

AEOLUS PHARMACEUTICALS, INC.

Form 10-K

December 31, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(MARK ONE)

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

For the fiscal year ended September 30, 2012

OR

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

For the transition period from _____ to _____

Commission File Number 0-50481

AEOLUS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

56-1953785
(I.R.S. Employer
Identification No.)

26361 Crown Valley Parkway, Suite 150
Mission Viejo, California
(Address of principal executive offices)

92691
(Zip Code)

Registrant's telephone number, including area code: 949-481-9825

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

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Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.01 par value per share

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the

Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant based upon the average of the bid and asked price on the OTC Bulletin Board as of March 31, 2012, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$6,994,038. Shares of common stock held by each executive officer and director and by each other stockholder who owned 10% or more of the outstanding common stock as of such date have been excluded in that such stockholder might be deemed to be an affiliate of the registrant. This determination of affiliate status might not be conclusive for other purposes.

As of December 18, 2012, the registrant had 62,731,963 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Information Statement to be filed pursuant to Regulation 14C in connection with the registrant's Written Consent in Lieu of the 2013 Annual Meeting of Stockholders are incorporated herein by reference into Part III hereof.

AEOLUS PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
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PART I

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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,” “i,” “continue” or the negative of these terms 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 Item 1A entitled “Risk Factors” beginning on page 43 of this report, as well as those discussed in our other filings with the Securities and Exchange Commission (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.

Item 1. Business.

General

Overview

Aeolus Pharmaceuticals, Inc. (“we,” “us” or “Aeolus”) is a Southern California-based biopharmaceutical company leveraging significant government investment to develop a platform of novel compounds in oncology and biodefense. 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.

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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. Our contract with BARDA calls for us to provide the data necessary for an EUA filing for AEOL 10150 as a MCM for Lung-ARS in the second half of 2013.

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:
 - o Have broader antioxidant activity,
 - o Have better tissue penetration,
 - o Have a longer life in the body, and
 - o 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- β) and, as demonstrated by immunohistochemistry of lung tissue, collagen deposition and TGF- β .

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 hematopoietic 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.

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.

Figure 7

Figure 8

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 \geq 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-existing distribution 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 parenchyma, 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 Study	January 2013
Complete Murine Radiation Dose Study Amendment (C57LJ)	December 2012

Complete Murine C57LJ 10150 Dose Escalation Study	January 2013
Complete First Batch of Bulk Drug Substance under New Methods	February 2013
Complete First Lot of Final Drug Product under New Methods	March 2013
File IND for Lung-ARS Indication	March 2013
Initiate Phase 1 Human Safety Study	2nd Quarter 2013
File for Fast Track with FDA	2nd Quarter 2013
Complete CBA AEOL 10150 Dose Evaluation Study	3rd Quarter 2013
Complete CBA Duration of Treatment Study	3rd Quarter 2013
Complete Murine Mechanism of Action Studies	3rd Quarter 2013
Complete NHP AEOL 10150 Dose Evaluation Study	4th Quarter 2013
Complete Phase 1 Human Safety Study	4th Quarter 2013

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:

- 1) AEOL10150 is biologically active as a countermeasure (specifically for GI-ARS)
- 2) 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.
- 3) 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 ($p < 0.05$, $n = 6/\text{group}$) 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- β 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 intraperitoneally 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., angiogenesis) 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 \pm 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 ($P < 0.001$) 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. Kepivance™ (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 C_{max} and AUC (0-8) appear to correlate with increases in dose, but the correlation is not strong.
- The mean C_{max} 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 C_{max} 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 patient'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, 6-tetrahydropyridine (“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.

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 21, 2012, our catalytic antioxidant small molecule technology base is described in 12 issued United States patents and five 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, 88 of which have issued, and one of which has been allowed as of December 21, 2012. Our 12 issued US 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 December 27, 2012, 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.

Executive Officers

Our executive officers and their ages as of December 27, 2012 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 became our full time employee in 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.

John L. McManus. Mr. McManus began as a consultant to Aeolus 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.

Item 1A. Risk Factors.

You should carefully consider the following information about risks described below, together with the other information contained in this annual report on Form 10-K 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 annual report. 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 \$180,714,000 as of September 30, 2012. 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 September 30, 2012, we had cash of approximately \$281,000. 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 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 September 30, 2012, we had an accumulated deficit of \$180,714,000 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 September 30, 2012, 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). Kepivance™ (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;

- finest; 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 September 30, 2012, Xmark Opportunity Partners, LLC ("Xmark") possessed voting power over 39,575,839 shares, or 63.1%, 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 63.1% of our outstanding common stock as of September 30, 2012. 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 81.3% of our outstanding common stock as of September 30, 2012. 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 September 30, 2012, we had 62,731,963 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 September 30, 2012, options to purchase 9,473,661 shares were outstanding at exercise prices ranging from \$0.23 to \$5.00 per share, with a weighted average exercise price of \$0.71 per share, and 2,250,909 shares were reserved for issuance under the 2004 Stock Incentive Plan. In addition, as of September 30, 2012, warrants to purchase 62,993,663 shares of common stock were outstanding at exercise prices ranging from \$0.258 to \$2.50 per share, with a weighted exercise price of \$0.31 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 may experience significant and unpredictable changes to the liability for warrants and record significant gains or losses to our statement of operations in each period the warrants are outstanding.

