

AEOLUS PHARMACEUTICALS, INC.

Form 10-K

December 12, 2008

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, 2008

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	56-1953785
(State or	(I.R.S.
Other	Employer
Jurisdiction of	Identification
Incorporation	No.)
or	
Organization)	

26361 Crown	
Valley Parkway,	
Suite 150	
Mission Viejo,	92691
California	
(Address of	(Zip Code)
principal	
executive offices)	

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

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

Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, \$.01 par value per share  
(Title of class)

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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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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, or a non-accelerated filer.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
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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, 2008, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$4,369,000. 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 affiliates. This determination of affiliate status might not be conclusive for other purposes.

As of December 10, 2008, the registrant had outstanding 32,030,874 shares of common stock.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive Proxy Statement to be filed pursuant to Regulation 14A for the registrant's 2009 Annual Meeting of Stockholders to be held on or about March 26, 2009 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 19 of this report, as well as those discussed in our other filings with the Securities and Exchange Commission and the following:

- our need for, and our ability to obtain, additional funds;
- uncertainties relating to 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 product 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

Aeolus Pharmaceuticals, Inc. (“we” or the “Company”), a Southern California-based biopharmaceutical company, is developing a new class of catalytic antioxidant compounds 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 mustard gas exposure, as a protective agent against radiation exposure, cancer radiation therapy, as a protective agent against the effects of chlorine gas exposure and amyotrophic lateral sclerosis, also known as “ALS” or “Lou Gehrig’s disease.” 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 also have a long-term clinical trial underway in a single patient with ALS to test the efficacy and further test the safety of AEOL 10150.

We were incorporated in the State of Delaware in 1994. Our common stock trades on the OTC Bulletin Board under the symbol “AOLS.” Our principal executive offices are located at 26361 Crown Valley Parkway, Suite 150 Mission Viejo, California 92691, and our phone number at that address is (949) 481-9825. Our website address is [www.aeoluspharma.com](http://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.

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 pharmaceuticals 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 have begun to extend our preclinical accomplishments into our 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 superoxide dismutase (“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 have created a class of small molecules that consume free radicals 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, has shown efficacy in a variety of animal models, including mustard gas exposure, as a protectant against radiation exposure, ALS, stroke, radiation injury, pulmonary diseases, and diabetes. We filed an Investigational New Drug Application ("IND") for AEOL 10150 in April 2004 under which clinical trials were conducted as more fully described below under the heading "AEOL 10150 Clinical Development Program." For a more detailed description of antioxidants see the section below titled "Background on Antioxidants."

#### AEOL 10150

Our lead drug candidate is AEOL 10150 and is the first in our class of catalytic antioxidant compounds to enter clinical evaluation. AEOL 10150 is a small molecule 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-derived free radicals are believed to have an important role in the pathogenesis of many diseases, we believe that Aeolus' catalytic antioxidants and AEOL 10150 may have a broad range of potential therapeutic uses. In particular, our catalytic antioxidants have been shown to significantly reduce tissue damage in animal models of mustard gas exposure, radiation exposure, radiation therapy, ALS, stroke and chronic obstructive pulmonary disease for which we have focused on mustard gas exposure, radiation exposure, radiation therapy, chlorine gas exposure and ALS.

#### AEOL 10150 in Treatment of the Effects of Mustard Gas Exposure

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. 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 lead to resurgence in research to develop a protectant against exposure.

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 Department of Health and Human Services, the National Institutes of Health ("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 Countermeasures Against Chemical Threats ("CounterACT") Research Network that includes Research Centers of Excellence, individual research projects, SBIRs, contracts and other programs. The CounterACT network will conduct 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.

The goal of the 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.

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.



Researchers at National Jewish Medical & Research Center and the University of Colorado Health Sciences in Denver, Colorado have been awarded a five year Center grant from the NIH CounterACT Research Network to support the development of compounds to protect and treat lung and skin injury associated with mustard gas exposure. One of the lead compounds being tested in these studies is 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 ameliorate 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.

Recent studies have found that the chemical warfare agent analog, 2-chloroethyl ethyl sulfide (“CEES”)-induced lung injury could be ameliorated 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 adult respiratory distress syndrome (“ARDS”) that requires supplemental oxygen therapy to maintain adequate tissue oxygenation.

