Stock and 1,600,000 shares are designated Series B Convertible Preferred Stock. The Board of Directors has the authority to issue Preferred Stock in one or more series, to fix the designation and number of shares of each such series, and to determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock, without any further vote or action by the stockholders of the Company.

In January 2001, the Company issued to Elan 28,457 shares of Series B Stock. In February 2002, the Company issued 58,883 additional shares of Series B Stock and 480,000 shares of common stock to Elan in exchange for the retirement of a $1,400,000 note payable to Elan. In May 2002, the Company sold 416,204 shares of Series B Stock to Elan for $3,000,000. On January 14, 2005, Elan converted 28,457 shares of the Series B Stock into 28,457 shares of common stock.

On February 7, 2011, the Company elected to exercise its right to repay a related party note payable to Elan, with a maturity value of approximately $663,000, with 50,993 shares of Series B Stock and a warrant to purchase an aggregate of 896,037 shares of Series B Stock at an exercise price of $0.01 per share. The warrant has a term of five years, a cashless exercise provision and customary anti-dilution adjustments in the event of stock splits, stock combination, reorganizations and similar events. In connection with the issuance, the Company amended its certificate of incorporation on February 7, 2011 to increase the authorized number of shares of Series B Stock from 600,000 to 1,600,000. The fair value of the warrants issued on February 7, 2011 was estimated to be $452,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 93.3%, risk free interest rate of 2.39% and an expected life of five years.

As of September 30, 2012 and 2011, 526,080 shares of Series B Stock were outstanding, respectively. There are no shares of Series A Convertible Preferred Stock issued or outstanding.

With respect to dividend rights and rights upon liquidation, winding up and dissolution, the Series B Stock ranks pari passu with the common stock. Subject to any rights of senior stock, holders of Series B Stock are entitled to receive dividends or distributions as, when and if declared by the Board of Directors. In the event the Board of Directors declares a dividend or distribution with respect to the outstanding common stock, the holders of Series B Stock are entitled to receive the amount of dividends per share in the same form payable on the common stock based on the

largest number of shares of common stock issuable upon conversion of the outstanding Series B Stock. In the event of a liquidation, winding up or dissolution of the Company, subject to any rights of senior stock, the holders of Series B Stock are entitled to receive, pari passu with the holders of the common stock, the assets of the Company based on the largest number of shares of common stock issuable upon conversion of the outstanding Series B Stock.

Each share of Series B Stock is convertible into one share of common stock. The Series B Stock can be converted into common stock at any time upon the election of the holders of the Series B Stock except to the extent such conversion would result in the holders of Series B Stock owning in the aggregate more than 9.99% of the outstanding common stock.

The Series B Stock is not entitled to vote on any matter submitted to the vote of holders of the common stock except that the Company must obtain the approval of a majority of the outstanding shares of Series B Stock to either amend the Company's Certificate of Incorporation in a manner that would adversely affect the Series B Stock (including by creating an additional class or series of stock with rights that are senior or pari passu to the Series B Stock) or change the rights of the holders of the Series B Stock in any other respect.

Common Stock

August 2010 Financing

On August 12, 2010, the Company announced an additional financing with certain existing investors (the "August 2010 Investors"). Under the terms of the agreement, the Company received $1,000,000 in gross proceeds in exchange for the issuance of 2,500,000 shares of common stock and warrants to purchase up to 1,875,000 shares at an exercise price of $0.50 per share. The Company also granted to the August 2010 Investors the option to acquire, collectively, up to an additional 2,500,000 units, comprised of an aggregate of 2,500,000 shares of common stock and warrants to purchase up to an aggregate of 1,875,000 additional shares of common stock at an exercise price of $0.50 (the "August 2010 Call Option"). In addition, the August 2010 Investors granted to the Company the option to require these August 2010 Investors, severally and not jointly, to acquire up to 2,500,000 additional units, less any additional units acquired under the August 2010 Call Option, at the per additional unit purchase price of $0.40 (the "August 2010 Put Option"). On December 28, 2010, the investors exercised their Call Option and the Company received $1 million in proceeds in exchange for 2,500,000 common shares and 1,875,000 warrants.

Net cash proceeds from the August 2010 Financing, after deducting for expenses, were approximately $900,000.