In June 2008, the Financial Accounting Standards Board (“FASB”) ratified what was originally referred to as Emerging Issues Task Force Issue No. 07-5 and recently codified by FASB as Accounting Standards Codification Topic 815, which contains 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 adopted this guidance on October 1, 2009 and began applying its provisions to outstanding instruments as of that date. A number of our outstanding warrants to purchase common stock are impacted by this guidance. As a result, liability recorded for a number of our outstanding warrants may increase or decrease, sometimes dramatically, from quarter-to-quarter. An increase in warrant liability for a period will result in a corresponding charge to our statement of operations for such period and a decrease in warrant liability for a period will result in a corresponding gain to our statement of operations for such period. Our outstanding warrants will continue to be revalued at each balance sheet date, which could result in significant and unpredictable changes to our reported liabilities and significant additional gains or losses charged to the statement of operations for each period regardless of any changes to our working capital, liquidity, or business operations.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

None.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Price Range of Common Stock

Our common stock is traded 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 Ended 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 Ended 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

Approximate Number of Equity Security Holders

As of December 18, 2012 the number of record holders of our common stock was 93, and we estimate that the number of beneficial owners was approximately 4,000.

Dividends

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. 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 four transactions (on each of October 6, 2009, July 30, 2010, August 11, 2010 and December 28, 2010), 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 to receive any such dividend paid.

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.

Recent Sales of Unregistered Securities

See the descriptions of the warrants issued to Roberts Mitani, LLC, Columbia Capital Securities and Monarch Bay Associates, LLC under the heading “Equity Compensation Plan and Additional Equity Information as of September 30, 2012 - Description of Equity Compensation Plans and Equity Securities Not Approved by Our Stockholders” under Part III, Item 12 below for information regarding our recent sales of unregistered securities. The securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended (the “Securities Act”), and Rule 506 promulgated thereunder, and thus have not been registered under the Securities Act. The securities may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act. Each of the agreements executed in connection with the issuance of the securities contain representations to support our reasonable belief that each warrant holder had access to information concerning our operations and financial condition, each warrant holder acquired the securities for its own account and not with a view to the distribution thereof in the absence of an effective registration statement or an applicable exemption from registration, and that each warrant holder is sophisticated within the meaning of Section 4(2) of the Securities Act and an “accredited investor” (as defined by Rule 501 under the Securities Act). In addition, the issuances did not involve any public offering; we made no solicitation in connection with the issuance of the warrants other than communications with the warrant holders; we did not use any form of advertising in connection with the issuance of the warrants; we obtained representations from each warrant holder regarding his or its investment intent, experience and sophistication; and each warrant holder either received or had access to adequate information about us in order to make informed investment decisions. At the time of their issuance, the securities were deemed to be restricted securities for purposes of the Securities Act, and the certificates representing the securities bear legends to that effect.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Item 6. Selected Financial Data.

Read the following selected financial data in conjunction with our consolidated financial statements and the notes to those statements and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Annual Report on Form 10-K. We derived the consolidated statements of operations data for the five fiscal years ended September 30, 2012 and the related consolidated balance sheet data at those dates from our audited consolidated financial statements. Except for the consolidated statements of operations for the fiscal years ended September 30, 2010, 2009 and 2008 and the consolidated balance sheet data at September 30, 2010, 2009 and 2008, each of these consolidated financial statements is included elsewhere in this Annual Report on Form 10-K.

Statement of Operations Data:

	2012	Year Ended September 30,				2008
		2011	2010	2009		
		(in thousands, except per share data)				
Revenue:						
Grant income and contract revenue	\$ 7,293	\$ 4,821	\$ —	\$ —		—
Costs and expenses:						
Research and development	6,468	5,055	1,690	711		977
General and administrative	3,196	3,668	1,954	1,292		1,540
Total costs and expenses	9,664	8,723	3,644	2,003		2,517
Loss from operations	(2,371)	(3,902)	(3,644)	(2,003)		(2,517)
Other income (expenses), net	4,069	4,222	(21,347)	144		(405)
Interest income (expense), net	—	(21)	(878)	(437)		(51)
Net income (loss)	1,698	299	(25,869)	(2,296)		(2,973)
Preferred stock dividend and accretion	—	—	—	—		—
Net income (loss) attributable to common stockholders	\$ 1,698	\$ 299	\$ (25,869)	\$ (2,296)	\$	(2,973)
Basic net income (loss) per share attributable to common stockholders	\$ 0.03	\$ 0.01	\$ (0.53)	\$ (0.07)	\$	(0.09)
Diluted net income (loss) per share attributable to common stockholders	\$ 0.02	\$ 0.00	\$ (0.53)	\$ (0.07)	\$	(0.11)
Weighted average common shares outstanding:						
Basic	61,593	59,474	49,151	34,789		31,953
Diluted	72,749	82,302	49,151	34,789		32,217