Preliminary studies suggest that AEOL 10150 at 5/mg/kg, sc dose can rescue acute lung injury responses when dosed 1 hour after the sulfur mustard gas analog exposure. The next steps are to determine whether this protective effect still occurs with authentic mustard gas and whether the compound can also provide protection against the chronic lung fibrotic effects of mustard gas exposures. This data suggests that AEOL 10150 may provide an effective countermeasure to mustard gas attacks that can be rapidly developed. We expect to conduct the study of AEOL 10150 as a protective agent against the effects on the lung of authentic mustard gas exposure during fiscal 2009. If the results of this study are positive, we would proceed to meet with the NIH and U.S. Food and Drug Administration (“FDA”) regarding the filing of a New Drug Application (“NDA”) for AEOL 10150 as a protectant against the exposure to mustard gas.

We are also in the process of testing AEOL 10150 as a protectant to the skin against exposure to mustard gas. Preliminary studies suggest that AEOL 10150 can reduce injury to the skin when dosed after the sulfur mustard gas analog exposure. The next steps are to determine whether this protective effect still occurs with authentic mustard gas. As with the study of the effects on the lung, this data suggests that AEOL 10150 may provide an effective countermeasure to mustard gas attacks that can be rapidly developed. We expect to conduct the study of AEOL 10150 as protective agent against the effects on the skin of authentic mustard gas exposure during fiscal 2009 immediately following the conclusion of the similar study for the lungs as described above.

#### AEOL 10150 as a Protectant against Radiation Exposure

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. The most important components of acute radiation sickness are the hematopoietic and gastrointestinal syndrome. However, both lethal hematopoietic and gastrointestinal syndromes are potentially avoidable with proper treatment and complications to later responding tissues may subsequently become a major problem. A nuclear incident is also 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. Research has shown that one of the primary concerns associated with the exposure to upper half body irradiation or total body irradiation is an acute but delayed onset of radiation pneumonitis with an incidence that rises

very steeply at relatively low radiation doses. Experience points out that one of the primary complications associated with the exposure to upper half body irradiation or total body irradiation is pulmonary tissue toxicity. In situations of accidental exposure, it was initially assumed that a whole-body dose exceeding 10 Gy was inevitably fatal. However, experience with nuclear accident victims suggests that when gastrointestinal and bone marrow syndromes are successfully treated, respiratory failure due to radiation pneumonitis and lung fibrosis later became the major cause of death. The goal of our research is to complete the development of a safe and effective medical product to mitigate radiation-induced pulmonary injury. AEOL 10150 has shown in preliminary studies to mitigate radiation-induced lung injury when given 2 hours, and possibly up to 8 weeks after irradiation. Our current research is aimed to determine the optimum dose level and duration of treatment to optimize mitigation of lung injury and to determine the length of the window of opportunity for initiation of treatment to achieve mitigation of lung injury. We are currently looking to confirm the efficacy of AEOL 10150 in a second model of upper-body irradiation. We expect to be able to report the results of this study during the second half of fiscal 2009.

We are also preparing to launch additional studies of AEOL 10150 to test the ability of the compound to protect lungs from exposure to radiation in the context of a nuclear accident or attack. This additional study will build on the results from the ongoing study described above. This study is designed to last 6 months and we are looking at the compound's impact on acute effects as well as pneumonitis and fibrosis. We expect to be able to report the results of this study in the first half of fiscal 2010.

Upon the completion of these studies and based upon positive results, we expect to be able to meet with representatives of the FDA to discuss the filing of an NDA for AEOL 10150 as a protectant against radiation exposure as early as fiscal 2010.

#### AEOL 10150 in Treatment of the Effects of Chlorine Gas Exposure

Because of the promise of AEOL 10150, and of our desire to find successful treatment of toxic gas inhalation, we have sought another relevant established model in which its efficacy can be tested immediately. Therefore we have considered study of another toxic oxidant gas, as or more likely than mustard gas to be used in military and civilian chemical warfare and/or terrorism events. One such gas is chlorine.

Like sulfur mustard, 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 US 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 Iraq War in the form of Chlorine bombs.

Worldwide, independent of warfare and chemical terrorism, chlorine is the greatest single cause of major toxic release incidents. In the US, 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 reactive oxygen species ("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 be a possible beneficial therapy for chlorine gas inhalation injury to the airways. We are preparing to launch a study to evaluate the potential efficacy of AEOL 10150 in rescue therapy of chlorine gas inhalation injury to the airways.

#### AEOL 10150 in Radiation Therapy

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 with an expected 566,000 Americans expected to die of cancer in 2008. In 2008, nearly 1.4 million new cancer cases are expected to be diagnosed in the United States. The National Institutes of Health ("NIH") estimates overall costs of cancer in 2007 in the United States at \$219.2 billion: \$89.0 billion for direct medical costs, \$18.2 billion for indirect morbidity costs (costs of lost productivity due to illness) and \$110.2 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 which limits the ability to escalate radiation doses in the treatment of tumors. The ability to deliver optimal radiation therapy for treatment of tumors without injury to surrounding normal tissue has important implications in oncology 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 transforming growth factor beta (TGF B) 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 1 below.