The fair value of the August 2010 Warrants was estimated to be $542,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 91.83%; risk free interest rate of 2.08%; and an expected life of seven years. The proceeds from the August 2010 financing were allocated based upon the relative fair values of the August 2010 Warrants and the August 2010 Shares. Due to the anti-dilution provisions of the August 2010 Warrants, these warrants were deemed to be a liability under current accounting guidance and, as a result, the warrant liability was increased by $542,000 of which $179,000 was recorded as a charge to the Statement of Operations and $363,000 of proceeds from the August 2010 financing was allocated to the value of the August 2010 Warrants.

On December 28, 2010, the investors exercised their Call Option and the Company received $1,000,000 in proceeds in exchange for 2,500,000 common shares and 1,875,000 warrants, with an initial exercise price of $0.50 per share, subject to adjustment as provided in the warrants (the "Additional Warrants"). The Additional Warrants are exercisable for a seven-year period from their date of issuance; contain a "cashless exercise" feature that allows the holder to exercise the Additional Warrants without a cash payment to the Company under certain circumstances; contain a dividend participation right which allows the holder to receive any cash dividends paid on the Common Stock without exercising the Additional Warrant; contain a provision that provides for the reduction of the exercise price to $0.01 in the event of any such payment of cash dividends by the Company or upon a change of control; and contain anti-dilution provisions in the event of a stock dividend or split, dividend payment or other issuance, reorganization, recapitalization or similar event.

The net cash proceeds to the Company from the December 2010 financing, after deducting for expenses, were approximately $990,000.

The fair value of the August 2010 Call Option warrants was estimated to be $912,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 90.51%; risk free interest rate of 2.89%; and an expected life of seven years. The proceeds from the August 2010 Call Option exercise were allocated based upon the relative fair values of the August 2010 Call Option Warrants and the August 2010 Put Option Shares. Due to the anti-dilution provisions of the August 2010 Call Option Warrants, these warrants were deemed to be a liability under current accounting guidance and as a result the warrant liability was increased by $912,000 of which $534,000 was recorded as a charge to the Statement of Operations and $378,000 of proceeds from the August 2010 Call Option exercise was allocated to the value of the October 2009 Warrants.

March 2012 Financing

On March 30, 2012 and April 4, 2012, the Company entered into Securities Purchase Agreements (the “Purchase Agreements”) with certain accredited investors (the “Purchasers”) and completed a financing (the “March 2012 Financing”). Under the terms of the Purchase Agreements, the Company received $660,000 in gross proceeds in exchange for the issuance of an aggregate of 2,200,166 units (the “March 2012 Units”), consisting of 2,200,166 shares of common stock and 1,650,126 warrants, at a purchase price of $0.30 per Unit. Each Unit consisted of (i) one share of common stock (the “March 2012 Common Shares”) and (ii) a five year warrant to purchase 0.75 of a share of the Company’s common stock (the “March 2012 Warrants”). The March 2012 Warrants have an initial exercise price of $0.40 per share.

On March 30, 2012, the Company received $530,000 in gross proceeds in exchange for the issuance of an aggregate of 1,766,833 March 2012 Units, which consisted of 1,766,833 shares of common stock and 1,325,126 warrants.

On April 4, 2012, the Company received $130,000 in gross proceeds in exchange for the issuance of an aggregate of approximately 433,333 March 2012 Units, which consisted of 433,333 shares of common stock and 325,000 warrants.

Net cash proceeds from the March 2012 Financing, after deducting for expenses, were $642,000. The Company also incurred non-cash expenses in the form of 12,501 warrants issued to consultants, at similar terms as the March 2012 Warrants, for services provided. Pursuant to the warrants, the Company is obligated to issue up to a total of 1,662,627 shares of common stock as of September 30, 2012 in connection with the March 2012 Financing.

The fair value of the March 2012 Warrants issued on March 30, 2012 was estimated to be $363,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 150.74%, risk free interest rate of 1.04% and an expected life of five years. The proceeds from the March 2012 Financing were allocated based upon the relative fair values of the March 2012 Financing Warrants and the March 2012 Common Shares.

The fair value of the March 2012 Warrants issued on April 4, 2012 was estimated to be $84,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 149.36%, risk free interest rate of 1.05% and an expected life of five years. The proceeds from the March 2012 Financing were allocated based upon the relative fair values of the March 2012 Financing Warrants and the March 2012 Common Shares.