Balance Sheet Data:

	2012	2011	September 30, 2010	2009	2008
			(in thousands)		
Cash and cash equivalents and marketable securities	281	518	2,355	646	399
Working capital (deficiency)	(1,048)	114	781	5	(1,336)
Total assets	1,256	2,290	2,433	811	1,120
Long-term portion of capital lease obligations and notes payable	—	—	—	1,194	266
Total liabilities	21,591	25,549	29,169	1,968	2,157
Total stockholders' deficit	(20,335)	(23,259)	(26,736)	(1,157)	(1,037)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Introduction

You should read the following discussion in conjunction with our consolidated financial statements and the notes appearing elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of various factors, including those discussed in Item 1A - "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are developing a new class of catalytic antioxidant compounds as a medical countermeasure against biological, chemical and radiological weapons as well as for diseases and disorders of the central nervous system, respiratory system, autoimmune system and oncology. Our initial target indications are as a protective agent against the effects of acute radiation syndrome, sulfur mustard gas exposure and chlorine gas exposure. We have reported positive safety results from two Phase I clinical trials of AEOL 10150, our lead drug candidate, with no serious adverse events noted.

We had net income of approximately \$1,698,000 and \$299,000 for the fiscal years ended September 30, 2012 and 2011, respectively. We had an accumulated deficit of approximately \$180,714,000 at September 30, 2012. We have not yet generated any revenue from product sales and do not expect to receive any product revenue from non-government sales in the foreseeable future, if at all. Under the BARDA Contract, we are expected to file an EUA in the second half of 2013, after which BARDA may begin purchasing AEOL 10150 for the Strategic National Stockpile.

We have not had any recurring revenue from product sales. Therefore, we have relied on public or private equity offerings, debt financings, collaboration arrangements and grants to finance our operations.

Corporate Matters

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. If all options are exercised, the period of performance would continue through at least 2016.

Activities conducted during the base period of performance include developing animal models with radiation survival curves, 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 options to extend the term of the BARDA Contract, optional 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.

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 the key items required to further advance development of AEOL 10150.

On February 15, 2012, we announced that we entered into a contract modification and no-cost extension with the 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, initiated 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 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.

Under the BARDA Contract, we plan to provide to BARDA the data necessary in order 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.

Results of Operations

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

As of September 30, 2012, we had approximately \$281,000 of cash and cash equivalents, a decrease of \$237,000 from September 30, 2011. 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 had net income of \$1,698,000 (including a non-cash gain for decreases in valuation of warrants of \$4,069,000) for the fiscal year ended September 30, 2012, compared to 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. For the same periods, we had cash outflows from operations of approximately \$879,000 and \$3,102,000, respectively. Our ongoing future cash requirements will depend on numerous factors, particularly the progress of our catalytic antioxidant program and clinical trials and our ability to negotiate and complete collaborative agreements or out-licensing arrangements. In order to help fund our on-going operating cash requirements, we intend to seek new collaborations for our antioxidant research program that include initial cash payments and on-going research support. In addition, we might sell additional shares of our stock and/or convertible debentures and explore other strategic and financial alternatives, including a merger 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. We expect to incur additional losses and negative cash flow from operations for several more years.

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. Additionally, In November 2010, we received approximately \$92,000 from the QTDP in support of our development of AEOL 11207 for Parkinson's Disease.

On February 11, 2011, we were awarded a contract by BARDA to fund the development of AEOL 10150 as an MCM 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 DEARE would be paid for by the U.S. government through BARDA funding. We recognized approximately \$7,293,000 in revenue during the fiscal year ended September 30, 2012 related to 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 fee 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 further accelerate or expand our programs, we expect to need to raise significant additional funds in order to pursue our oncology program.

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, clinical trials and 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, could result in substantial dilution to existing stockholders.

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.

Contractual Obligations

Our contractual obligations (in thousands) as of September 30, 2012 were as follows:

Contractual Obligations	Total	Payments due by period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Short and long-term debt	\$	—\$	—\$	—\$	—\$
Capital lease obligations		—	—	—	—
Operating leases	3	3	—	—	—
Purchase obligations		—	—	—	—
Total	\$ 3	\$ 3	\$ —	\$ —	—

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 September 30, 2012, 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 63.1% of our outstanding common stock and had beneficial ownership, calculated based on SEC requirements, of approximately 63.2% 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.

In addition, under the terms of the warrants to purchase up to 61,822,749 shares of our common stock issued to Xmark on October 6, 2009 as well as subsequent warrant issuances on July 30, 2010, August 11, 2010 and December 28,

2010 (collectively, the “Xmark Warrants”), 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 receive any such dividend paid. The Xmark Warrants also contain a provision that provides for the reduction of the exercise price to \$0.01 upon a change of control and anti-dilution provisions in the event of a stock dividend or split, dividend payment or other issuance, reorganization, recapitalization or similar event. In addition, the Xmark Warrants, among other restrictions, prohibit the sale of Aeolus to an entity other than one that is publicly traded.