Figure 1 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.

A number of preclinical studies by Zjelko Vujaskovic, MD, PhD; Mitchell Anscher, MD, et al of 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 (one week) or long-term (ten weeks) drug administration via osmotic pumps. Animals received single dose radiation therapy of 28 Gray ("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. There were no significant differences between the irradiated controls, and the 3 groups receiving short-term administration of AEOL 10150 and single dose radiation therapy. Figure 2 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 2 above show that AEOL 10150 treatment decreases the severity of damage and increases the percentage of lung tissue with no damage from radiation therapy in a study by Zjelko Vujaskovic, MD, PhD; Mitchell Anscher, MD, et al of Duke University.

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 bid dosing regime (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- $\beta$ ) and, as demonstrated by immunohistochemistry of lung tissue, collagen deposition and TGF- $\beta$ .

An important consideration for the use of an antioxidant in radioprotection of normal adjacent tissue is the potential interference 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 affect 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.

Figure 3. 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.

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.

Figure 4 above measures tumor volume against time after implantation of RM-9 tumor cells and shows that AEOL 10150 treatment resulted in inhibition of tumor re-growth in a study performed by Dr. Gridley of Loma Linda University. Daily intraperitoneal injections of AEOL 10150 were initiated on day 1. At 12 days, approximately one half of each tumor-bearing group and control mice with no tumor were euthanized for in vitro analyses; remaining mice/group were followed for tumor growth and euthanized individually when maximum allowed tumor volume was attained. Each point represents the mean +/- standard error of the mean. Two-way analysis of the variance for days 8 to 14 revealed that group and time had highly significant main effects ( $P < 0.001$ ) and a group x time interaction was noted ( $P < 0.001$ ).

Figure 5 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.

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 also shown to be reduced in animals treated with higher doses of AEOL 10150. Studies have also shown that AEOL 10150 does not adversely affect 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.

## AEOL 10150 in ALS

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. 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.

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 6.



Table 1 and Figure 6 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.

In November 2003, the U.S. Food and Drug Administration (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.

#### 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 single 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<sub>max</sub> and AUC(0-8) appear to correlate with increases in dose, but the correlation is not strong.
- The mean C<sub>max</sub> 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<sub>max</sub> 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.

In September 2008, we launched 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 is being conducted at the University of California, Los Angeles by Martina Wiedau-Pazos, M.D., and is designed to evaluate the safety and efficacy of AEOL 10150 in an ALS patient over an extended period of time. The patient will receive a subcutaneous injection of 75mg of AEOL 10150 two times each day for up to 24 weeks. Efficacy and safety data will be monitored in real-time for the duration of the study. The primary objective of this study is to assess the clinical efficacy of AEOL 10150 with respect to the patient's baseline assessment of functional status. Secondary objectives include the assessments of muscle strength, respiratory function, quality of life and safety.

#### AEOL 11207

We have selected AEOL 11207 as our second development candidate based upon results from data obtained from our Pipeline Initiative discussed below. 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 1.5 million people in the United States, with approximately 60,000 new cases diagnosed in the United States each year. It is estimated by the National Parkinson Foundation that each patient spends an average of \$2,500 a year for medications. After factoring in office visits, Social Security payments, nursing home expenditures and lost income, the total cost to the United States is estimated to be nearly \$25 billion annually.

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.

Data developed by our scientists and Dr. Manisha Patel at 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.

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 until 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 the Aeolus 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.

#### Aeolus Pipeline

The Aeolus Pipeline Initiative is an internal development initiative focused on advancing several of the most promising catalytic antioxidant compounds from our proprietary library of compounds. The initial therapeutic focus areas for the Aeolus Pipeline Initiative are: Parkinson's disease; Cystic Fibrosis; Chronic Obstructive Lung Disease; colitis, biodefense/ radioprotection; tumor suppression/bone marrow transplantation; and stroke. These therapeutic focus areas were selected based upon preliminary data developed using our catalytic antioxidant compounds.

In addition to AEOL 11207, two Aeolus compounds from its Pipeline Initiative, AEOL 11203 and AEOL 11216, have shown very promising results in pre-clinical models and we believe have the potential to be excellent drug candidates for non-CNS indications. These compounds are also orally bioavailable. However at this time, we do not have any plans to further develop the Aeolus Pipeline compounds until funding for this purpose is obtained.