Dividends

The Company has never paid a cash dividend on its common stock and does not anticipate paying cash dividends on its common stock in the foreseeable future. If we pay a cash dividend on our common stock, we also must pay the same dividend on an as converted basis on our Series B preferred stock. In addition, under the terms of the warrants to purchase up to 59,149,999 shares of our common stock issued to Xmark Opportunity Partners, LLC or its affiliates (“Xmark”) in three transactions (on each of October 6, 2009, July 30, 2010 and August 11, 2010), and any additional warrants issued pursuant to the put and/or option right granted in our August 2010 financing, if we were to pay a dividend on our common stock, the exercise price of these warrants would be reset from $0.28 per share or $0.50 per share, as applicable, to $0.01 per share and the warrant holders would also be entitled receive any such dividend paid.

Warrants

As of September 30, 2012, warrants to purchase an aggregate of 62,132,626 shares of common stock were outstanding. Details of the warrants for common stock outstanding at September 30, 2012 were as follows:

Number of Shares	Exercise Price	Expiration Date
100,000	$ 0.50	May 2014
100,000	$ 1.00	May 2014
100,000	$ 1.50	May 2014
125,000	$ 0.65	June 2014
125,000	$ 1.00	June 2014
20,000	$ 0.39	September 2014
15,000	$ 0.50	

			September 2014
15,000	$	0.60	September 2014
50,000	$	0.38	April 2015
50,000	$	0.50	May 2016
50,000	$	0.50	July 2016
50,000	$	1.00	July 2016
50,000	$	1.50	July 2016
50,000	$	2.00	July 2016
50,000	$	2.50	July 2016
43,614,285	$	0.28	October 2016
1,337,627	$	0.40	March 2017
325,000	$	0.40	April 2017
300,000	$	0.258	June 2017
11,785,714	$	0.28	July 2017
35,000	$	0.30	August 2017
1,875,000	$	0.50	August 2017
35,000	$	0.44	September 2017
1,875,000	$	0.50	December 2017
62,132,626			

As of September 30, 2012, one warrant to purchase an aggregate of 896,037 shares of preferred stock was outstanding. Details of the warrant for preferred stock outstanding at September 30, 2012 were as follows:

Number of Shares	Exercise Price	Expiration Date
896,037	$0.01	February 2016
896,037		

As of September 30, 2011, warrants to purchase an aggregate of 61,039,999 shares of common stock were outstanding. Details of the warrants for common stock outstanding at September 30, 2011 were as follows:

Number of Shares	Exercise Price	Expiration Date
940,000	$ 0.28	May 2012
100,000	$ 0.45	May 2014
100,000	$ 1.00	May 2014
100,000	$ 1.50	May 2014
125,000	$ 0.65	June 2014
125,000	$ 1.00	June 2014
20,000	$ 0.39	September 2014
15,000	$ 0.50	September 2014
15,000	$ 0.60	September 2014
50,000	$ 0.38	April 2015
50,000	$ 0.50	May 2016
50,000	$ 0.50	July 2016
50,000	$ 1.00	July 2016
50,000	$ 1.50	July 2016
50,000	$ 2.00	July 2016
50,000	$ 2.50	July 2016
43,614,285	$ 0.28	October 2016
11,785,714	$ 0.28	July 2017
1,875,000	$ 0.50	August 2017
1,875,000	$ 0.50	December 2017
61,039,999		

As of September 30, 2011, one warrant to purchase an aggregate of 896,037 shares of preferred stock was outstanding. Details of the warrant for preferred stock outstanding at September 30, 2011 were as follows:

Number of Shares	Exercise Price	Expiration Date
896,037	$0.01	February 2016
896,037		

Below is a summary of warrant activity for the last three fiscal years ended September 30:

	Number of Shares	Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at 9/30/2010	66,901,667	$ 0.34	5.5 years	$ 16,278
Granted	3,821,037	$ 0.58	6.6 years	$ 367
Exercised	(1,336,668)	$ 0.28	0.5 years	$ 580
Cancelled	(7,250,000)	$ 0.78		$ -
Forfeited	(200,000)	$ 1.75		$ -
Outstanding at 9/30/2011	61,936,036	$ 0.30	5.2 years	$ 8,258
Granted	1,997,627	$ 0.38	4.5 years	$ 35
Exercised	(940,000)	$ 0.28		$ -
Cancelled	-	$ -		$ -
Forfeited	-	$ -		$ -
Outstanding at 9/30/2012	62,993,663	$ 0.30	4.2 years	$ 5,344
Exercisable at 9/30/2012	62,993,663	$ 0.30	4.2 years	$ 5,344