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.

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.

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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Market Risk

Our exposure to market risk is presently limited to the interest rate sensitivity of our cash and cash equivalents, which is affected by changes in the general level of U.S. interest rates. However, we believe that we are not subject to any material market risk exposure and do not expect that changes in interest rates would have a material effect upon our financial position. A hypothetical 10% change in interest rates would not have a material effect on our Statement of Operations or Cash Flows for the fiscal year ended September 30, 2012. We do not have any foreign currency or other derivative financial instruments. Our debt bears interest at a fixed rate.

Item 8. Financial Statements and Supplementary Data.

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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.

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

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
Prepays 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 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
Basic net income (loss) per common share	\$ 0.03	\$ 0.01
Diluted net income (loss) per common share	\$ 0.02	\$ —
Weighted average common shares outstanding:		
Basic	61,593	59,474
Diluted	72,749	82,302

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		Common Stock		Additional	Accumulated	Total
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Deficit	Stockholders' 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)
Noncash consulting and license fee	—	—
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 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 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 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.

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 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 basic net income (loss) per weighted average share attributable to common stockholders using the weighted average number of shares of common stock outstanding during the period. The Company computes diluted net income (loss) per weighted average share attributable to common stockholders using the weighted average number of shares of common and dilutive potential common shares outstanding during the period. Potential common shares outstanding consist of stock options, convertible debt, warrants and convertible preferred stock using the treasury stock method and are excluded if their effect is anti-dilutive. Diluted weighted average common shares included incremental shares of approximately 11,156,000 and 22,828,000 shares for the fiscal years ended September 30, 2012 and 2011 issuable upon the exercise or conversion of convertible debt, stock options to purchase common stock, convertible preferred stock and warrants to purchase common stock. Diluted weighted average common shares excluded incremental shares of approximately 61,847,000 and 48,577,000, respectively, for the fiscal year 2012 and 2011, due to their anti-dilutive effect.

	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
Earnings per share – basic	\$ 0.03	\$ 0.01
Earnings per share – diluted	\$ 0.02	\$ 0.00

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

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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:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	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

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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

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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 (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in thousands, except per share amounts)				
Fiscal 2012					
Total revenue	\$ 2,215	\$ 2,231	\$ 1,448	\$ 1,399	\$ 7,293
Net income (loss) attributable to common stockholders	\$ 2,977	\$ 2,763	\$ 3,064	\$ (7,106)	\$ 1,698
Basic net income (loss) per common share attributable to common stockholders	\$ 0.05	\$ 0.05	\$ 0.05	\$ (0.11)	\$ 0.03
Diluted net income (loss) per common share attributable to common stockholders	\$ 0.04	\$ 0.04	\$ 0.05	\$ (0.11)	\$ 0.02

Fiscal 2011

Total revenue	\$	—	\$	785	\$	1,912	\$	2,124	\$	4,821
Net income (loss) attributable to common stockholders	\$	(7,620)	\$	3,778	\$	6,293	\$	(2,152)	\$	299
Basic net income (loss) per common share attributable to common stockholders	\$	(0.13)	\$	0.06	\$	0.10	\$	(0.04)	\$	0.01
Diluted net income (loss) per common share attributable to common stockholders	\$	(0.13)	\$	0.03	\$	0.07	\$	(0.04)	\$	0.00

K. Subsequent Events

Management has evaluated for subsequent events through the date these financial statements were audited, December 28, 2012, and determined that no other material subsequent events have occurred.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer (our Principal Executive Officer) and Chief Financial Officer (our Principal Financial and Accounting Officer), of the effectiveness of our disclosure controls and procedures required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based upon that evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2012 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15 (f) and 15d-15 (f) of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, errors or fraud. Also, projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of September 30, 2012. In making this assessment, our management used criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in an Internal Control Integrated Framework. Based on the criteria set forth by COSO, management concluded that our internal control over financial reporting was effective as of September 30, 2012.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K.

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the quarter ended September 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we expect to file a definitive information statement in connection with our Written Consent in Lieu of 2013 Annual Meeting of Stockholders (the "Information Statement") within 120 days after the end of our fiscal year pursuant to Regulation 14C promulgated under the Exchange Act, and the information included therein is incorporated herein by reference to the extent provided below.

Item 10. Directors, Executive Officers and Corporate Governance.

The information set forth under the headings "Matter No. 1: Election of Directors," "Information Concerning the Board of Directors and its Committees" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Information Statement is incorporated herein by reference. The information required by this Item 10 concerning our executive officers is set forth under the heading "Executive Officers" located at the end of Part I Item 1 of this Annual Report on Form 10-K.

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.

Item 11. Executive Compensation.