AEOL 11203 and AEOL 11216, as with all of the Aeolus compounds, are patent-protected and have the same chemical core structure as AEOL 10150. Because of this common structural feature, it is anticipated that the Aeolus compounds that are selected for clinical evaluation from the Pipeline Initiative will evidence substantially the same safety profile in clinical evaluations as observed with AEOL 10150, making clinical trial design and testing of the Aeolus compounds more robust and facile. Furthermore, all of the Aeolus compounds evidence the ability to scavenge and decrease ROS and RNS, all of which are implicated in a variety of central nervous system diseases.

#### 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 superoxide dismutase ("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 have 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. Ethylol, 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.

#### Collaborative and Licensing Arrangements

##### Duke Licenses

Through our wholly owned subsidiary, Aeolus Sciences, Inc., we have obtained exclusive worldwide rights from Duke University ("Duke") to products using antioxidant technology and compounds developed by Dr. Irwin Fridovich and other scientists at Duke. Further discoveries in the field of antioxidant research from these scientists' laboratories at Duke also are covered by the licenses from Duke. We must pay royalties to Duke on net product sales during the term of the Duke licenses, and must make payments upon the occurrence of development milestones. In addition, we are obligated under the Duke licenses to pay patent filing, prosecution, maintenance and defense costs. The Duke licenses are terminable by Duke in the event of breach by us and otherwise expire when the last licensed patent expires.

##### National Jewish Medical and Research Center License

In November 2000, we obtained an exclusive worldwide license from the National Jewish Medical and Research Center (the "NJC") 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 NJC upon the occurrence of development milestones and pay royalties on net sales. We are also obligated to pay patent filing, prosecution, maintenance and defense costs. The NJC agreement is terminable by the NJC in the event of breach and otherwise expires when the last licensed patent expires.

#### Research and Development Expenditures



Expenditures for research and development activities related to our continuing operations were \$977,000, \$1,381,000, and \$3,480,000 during the years ended September 30, 2008, 2007 and 2006, respectively. Research and development expenses for fiscal 2008 related primarily to the advancement of our lead compound, AEOL 10150.

#### Manufacturing

We currently do not have the capability to manufacture any of our product candidates on a commercial scale. Assuming the successful development of one or more of our catalytic antioxidant compounds, we plan to contract with third parties to manufacture them.

#### Commercialization

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.

## 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 product 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. The following discussion is a summary of information known to us and is not meant to be an exhaustive list of our competitors or their products or product candidates.

### 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.

### Countermeasures against Chemical Threat Agents

Our biodefense drug candidates face significant competition for U.S. government funding for both development and procurement 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 drugs candidates under development as a possible countermeasure against chemical threat agents.

### Countermeasures against Radiation Exposure

Our drug candidates face significant competition for U.S. government funding for both development and procurement 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.

### Reduction of Radiation Induced-Injury in Cancer Therapy

There are currently three drugs approved for the treatment of the side effects of radiation therapy. Amifostine (Ethyol®) is approved by the U.S. Food and Drug Administration (“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 is studying amifostine in other indications of radiation therapy. Kevivance™ (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 is also studying Kevivance as an antimucositis agent in patients with head and neck cancer, non small cell lung

cancer and colon cancer. Salagen Tablets (pilocarpine hydrochloride) ("Salagen") 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. In addition, there are many drugs under development to treat the side effects of radiation therapy.

## ALS

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.

## 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 10, 2008, our catalytic antioxidant small molecule technology base is described in eleven issued United States patents and six United States pending patent applications. These patents and patent applications belong in whole or in part to Duke or the NJC 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, 64 of which have issued as of December 10, 2008.

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 investigational new drug (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 test 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 practice (“GCP”) 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.

#### 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, of which we own 35% and Indevus Pharmaceuticals, Inc. owns 65%.

In July 1999, the Department of Veterans Affairs and the National Heart, Lung, and Blood Institute, a division of the NIH, terminated the Phase III heart failure study of bucindolol earlier than scheduled, based on an interim analysis that revealed a reduction in mortality in subpopulations that had been reported in other trials and who constituted the majority of patients in the trial, but no efficacy in some other subpopulations that had not been previously investigated in beta-blocker heart failure trials. As a result, we discontinued development of bucindolol for heart failure in 1999.