G. Stock-Based Compensation

As an integral component of a management and employee retention program designed to motivate, retain and provide incentive to the Company's management, employees and key consultants, the Board of Directors approved the 2004 Stock Incentive Plan (the "2004 Plan") and reserved 10,000,000 shares of common stock for issuance under the 2004 Plan. As of September 30, 2012, 2,250,909 shares were available to be granted under the 2004 Plan. The exercise price of the incentive stock options ("ISOs") granted under the 2004 Plan must not be less than the fair market value of the common stock as determined on the date of the grant. The options may have a term up to 10 years. Options typically vest immediately or up to one year following the date of the grant.

Under the Company's 1994 Stock Option Plan (the "1994 Plan"), incentive stock options or non-qualified stock options to purchase 2,500,000 shares of Aeolus' common stock may be granted to employees, directors and consultants of the Company. As of September 30, 2012, there were no shares available to be granted under the 1994 Plan. The exercise price of the ISOs granted under the 1994 Plan must not be less than the fair market value of the common stock as determined on the date of the grant. The options may have a term up to 10 years. Options typically vest over one to three years following the date of the grant.

Below is a summary of stock option activity for the last three fiscal years ended September 30:

	Number of Shares	Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at 9/30/2010	7,921,904	$ 1.12	7.0 years	$ 874
Granted	1,095,000	$ 0.53	9.5 years	$ 8
Exercised	-	$ -		$ -
Cancelled	(74,276)	$ 28.30		$ -
Forfeited	-	$ -		$ -
Outstanding at 9/30/2011	8,942,628	$ 0.82	6.5 years	$ 259
Granted	691,250	$ 0.30	9.6 years	$ 49
Exercised	-	$ -		$ -
Cancelled	(85,217)	$ 10.77		$ -
Forfeited	(75,000)	$ 0.41		$ 3
Outstanding at 9/30/2012	9,473,661	$ 0.70	5.8 years	$ 154
Exercisable at 9/30/2012	9,066,895	$ 0.71	5.6 years	$ 120

Stock options granted to consultants during fiscal year 2012 and 2011 were fully vested when issued or vested over a twelve month period. Stock option expense for stock options granted to consultants was $14,000 and $26,000 for fiscal year 2012 and 2011, respectively. For the fiscal years 2012 and 2011, all stock options were issued at or above fair market value of a share of common stock. The weighted-average grant-date fair value of options granted during fiscal years 2012 and 2011 was $0.28 and $0.54, respectively.

A summary of the status of non-vested shares for the fiscal years ended September 30 was:

	Number of Shares	Weighted Average Grant-Date Fair Value
Nonvested at September 30, 2010	1,749,161	613,461
Granted	1,095,000	595,315
Vested	(2,251,254)	(913,167)
Forfeited	-	-
Nonvested at September 30, 2011	592,907	295,461
Granted	691,250	190,660
Vested	(839,891)	(369,320)
Forfeited	(37,500)	(10,607)
Nonvested at September 30, 2012	406,766	106,194

The total unrecognized compensation expense for outstanding stock options was $98,000 as of September 30, 2012, which will be recognized over a weighted average period of eight months. The total fair value of shares vested during fiscal years 2012 and 2011 was $369,000 and $913,000, respectively.