The information set forth under the headings "Director Compensation" and "Executive Compensation" in our Information Statement is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Equity Compensation Plan and Additional Equity Information as of September 30, 2012

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by our stockholders:			
2004 Stock Option Plan	7,749,091	\$ 0.47	2,250,909
1994 Stock Option Plan	1,724,570	\$ 1.73	0
Equity compensation plans and securities not approved by our stockholders:			
Warrants to purchase Common Stock Issued to National Securities	50,000	\$ 0.38	Not applicable
Warrants to Purchase Common Stock Issued to Dan Delmonico	50,000	\$ 0.49	Not applicable
Warrants to Purchase Common Stock Issued to Michael Kruger	50,000	\$ 0.50	Not applicable
Warrants to Purchase Common Stock Issued to Noble International Investments, Inc.	300,000	\$ 1.00	Not applicable
Warrants to Purchase Common Stock Issued to CEOcast, Inc.	250,000	\$ 0.83	Not applicable
Warrants to Purchase Common Stock Issued to Market Pathways	250,000	\$ 1.50	Not applicable
Warrants to Purchase Common Stock Issued to Roberts Mitani, LLC	300,000	\$ 0.258	Not applicable
Warrants to Purchase Common Stock Issued to Columbia Capital Securities, Inc.	35,000	\$ 0.37	Not applicable
Warrants to Purchase Common Stock Issued to Monarch Bay Associates, LLC	35,000	\$ 0.37	Not applicable
Total – Common Stock	10,793,661		2,250,909
Warrants to purchase Series B Preferred Stock	896,037	\$ 0.01	Not applicable
Total – Series B Preferred Stock	896,037		177,883

Description of Equity Compensation Plans and Equity Securities Not Approved by Our Stockholders

The warrants to purchase shares of our common stock issued to Dan Delmonico in September 2009 have not been approved by our stockholders. In consideration for services provided by Mr. Delmonico to us, we issued three

warrants each to purchase up to 20,000, 15,000 and 15,000 shares of our common stock with an exercise price of \$0.39, \$0.50 and \$0.60, respectively. The warrants are exercisable for five years from the date of grant and contain standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock.

The warrants to purchase shares of our common stock issued to National Securities Corporation (“NSC”) have not been approved by our stockholders. In January 2010, we entered into an agreement with NSC pursuant to which we retained NSC as a non-exclusive financial advisor for the period from January 6, 2010 through January 6, 2011. For these services, we issued a warrant to purchase up to 50,000 shares of our common stock with an exercise price of \$0.38. The warrant is exercisable for five years from the date of grant and contains standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock.

The warrants to purchase shares of our common stock issued to Michael Kruger (“Kruger”) have not been approved by our stockholders. In May 2011, we entered into an agreement with Kruger as a consultant to assist us with investor relations for a one-year period. For these services, on May 10, 2011, we issued five warrants, each to purchase up to 50,000 shares of our common stock with an exercise price of \$0.50, \$1.00, \$1.50, \$2.00 and \$2.50 and vesting dates of May 10, 2011, August 8, 2011, November 6, 2011, February 4, 2012 and May 4, 2012, respectively. The warrants are exercisable for five years from the date of grant and contain standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock. In addition, we are required to give Kruger advance notice of a change in control of Aeolus during the term of the warrants. We terminated the agreement with Kruger on July 29, 2011, and the warrants to purchase shares of our common stock with the exercise prices of \$1.00, \$1.50, \$2.00 and \$2.50 were cancelled concurrently with the termination of our agreement with Kruger.

The warrants to purchase shares of our common stock issued to Noble International Investments, Inc. (“Noble”) have not been approved by our stockholders. In May 2011, we entered into an agreement with Noble to provide us with financial advisory services in connection our strategic initiatives for a one-year period. For these services, on May 18, 2011, we issued three warrants each to purchase up to 100,000 shares of our common stock with an exercise price of \$0.50, \$1.00 and \$1.50, respectively, and vesting at a rate of 8,333 shares of our common stock per month. The warrants are exercisable for three years from the date of grant and contain standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock. In addition, we are required to give Noble advance notice of a change in control of Aeolus during the term of the warrants.

The warrants to purchase shares of our common stock issued to CEOcast, Inc. (“CEOcast”) have not been approved by our stockholders. In June 2011, we entered into a consulting agreement with CEOcast to provide us with investor relations services for a one-year period. For these services, on June 1, 2011, we issued two warrants each to purchase up to 125,000 shares of our common stock with an exercise price of \$0.51 and \$1.00, respectively, and vesting at a rate of 10,416.67 shares of our common stock per month. The warrants are exercisable for three years from the date of grant and contain standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock. In addition, we are required to give CEOcast advance notice of a change in control of Aeolus during the term of the warrants.

The warrants to purchase shares of our common stock issued to Market Pathways have not been approved by our stockholders. In July 2011, we entered into an agreement with Market Pathways to assist us with investor relations for a one-year period. For these services, on July 22, 2011, we issued five warrants each to purchase up to 50,000 shares of our common stock with an exercise price of \$0.50, \$1.00, \$1.50, \$2.00 and \$2.50 and vesting dates of July 22, 2011, October 20, 2011, January 18, 2012, April 17, 2012 and July 16, 2012, respectively. The warrants are exercisable for five years from the date of grant and contain standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock. In addition, we are required to give Market Pathways advance notice of a change in control of Aeolus during the term of the warrants.