ARCA Biopharma, Inc. ("ARCA") of Broomfield, Colorado, and its academic collaborators, have reexamined this clinical trial data and have identified a genetic marker that highly correlates with patients who did not respond to bucindolol. ARCA believes that bucindolol's unique pharmacology is suitable for therapy of most heart failure patients who do not exhibit this genetic marker, in other pharmacogenetically-identified subpopulations that are ideally suited for bucindolol's novel therapeutic action, and for the treatment of ischemia in the setting of left ventricular dysfunction. In October 2003, CPEC outlicensed bucindolol to ARCA. Terms of the license call for future royalty and milestone payments to CPEC upon the development and commercialization of bucindolol.

During fiscal 2006, CPEC agreed to modify the license agreement between CPEC and ARCA and received 400,000 shares of ARCA common stock as consideration for the amendment. In addition, during fiscal 2006, CPEC received a milestone payment of \$1,000,000 as a result of ARCA completing a financing.

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 a New Drug Application for bucindolol. If approved by the FDA, bucindolol could become the first genetically targeted cardiovascular therapy. Future milestone payments and royalty payments to CPEC and Aeolus, 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 New Drug Application with the US Food and Drug Administration, we are obligated to pay \$412,500 in the form of cash or stock at our election to the majority owner of CPEC who will in turn pay the original licensors of bucindolol per the terms of the 1994 Purchase Agreement of CPEC.. The obligation is included in our financial statements under the heading "Accounts Payable."

ARCA recently announced that it will merge with Nuvelo Inc., a biopharmaceutical company, in early 2009. Under the disclosed terms of the merger agreement between ARCA and Nuvelo Inc., ARCA's shareholders will hold two-thirds of the combined entity's stock as of immediately following the merger.



## Employees

At December 10, 2008, we had one employee, John L. McManus, our President and Chief Executive Officer. Mr. McManus is not represented by a labor union. Each of our other executive officers and service providers are consultants.

## Executive Officers

Our executive officers and their ages as of December 10, 2008 were as follows:

Name	Age	Position(s)
John L. McManus	44	President and Chief Executive Officer
Brian J. Day, Ph.D.	48	Chief Scientific Officer
Michael P. McManus	39	Chief Financial Officer, Treasurer and Secretary

John L. McManus. Mr. McManus began as a consultant to the Company in June 2005 as President. He became employed as our President and Chief Operating Officer in July 2006 and was appointed President and Chief Executive Officer in March 2007. Mr. McManus, who received his degree in business administration from the University of Southern California in 1986, is the founder and president of McManus Financial Consultants, Inc. ("MFC"), which provides strategic, financial and investor relations advice to senior managements and boards of directors of public companies, including advice on mergers and acquisitions. These companies have a combined value of over \$25 billion. He has served as president of MFC since 1997. In addition, Mr. McManus previously served as Vice President, Finance and Strategic Planning to Spectrum Pharmaceuticals, Inc. 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.

Brian J. Day, Ph.D. Dr. Day is a part-time consultant and was appointed Chief Scientific Officer of Aeolus in September 2004. Dr. Day has extensive training in both pharmacology and toxicology with over 14 years experience. Since 1994 he has helped guide the design and synthesis of metalloporphyrins and has discovered a number of their novel activities in biological systems. Dr. Day has authored over 70 original scientific publications and served as a consultant to biotechnology companies for over 10 years. He is an active member of a number of scientific societies including the American Chemical Society, Society for Free Radicals in Biology and Medicine, and Society of Toxicology, where he served on the Board of Publications. Dr. Day has been at the NJC since 1997 and currently is a Professor in the Environmental and Occupational Health Sciences Division. He is one of the scientific co-founders of Aeolus and an inventor on a majority of the catalytic antioxidant program's patents.

Michael P. McManus. Mr. McManus began as a consultant to the Company in June 2005, serving as Chief Accounting Officer, Treasurer and Secretary. In July 2006, Mr. McManus was appointed Chief Financial Officer, Treasurer and Secretary. Mr. McManus has served as the Executive Vice President of MFC since 1995. MFC is a leading provider of financial, management and investor relations consulting and support services to publicly traded companies. From 2001 to 2003, Mr. McManus also served as Controller and Principal Accounting Officer of Spectrum Pharmaceuticals, Inc., where he was responsible for restructuring Spectrum's accounting and administration functions. Prior to joining MFC, from 1991 to 1995, he worked at Price Waterhouse LLP (now PricewaterhouseCoopers LLP) as an audit manager for healthcare and financial services companies. Mr. McManus is a retired Certified Public Accountant and holds a B.S. in Accounting from the University of Southern California.