The details of stock options for the fiscal year ended September 30, 2012 are as follows:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding at September 30, 2012	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Number Exercisable at September 30, 2012	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
$0.23-$0.30	1,601,250	$0.29	7.28	1,318,856	$0.30	6.75
$0.31-$0.40	3,767,750	$0.38	7.67	3,643,378	$0.39	7.61
$0.41-$0.50	177,000	$0.46	6.75	177,000	$0.46	6.75
$0.51-$0.60	963,750	$0.59	6.64	963,750	$0.59	6.64
$0.61-$0.70	66,500	$0.68	3.88	66,500	$0.68	3.88
$0.71-$0.80	382,250	$0.75	4.66	382,250	$0.75	4.66
$0.81-$0.90	769,835	$0.88	3.66	769,835	$0.88	3.66
$0.91-$1.00	44,500	$0.94	2.99	44,500	$0.94	2.99
$1.01-$1.50	1,337,519	$1.48	0.93	1,337,519	$1.48	0.93
$1.51-$5.00	363,307	$2.77	1.75	363,307	$2.77	1.75

Stock-based compensation expense recognized in the statement of operations is as follows (in thousands):

	For the fiscal year ended September 30,	
	2012	2011
Research and Development Expenses	$ 14	$ 79
General and Administrative Expenses	554	914
Total Stock-based Compensation Expense	$ 568	$ 993

The fair value of the options associated with the above compensation expense was determined at the date of the grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	For the fiscal year ended September 30,	
	2012	2011
Dividend yield	0%	0%
Expected volatility	146%	89% - 179%
Risk-free interest rate	0.90%	1.1% - 3.7%
Expected option life after shares are vested	5.23 years	8.35 years

Effective July 1, 2011, the Company began using historical information regarding the volatility of its own stock price for purposes of calculating an expected volatility rate for stock option valuation purposes. From April 1, 2009 through June 30, 2011, the Company used a peer group of publicly traded entities to determine an expected volatility rate for stock option valuation. There was no material impact on the financial statements as a result of this change as of July 1, 2011. In addition, the Company changed its method of amortization of stock-based compensation from the multiple attribute method to straight line for option grants made on and subsequent to April 1, 2009. There was no material

impact on the financial statements as a result of this change as of April 1, 2009. The Company believes the use of its historical stock price and straight line amortization results in a better estimate of the Company's stock-based compensation expense.

H. Income Taxes

As of September 30, 2012 and 2011, the Company had federal net operating loss ("NOL") carry-forwards of $110,986,000 and $111,347,000, respectively and state operating loss carry-forwards of $32,912,000 and $34,757,000, respectively. The use of these federal and state NOL carry-forwards might be subject to limitation under the rules regarding a change in stock ownership as determined by the Internal Revenue Code (the "Code"). The Company may have had a change of control under Section 382 of the Code during fiscal 2004 and 2006; however, a complete analysis of the limitation of the NOL carry-forwards will not be completed until the time the Company projects it will be able to utilize such NOLs. The federal net operating and the state net operating losses began to expire in 2010. Additionally, the Company had federal research and development carry-forwards as of September 30, 2012 and 2011 of $3,587,000 and $3,329,000, respectively. The Company had state research and development carry-forwards as of September 30, 2012 and 2011 of $892,000 and $624,000, respectively.

Significant components of the Company's deferred tax assets at September 30, 2012 and 2011 consisted of the following (in thousands):

	2012	2011
Net operating loss carry-forwards	$ 40,645	$ 40,939
Research and development credit carry-forwards	4,479	3,953
Accrued payroll related liabilities	2,802	2,750
Depreciation and amortization	939	—
State Taxes	(1,554)	(1,450)
Total deferred tax assets	47,311	46,192
Deferred tax liabilities	—	—
Valuation allowance for deferred assets	(47,311)	(46,192)
Net deferred tax asset	$ —	$ —

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, all of the deferred tax assets have been fully offset by a valuation allowance. The change in the valuation allowance is primarily a result of the net operating loss carry-forwards.

Taxes computed at the statutory federal income tax rate of 34% are reconciled to the provision for income taxes as follows (dollars in thousands):

	2012	2011
Effective income tax rate	0%	0%
United States Federal income tax at statutory rate	$ 577	$ 95
State income taxes (net of federal benefit)	99	2
Warrant expense	(1,621)	(1,311)
Prior year deferred true up	1,119	1,178
Change in valuation reserves	(365)	(212)
Other	193	250
Provision for income taxes	$ 2	$ 2