The warrant to purchase shares of our Common Stock issued to Roberts Mitani, LLC have not been approved by our stockholders. In June 2012, we entered into an advisory agreement with Roberts Mitani, LLC whereby we engaged Roberts Mitani, LLC to serve as an advisor to provide strategic advisory services to us on a non-exclusive basis. For these services, on June 26, 2012, we issued a warrant to purchase up to 300,000 shares of our Common Stock with a per share exercise price of \$0.258. The warrant is exercisable for seven years from the date of grant and contains standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock.

The warrants to purchase shares of our Common Stock issued to Columbia Capital Securities, Inc. and Monarch Bay Associates, LLC have not been approved by our stockholders. In August 2012, we entered into an advisory agreement with Columbia Capital Securities, Inc. and Monarch Bay Associates, LLC whereby we engaged them to serve as an advisor to provide strategic advisory services to us on a non-exclusive basis. For these services, we have agreed to pay each of Columbia Capital Securities, Inc. and Monarch Bay Associates, LLC a monthly retainer in the form of a warrant to purchase up to an aggregate of 17,500 shares of Common Stock, commencing on August 17, 2012 and continuing monthly thereafter during the term of their engagement under the advisory agreement. Each of these warrants has an exercise price equal to the closing price of the Common Stock on the date of issuance, is deemed fully vested upon issuance, is exercisable at any time on or before the five year anniversary of the date of issuance and contains standard adjustment provisions in the event we declare a stock dividend or engage in a recapitalization, reclassification or reorganization of our capital stock. On August 17, 2012, we issued a warrant to purchase up to an aggregate of 17,500 shares of Common Stock with a per share exercise price of \$0.30 to each of Columbia Capital Securities, Inc. and Monarch Bay Associates, LLC. On September 17, 2012, we issued a warrant to purchase up to an aggregate of 17,500 shares of Common Stock with a per share exercise price of \$0.44 to each of Columbia Capital Securities, Inc. and Monarch Bay Associates, LLC.

The information set forth under the headings “Security Ownership of Certain Beneficial Owners and Management” in our Information Statement is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information set forth under the headings “Information Concerning the Board of Directors and its Committees” and “Certain Related Transactions” in our Information Statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information set forth under the heading “Independent Registered Public Accounting Firm — Fees” in our Information Statement is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following financial statement schedules and exhibits are filed as part of this report or incorporated herein by reference:

(1) Financial Statement Schedules.

All financial statement schedules for which provision is made in Regulation S-X are omitted because they are not required under the related instructions, are inapplicable, or the required information is given in the financial statements, including the notes thereto.

(2) Exhibits.

Exhibit Number	Description of Document	Incorporated by Reference To			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
2.1	Agreement and Plan of Merger and Reorganization dated September 16, 2003 between Incara, Inc. and Incara Pharmaceuticals Corporation	S-4	09/19/03	2.1	
<u>3.1</u>	Amended and Restated Certificate of Incorporation				X
4.1	Form of Common Stock Certificate	10-Q	08/11/04	4.1	
4.2	Form of Series B Preferred Stock Certificate	S-4	09/19/03	4.8	
4.3	Form of Warrant to Purchase Common Stock dated June 5, 2006.	8-K	06/06/06	10.3	
4.4	Registration Rights Agreement dated May 22, 2007 by and among the Company and each of the Purchasers whose names appear on the Schedule attached thereto.	8-K	5/23/07	4.1	
4.5	Registration Rights Agreement dated October 6, 2009 by and among the	8-K	10/06/09	4.1	

Company and the investors whose names
appear on the signature pages thereof.

4.6	Form of Warrant to Purchase Common Stock dated May 22, 2007.	8-K	5/23/07	10.2
4.7	Form of Warrant to Purchase Common Stock	8-K	10/06/09	10.2