#### 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 the money you paid to buy our capital stock.

##### 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, including net losses of \$3.0 million, \$3.0 million and \$5.8 million for the years ended September 30, 2008, 2007 and 2006, respectively, and we had an accumulated deficit of

approximately \$158.9 million as of September 30, 2008. Our operating losses have been due primarily to our expenditures for research and development on our product candidates and for general and administrative expenses and our lack of significant revenues. We are likely to continue to incur operating losses until such time, if ever, that we generate significant recurring revenues. We anticipate it will take a minimum of two years (and possibly longer) for us to generate recurring revenues, since 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.

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. 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 any of our products that may be approved by the FDA or any international regulatory authority.

As of September 30, 2008, we had cash of approximately \$399,000. We expect to use these funds, including any additional

funds received pursuant to the issuance of additional Senior Convertible Notes and the exercise of outstanding warrants to purchase our capital stock, to continue the development of our product candidates, to expand the development of our drug pipeline and for working capital.

We believe we have adequate financial resources to fund our current operations through the second quarter of fiscal year 2009. However, in order to fund on-going cash requirements beyond that point, or to further accelerate or expand our programs, we will need to raise additional funds. We are considering strategic and financial options available to us, including public or private equity offerings, debt financings and 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 beyond the second quarter of fiscal 2009, we would have to discontinue some or all of our activities, merge with or sell 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 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, 2008 and 2007 and our consolidated statements of operations, stockholder's equity and cash flows for the years ended September 30, 2008, 2007 and 2006, 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 limited operating history, have a history of operating losses, expect to continue to incur substantial losses and may never become profitable.

We have a limited operating history and no products approved for commercialization in the United States or abroad. Our product candidates are still being developed, and all but our AEOL 10150 candidate are still in early stages of development. Our product 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.

As of September 30, 2008, we had an accumulated deficit of \$158.9 million 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. There can be no assurance that we will be able to successfully develop or market any of our proposed products or procedures.

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 product 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 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. Product 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 product candidates may not necessarily indicate the results that will be obtained from later or more extensive testing. 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 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 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 of 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 product 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 on collaborations with third parties for the development of new products, and adverse events involving these collaborations could prevent us from developing and commercializing our product 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 product candidates. In addition, we expect to enter into agreements with third parties both to license rights to our product candidates and to develop and commercialize new products. 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 University and the National Jewish Medical and Research Center. 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 good clinical practices (“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.

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 recently 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 additional debt financing on favorable terms or at all. In addition, Federal legislation to deal with the current disruptions in the financial markets could have an adverse affect on our financial condition and results of operations.

We will need to enter into collaborative arrangements for the manufacturing and marketing of our product 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 product candidates being developed in our catalytic antioxidant program. As a result, we will need to enter into collaborative arrangements to develop, commercialize, manufacture and market products that we expect to emerge from our catalytic antioxidant program, or



develop the expertise within the company. 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. Outside the United States in some jurisdictions, 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 product 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.

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 December 10, 2008, we had one full-time employee, our President and Chief Executive Officer. We utilize consultants to assist with our operations and are highly dependent on the services of our executive officers. 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 product 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 product 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 product 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). Kevivance™ (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.

Currently, Rilutek®, which was developed by Aventis Pharma AG, is the only drug of which we are aware that has been approved by the FDA for the treatment of ALS. However, there are many companies are working to develop pharmaceuticals to

treat ALS. In addition, ALS belongs to a family of diseases called neurodegenerative diseases, which includes Alzheimer's disease, Parkinson's disease and Huntington's disease. Due to similarities between these diseases, a new treatment for one disease 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.

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 pay milestone 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 exposed to risks if we are unable to comply with changes to laws affecting public companies, including the Sarbanes-Oxley Act of 2002, and also to increased costs associated with complying with such laws.

Laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 in the U.S., 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 the Company 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.

We have reported a material weakness in the effectiveness of our internal control over financial reporting, and if we cannot maintain effective internal controls or provide reliable financial and other information, investors may lose confidence in our SEC reports.

In this Annual Report, we are reporting a material weakness in the effectiveness of our internal control over financial reporting related to adequate segregation of duties, which are described in more detail below under the heading “Controls and Procedures.” Based on the material weakness, we are also reporting in this Annual Report that our disclosure controls and procedures were not effective as of September 30, 2008.

Effective internal control over financial reporting and disclosure controls and procedures are necessary for us to provide reliable financial and other reports and effectively prevent fraud. If we cannot maintain effective internal control or disclosure controls and procedures, or provide reliable financial or SEC reports or prevent fraud, investors may lose confidence in our SEC reports, our operating results and the trading price of our common stock could suffer and we may become subject to litigation.