I. Agreements

Duke Licenses

The Company has obtained exclusive worldwide licenses (the "Duke Licenses") from Duke University ("Duke") to develop, make, have made, use and sell products using certain technology in the field of free radical and antioxidant research, developed by certain scientists at Duke. Future discoveries in the field of antioxidant research from these scientists' laboratories at Duke are also covered by the Duke Licenses. The Duke Licenses require the Company to use its best efforts to pursue development of products using the licensed technology and compounds. These efforts are to include the manufacture or production of products for testing, development and sale. Aeolus is also obligated to use its best efforts to have the licensed technology cleared for marketing in the United States by the U.S. Food and Drug Administration and in other countries in which Aeolus intends to sell products using the licensed technology. Aeolus will pay royalties to Duke on net product sales during the terms of the Duke Licenses, and milestone payments upon certain regulatory approvals and annual sales levels. In addition, Aeolus is obligated under the Duke Licenses to pay all or a portion of patent prosecution, maintenance and defense costs. Unless earlier terminated, the Duke Licenses continue until the expiration of the last to expire issued patent on the licensed technology.

National Jewish Medical and Research Center Agreements

Aeolus has an exclusive worldwide license ("NJH License") from National Jewish Health to develop, make, have made, use and sell products using certain technology developed by certain scientists at NJH. The NJH License requires Aeolus to use commercially reasonable efforts to diligently pursue the development and government approval of products using the licensed technology. Aeolus will be obligated to pay royalties to NJH on net product sales during the term of the NJH License and a milestone payment upon regulatory approval, if obtained. In addition, Aeolus is obligated under the NJH License to pay all or a portion of patent prosecution, maintenance and defense costs. Unless earlier terminated, the NJH License continues until the expiration of the last to expire issued patent on the licensed technology.

Elan Corporation, plc

In May 2002, the Company entered into a collaboration transaction with affiliates of Elan Corporation, plc for the development of the Company's catalytic antioxidant compounds as a treatment for tissue damage from cancer radiation and chemotherapy. Although Elan and the Company terminated this collaboration in January 2003, the Company will pay Elan a royalty on net sales of its catalytic antioxidant products sold, if any, for the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage.

J. Quarterly Financial Data (as restated) (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
Fiscal 2012					
Total revenue	$ 2,215	$ 2,231	$ 1,448	$ 1,399	$ 7,293
Net income (loss) (1)	$ 2,977	$ 2,763	$ 3,064	$ (7,106)	$ 1,698
Net income available to stockholders – Basic (2)	$ 1,487	$ 1,381	$ 1,558	$ (7,106)	$ 856
Net income available to stockholders – Diluted (2)	$ (415)	$ (283)	$ (307)	$ (7,106)	$ (2,161)
Basic net income (loss) per common share attributable to common stockholders (2)	$ 0.02	$ 0.02	$ 0.02	$ (0.11)	$ 0.01
Diluted net income (loss) per common share attributable to common stockholders (2)	$ (0.01)	$ 0.00	$ 0.00	$ (0.11)	$ (0.03)
Fiscal 2011					
Total revenue	$ —	$ 785	$ 1,912	$ 2,124	$ 4,821
Net income (loss) (1)	$ (7,620)	$ 3,778	$ 6,293	$ (2,152)	$ 299
Net income available to stockholders – Basic (2)	$ (7,620)	$ 1,879	$ 3,144	$ (2,152)	$ 149
Net income available to stockholders – Diluted (2)	$ (7,620)	$ (937)	$ (687)	$ (2,152)	$ (3,254)
Basic net income (loss) per common share attributable to common stockholders (2)	$ (0.13)	$ 0.03	$ 0.05	$ (0.04)	$ 0.00
Diluted net income (loss) per common share attributable to common stockholders (2)	$ (0.13)	$ (0.01)	$ (0.01)	$ (0.04)	$ (0.04)

(1) The net income (loss) per share restatement did not impact net income (loss) reported by the Company.

(2) Amounts restated from the Company's Form 10-K filing on December 31, 2012. See note K.

K. Net Income (Loss) Per Common Share (restated)

As referenced in note B and J, the Company identified an error in the calculation of net income (loss) per common share since the filing of the 10-K on December 31, 2012. All references or presentations of net income (loss) per common share have been restated from the original filing of the 10-K on December 31, 2012.

Basic net income (loss) per share

As discussed in Note B, the Company computes basic net income (loss) per weighted average share attributable to common stockholders using the two-class method. Previously the Company used the weighted average number of shares of common stock outstanding during the period.