Exhibit Number	Description of Document	Incorporated by Reference To			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
4.8	Registration Rights Agreement dated September 16, 2003 among Incara Pharmaceuticals Corporation, Incara, Inc. and Goodnow Capital, L.L.C.	S-4	09/19/03	10.101	
4.9	Registration Rights Agreement dated August 11, 2010 by and among Aeolus Pharmaceuticals, Inc. and the investors listed therein	8-K	8/12/10	4.1	
10.1*	License Agreement between Duke University and Aeolus Pharmaceuticals, Inc., dated July 21, 1995	S-1	12/08/95	10.4	
10.2	Amended and Restated Limited Liability Company Agreement of CPEC LLC dated July 15, 1999, among CPEC LLC, Intercardia, Inc. and Interneuron Pharmaceuticals, Inc.	8-K	07/23/99	10.42	
10.3	Assignment, Assumption and License Agreement dated July 15, 1999, between CPEC LLC and Intercardia, Inc.	8-K	07/23/99	10.43	
10.4*	License Agreement dated January 19, 2001 between Incara Pharmaceuticals Corporation and Incara Development, Ltd.	10-Q	02/13/01	10.59	
10.5*	License Agreement dated January 19, 2001 between Elan Corporation, plc, Elan Pharma International Ltd. and Incara Development, Ltd.	10-Q	02/13/01	10.60	
10.6	Registration Rights Agreement dated December 21, 2000 among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Ltd.	10-Q	02/13/01	10.62	
10.7	Agreement and Amendment, effective as of January 22, 2001, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited	10-Q	05/14/01	10.64	
10.8	Second Agreement and Amendment, effective as of January 22, 2001, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited	10-Q	05/14/01	10.65	
10.9	Third Agreement and Amendment, effective as of January 22, 2001, by and among Incara Pharmaceuticals	8-K	06/01/01	10.66	

Corporation, Elan International Services, Ltd. and Elan Pharma International Limited

10.10	Agreement and Fourth Amendment, effective February 13, 2002, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd., Elan Pharma International Limited and Elan Pharmaceutical Investments III, Ltd.	10-Q	02/14/02	10.75
10.11*	License Agreement dated June 25, 1998 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	05/15/02	10.82
10.12*	License Agreement dated May 7, 2002 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	05/15/02	10.83
10.13*	License Agreement dated November 17, 2000 between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc.	10-Q	02/13/01	10.56

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Exhibit Number	Description of Document	Incorporated by Reference To		Exhibit Number	Filed Herewith
		Registrant's Form	Date Filed with the SEC		
10.14	Exclusive License Agreement, dated January 15, 2009, by and between the Company and National Jewish Health	10-Q	05/16/11	10.7	
10.15*	Securities Purchase Agreement dated as of May 15, 2002, among Incara Pharmaceuticals Corporation, Aeolus Pharmaceuticals, Inc., Elan Pharma International Limited and Elan International Services, Ltd.	8-K/A	07/03/02	10.84	
10.16*	Development and Option Agreement dated May 15, 2002, among Elan Pharma International Limited, Incara Pharmaceuticals Corporation and Aeolus Pharmaceuticals, Inc.	8-K/A	07/03/02	10.85	
10.17	Amended and Restated Registration Rights Agreement dated as of May 15, 2002, among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited	8-K/A	07/03/02	10.86	
10.18	Amendment No. 1 to License Agreement dated May 14, 2002, between Aeolus Pharmaceuticals, Inc. and Duke University (amending License Agreement dated July 21, 1995)	8-K/A	07/03/02	10.87	
10.19	Amendment No. 1 to License Agreement dated May 14, 2002, between Aeolus Pharmaceuticals, Inc. and Duke University (amending License Agreement dated June 25, 1998)	8-K/A	07/03/02	10.88	
10.20	Amendment No. 1 to License Agreement dated May 14, 2002, between Aeolus Pharmaceuticals, Inc. and National Jewish Medical and Research Center (amending License Agreement dated November 17, 2000)	8-K/A	07/03/02	10.89	
10.21*	Subaward Agreement, dated March 16, 2011, by and between the Company and the Office of Research and Development of the University of Maryland, Baltimore	10-Q	05/16/11	10.4	
10.22	Letter dated May 17, 2004 from Elan International Services, Limited and Elan Pharma International Limited to Incara Pharmaceuticals Corporation	10-Q	08/11/04	10.106	
10.23+	Aeolus Pharmaceuticals, Inc. 1994 Stock Option Plan, as amended	10-Q	08/11/04	10.109	

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10.24+	Aeolus Pharmaceuticals, Inc. Amended and Restated 2004 Stock Incentive Plan	S-8	04/28/11	99.1
10.25+	Amended and Restated Employment Agreement dated July 30, 2010 between Aeolus Pharmaceuticals, Inc. and John L. McManus	8-K	08/02/10	10.4
10.26+	Letter Agreement dated July 10, 2006 between Aeolus Pharmaceuticals, Inc. and McManus & Company, Inc.	8-K	07/10/06	10.2
10.27+	Form of Indemnity Agreement	10-K	12/27/11	10.27
10.28	Terms of Outside Director Compensation	10-K	12/17/04	10.114
10.29+	Form of Incentive Stock Option Agreement	10-Q	02/08/05	10.115
10.30+	Form of Nonqualified Stock Option Agreement	10-Q	02/08/05	10.116
10.31	Subscription Agreement dated June 5, 2006 by and between the Company and the investors whose names appear on the signature pages thereof.	8-K	06/06/06	10.1