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, we cannot provide any assurance that governmental authorities will 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.

We may be unable to repay our substantial indebtedness and other obligations.

Under the terms of the indentures governing our debt instruments, we are obligated to repay in cash the aggregate principal balance of any such notes upon maturity and in some cases upon demand. As of the filing date of this report, we do not have available cash, cash equivalents and investments sufficient to repay all of the notes, if presented. In addition, there are no restrictions on our use of this cash and the cash available to repay indebtedness may decline over time. If we do not have sufficient funds available to repay the principal balance of notes, we will be required to raise additional funds. Because the financing markets may be unwilling to provide funding to us or may only be willing to provide funding on terms that we would consider unacceptable, we may not have cash available or be able to obtain funding to permit us to meet our repayment obligations, thus adversely affecting the market price for our securities.

We are involved in, and may become involved in the future in additional, legal proceedings that, if adversely adjudicated or settled, could materially impact our financial condition.

As a pharmaceutical company, we are or may become a party to litigation in the ordinary course of our business, including, among others, matters alleging product liability, patent or other intellectual property rights infringement, patent invalidity or breach of commercial contract. In general, litigation claims can be expensive and time consuming to bring or defend against and could result in settlements or damages that could significantly impact results of operations and financial condition. We currently are vigorously pursuing the claims as more fully disclosed in Part I, Item 3 of this Annual Report on Form 10-K. While we currently do not believe that the settlement or adverse adjudication of this litigation matter would materially impact our results of operations or financial condition, the final resolution of this matter and the impact, if any, on our results of operations, financial condition or cash flows is unknown but could be material.

We invest in securities that are subject to market risk and the recent issues in the financial markets could adversely affect the value of our assets.

At September 30, 2008, \$440,000 of our marketable securities portfolio is invested in AA and AAA rated investments in auction-rate debt securities. Auction-rate securities are long-term variable rate bonds tied to short-term interest rates. After the initial issuance of the securities, the interest rate on the securities is reset periodically, at intervals established at the time of issuance (e.g., every seven, twenty-eight, or thirty-five days; every six months; etc.), based on market demand for a reset period. Auction-rate securities are bought and sold in the marketplace through a competitive bidding process often referred to as a “Dutch auction”. If there is insufficient interest in the securities at the time of an auction, the auction may not be completed and the rates may be reset to predetermined “penalty” or “maximum” rates. Following such a failed auction, we would not be able to access our funds that are invested in the corresponding auction-rate securities until a future auction of these investments is successful or new buyers express interest in purchasing these securities in between reset dates.

In February 2008, auctions for our auction-rate securities failed rendering these securities illiquid through the normal auction process. At the time of our initial investment and through the date of this Report, all of our auction-rate securities in which we invest remain AA and AAA rated. The underlying assets of our auction-rate securities are student loans. Student loans are insured by either the Federal Family Education Loan Program (FFELP), a combination of FFELP and other monoline insurers such as Ambac Assurance Corp. (“AMBAC”) and MBIA Insurance



Corp. (MBIA) or AMBAC. As of September 30, 2008, AMBAC was rated A3 by Moody's and A by Standard and Poor's. Although these insurers are highly rated, they are reported to be experiencing financial difficulty, which could negatively affect their ratings and thus the ratings of the auction-rate securities that we hold. If the underlying issuers are unable to successfully clear future auctions or if their credit rating deteriorates and the deterioration is deemed to be other-than-temporary, we would be required to adjust the carrying value of the auction-rate securities through an impairment charge to earnings. Any of these events could materially affect our results of operations and our financial condition. In the event we need to access these funds, we could be required to sell these securities at an amount below our original purchase value. In October 2008, we entered into an agreement with UBS Financial Services, Inc. ("UBS") in which UBS has agreed to repurchase our auction-rate securities anytime after January 2, 2009 at the original purchase price. Based on the agreement with UBS and our ability to access our cash and cash equivalents, our existing financing arrangements and our expected operating cash flows, we do not expect to be required to sell these securities at a loss.

## 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 December 10, 2008, Xmark Opportunity Partners, LLC (“Xmark”) possessed voting power over 15,247,323 shares, or 47.6%, of our common stock outstanding, 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 Opportunity Partners, LLC and the Company (the “Xmark Voting Trust”) with respect to 1,000,000 shares. In addition, the Xmark Funds own \$1,000,000 of our Senior Convertible Notes which are convertible into 2,857,142 shares of our common stock at the election of Xmark. 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.