The restatement to our calculation relates to an unaccounted term in our preferred shares, preferred warrants and the majority of our common warrants (59,149,999 warrants). Each of these shares and warrants would participate in any potential common stock dividends declared by the Company. Dividend participation by these shares and warrants requires the two-class method of net income (loss) per share calculation in accordance with ASC 260-10-45-60.

Our previous basic income (loss) per share calculation was as follows:

	Fiscal year ended September 30,	
	2012	2011
Numerator:		
Net income (loss)	$ 1,698	$ 299
Denominator:		
Weighted-average number of shares – basic	61,593	59,474
Net income (loss) per share – basic	$ 0.03	$ 0.01

Our restated basic income (loss) per share calculation is as follows:

	Fiscal year ended September 30,	
	2012	2011
Net income (loss)	$ 1,698	$ 299

	Weighted-average		Weighted-average	
Common stock and participating shares	Number of shares	Net income	Number of shares	Net income
Common stock	61,593	$ 856	59,474	$ 149
Participating common stock warrants	59,150	$ 822	51,150	$ 148
Participating series B preferred stock	526	$ 7	526	$ 1
Participating series B preferred warrants	896	$ 12	896	$ 2
	122,165	$ 1,698	112,046	$ 299
Numerator:				
Weighted-average net income (loss)		$ 856		$ 149
Denominator:				
Weighted-average number of basic shares	61,593		59,474	
Basic net income (loss) per share		$ 0.01		$ 0.00

Diluted net income (loss) per share

As discussed in Note B, the Company computes diluted net income (loss) per weighted average share attributable to common stockholders using the two-class method, and when appropriate, the treasury method. Previously the Company used the weighted average number of shares of common and dilutive potential common shares outstanding during the applicable period. Potential common shares outstanding consist of stock options, warrants and convertible preferred stock using the treasury stock method and are excluded if their effect is anti-dilutive.

The restatement to our calculation relates to the required removal of fair value adjustments relating to our common stock warrants subject to warrant liability accounting from our calculation of net income (loss) available to diluted shareholders. Each of these warrants would participate in any potential common stock dividends in the future. The Company did not account for the removal of any non-cash gain (loss) from the fluctuation of the warrant liability associated with the incremental warrants in our calculation of net income (loss) per common share.

Our previous diluted income (loss) per share calculation was as follows:

	Fiscal year ended September 30,	
	2012	2011
Numerator:		
Net income (loss)	$ 1,698	$ 299
Denominator:		
Weighted-average number of shares – basic	61,593	59,474
Dilutive securities – equity awards	11,156	22,828
Weighted-average number of shares – diluted	72,749	82,302
Net income (loss) per share – diluted	$ 0.02	$ 0.00

Our restated diluted income (loss) per share calculation is as follows:

	Fiscal year ended September 30, 2012			Fiscal year ended September 30, 2011		
Net income (loss)	$ 1,698			$ 299		
Less gain (loss) on warrant liability:						
Participating common warrants	3,859			3,553		
Undistributed net income (loss)	$ (2,161)			$ (3,254)		
Common stock and common stock equivalents in order of dilutive effect	Outstanding	Incremental Dilutive shares *	Dilutive shares	Outstanding	Incremental Dilutive shares *	Dilutive shares
Common stock	61,593			59,474		
Participating common warrants	59,150	9,448	71,041	59,150	26,388	85,862
Participating preferred warrants	896	869	**	896	879	**
Series B preferred shares	526	526	**	526	526	**
Common stock options	9,474	240	**	8,943	1,497	**
Non-participating common stock warrants	2,983	75	**	1,890	476	**
			71,041			85,862
Numerator:						
Weighted-average net income (loss)	$ (2,161)			$ (3,254)		
Denominator:						
	71,041			85,862		

Weighted-average number of basic shares		
Diluted net income (loss) per share	$ (0.03)	$ (0.04)

** Excluded as the effect is anti-dilutive

Diluted weighted average common shares included incremental shares of approximately 9,448,000 and 26,388,000 shares for the fiscal years ended September 30, 2012 and 2011 issuable upon the exercise of warrants to purchase common stock. Diluted weighted average common shares excluded incremental shares of approximately 51,364,000 and 35,680,000, respectively, for the fiscal year 2012 and 2011, due to their anti-dilutive effect.

30,591,501
Shares of Common Stock

_____

PROSPECTUS

_____

June 14, 2013