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Exhibit Number	Description of Document	Incorporated by Reference To			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.32	Board Observer Letter dated June 5, 2006 by and among the Company and Efficacy Biotech Master Fund Ltd.	8-K	06/06/06	10.6	
10.33+	Consulting Agreement, dated December 1, 2010, between Aeolus Pharmaceuticals, Inc. and Brian J. Day	8-K	12/03/10	10.1	
10.34*	Sponsored Research Agreement (Non-Clinical), dated April 12, 2011, by and between the Company and Duke University	10-Q	05/16/11	10.5	
10.35	Securities Purchase Agreement dated August 11, 2010 by and among Aeolus Pharmaceuticals, Inc. and the investors listed therein	8-K	8/12/10	10.1	
10.36	Form of Warrant pursuant to Securities Purchase Agreement dated August 11, 2010 by and among Aeolus Pharmaceuticals, Inc. and the investors listed therein	8-K	8/12/10	10.2	
10.37	Convertible Promissory Note dated February 7, 2007 issued by Aeolus Pharmaceuticals, Inc. to Elan Pharma International Ltd.	S-1	06/04/07	10.43	
10.38	Amendment No. 1 To Convertible Promissory Note dated February 7, 2009 by and between Aeolus Pharmaceuticals, Inc. and Elan Pharma International Limited	8-K	3/16/09	10.1	
10.39+	Form of Restricted Share Award Agreement	S-8 POS	3/31/08	99.2	
10.40	Securities Purchase and Exchange Agreement dated October 6, 2009 by and among the Company and the investors whose names appear on the signature pages thereof	8-K	10/06/09	10.1	
10.41	Amendment Agreement to the Securities Purchase and Exchange Agreement, dated December 24, 2009, by and among the Company and the investors whose names appear on the signature pages thereof	8-K	12/28/09	10.1	
10.42+	Offer Letter, dated September 1, 2010 between the Company and Russell Skibsted	8-K	02/16/11	10.1	
10.43*	Contract No. HHSO100201100007C, dated February 11, 2011, by and between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority	10-Q	05/16/11	10.1	
10.44*	Research and Manufacturing Agreement, dated February 18, 2011 (the "JMPS Agreement"), by and between the Company and Johnson Matthey Pharmaceutical Materials, Inc. (d/b/a Johnson	10-Q	05/16/11	10.2	

	Matthey Pharma Services).			
10.45*	Appendix 2 to the JMPS Agreement, dated February 18, 2011	10-Q	8/14/12	10.4
10.46*	Appendix 3 to the JMPS Agreement, dated April 30, 2012	10-Q	8/14/12	10.5
10.47*	Appendix 4 to the JMPS Agreement, dated April 30, 2012	10-Q	8/14/12	10.6
10.48*	Appendix 5 to the JMPS Agreement, dated April 30, 2012	10-Q	8/14/12	10.7

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Exhibit Number	Description of Document	Incorporated by Reference To			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.49*	Appendix 6 to the JMPS Agreement, dated April 30, 2012	10-Q	8/14/12	10.8	
10.50*	General Management Consulting Assignment, dated February 23, 2011, by and between the Company and Booz Allen Hamilton Inc.	10-Q	05/16/11	10.3	
10.51	Form of Securities Purchase Agreement by and among the Company and the investors whose names appear on the signature pages thereof	8-K	4/5/12	10.1	
10.52	Form of Registration Rights Agreement by and among the Company and the investors party thereto	8-K	4/5/12	10.2	
10.53	Form of Warrant issued to investors in March and April 2012	8-K	4/5/12	10.3	
<u>21.1</u>	List of Subsidiaries				X
<u>23.1</u>	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm				X
<u>31.1</u>	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a)				X
<u>31.2</u>	Certification of the Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) and 15d-14(a)				X
<u>32.1</u>	Certification by the Principal Executive Officer and Principal Financial and Accounting Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS†	XBRL Instance Document				X
101.SCH†	XBRL Taxonomy Extension Schema Document				X
101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB†	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document				X

* The Company has received confidential treatment of certain portions of this agreement which have been omitted and filed separately with the U.S. Securities and Exchange Commission.

+ Indicates management contract or compensatory plan or arrangement.

† Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AEOLUS PHARMACEUTICALS, INC.

By: /s/ John L. McManus
John L. McManus
President and Chief Executive Officer

Date: December 31, 2012

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE(S)	DATE
/s/ John L. McManus John L. McManus	President and Chief Executive Officer (Principal Executive Officer)	December 31, 2012
/s/ Russell Skibsted Russell Skibsted	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	December 31, 2012
/s/ David C. Cavalier David C. Cavalier	Chairman of the Board of Directors	December 31, 2012
/s/ John M. Farah, Jr., Ph.D. John M. Farah, Jr., Ph.D.	Director	December 31, 2012
_____ Joseph J. Krivulka	Director	December 31, 2012
/s/ Amit Kumar, Ph.D. Amit Kumar, Ph.D.	Director	December 31, 2012
/s/ Michael E. Lewis, Ph.D. Michael E. Lewis, Ph.D.	Director	December 31, 2012

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/s/_Chris A.

December 31 , 2012

Rallis_____

Director

Chris A. Rallis

/s/_Peter D. Suzdak,

December 31 , 2012

Ph.D._____

Director

Peter D. Suzdak, Ph.D.

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