Also as of December 10, 2008, Efficacy Capital Ltd. (“Efficacy Capital”) owned 9,800,000 shares, or 30.6%, of our outstanding common stock, through its management of Efficacy Biotech Master Fund Ltd. As a result, Efficacy Capital 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 Efficacy Capital may be different than the interests of other stockholders on these and other matters. This concentration of ownership could also 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.

We may need to sell additional shares of our common stock, preferred stock or other securities to meet our capital requirements. If we need to sell additional shares of our common stock, preferred stock or other securities to meet our capital requirements, or upon conversion of our preferred stock and exercises of currently outstanding options and warrants, the ownership interests of our current stockholders could be substantially diluted. The possibility of dilution posed by shares available for future sale could reduce the market price of our common stock and could make it more difficult for us to raise funds through equity offerings in the future.

As of December 10, 2008, we had 32,030,874 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 Option Plan. In addition, as of December 10, 2008, options to purchase 4,285,281 shares were outstanding at exercise prices ranging from \$0.32 to \$51.25 per share, with a weighted average exercise price of \$2.48 per share, and 2,524,895 shares were reserved for issuance under the 2004 Stock Option Plan. In addition, as of December 10, 2008, warrants to purchase 15,988,668 shares of common stock were outstanding at exercise prices ranging from \$0.35 to \$4.00 per share, with a weighted exercise price of \$0.99 per share. The Company also has \$1,000,000 in Senior Convertible Notes outstanding which, as of December 10, 2008, were convertible into 2,857,142 shares of our common stock. In addition, we have reserved 30,500,000 shares of our common stock for any future issuances of Senior Convertible Notes, the payment of interest on the Senior Convertible Notes and a reserve for any future adjustments. We have also reserved 475,087 shares of common stock for the conversion of our outstanding Series B Preferred stock.

In connection with prior collaborations and financing transactions, we also have issued Series B preferred stock and a promissory note convertible into 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 exercise or 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 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 \$0.25 to \$1.50 during the last two years.

Our common stock is quoted on the OTC Bulletin Board 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 Efficacy Capital and Xmark (through its management of Goodnow and the Xmark Funds), 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. 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 preferred stock, warrants to purchase Series B preferred stock and a promissory note 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 preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, 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.

Future sales of our common stock could adversely affect its price.

Sales of substantial amounts of common 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.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

None.

Item 3. Legal Proceedings.

In June 2008, we filed an arbitration and mediation claim against UBS Financial Services, Inc., UBS Securities, LLC and UBS International, Inc. (collectively “UBS”) with the Financial Industry Regulatory Authority. The claim seeks rescission of the purchase transactions of our four auction-rate securities, reimbursement for lost interest income and lost revenue due to delays in the development of its drug candidates and punitive damages. UBS did not agree to mediation and the request for mediation was dismissed. In regards to the arbitration claim, UBS requested and we agreed to two extensions to the UBS’ deadline to file a response to the arbitration claim. In October 2008, UBS filed a response to our arbitration claim denying all allegations and seeking recovery of legal fees and costs. Also in October 2008, we received notification from UBS that it has entered into a settlement agreement with the New York Attorney General in which UBS agreed to repurchase certain auction-rate securities of certain of its clients at par value for which all of our auction-rate securities are included in the settlement with the New York

Attorney General. UBS indicated that we can exercise the option for UBS to repurchase for a two year period beginning January 2, 2009. We have submitted the required documentation and intend to exercise our option to sell the four auction-rate securities to UBS on January 2, 2009. We are currently in the discovery phase of the arbitration proceeding. We intend to pursue the arbitration claim vigorously; however there can be no assurance as to the ultimate outcome of this claim.

#### Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted to us by a vote of the security holders during the quarter ended September 30, 2008.

## PART II

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

##### (a) 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, 2007		
October 1, 2006 through December 31, 2006	\$ 0.85	\$ 0.51
January 1, 2007 through March 31, 2007	\$ 0.75	\$ 0.34
April 1, 2007 through June 30, 2007	\$ 1.50	\$ 0.51
July 1, 2007 through September 30, 2007	\$ 1.01	\$ 0.37
Fiscal Year Ended September 30, 2008		
October 1, 2007 through December 31, 2007	\$ 0.55	\$ 0.33
January 1, 2008 through March 31, 2008	\$ 0.40	\$ 0.31
April 1, 2008 through June 30, 2008	\$ 0.48	\$ 0.32
July 1, 2008 through September 30, 2008	\$ 0.45	\$ 0.25

##### (b) Approximate Number of Equity Security Holders

As of December 10, 2008, the number of record holders of our common stock was 179 and we estimate that the number of beneficial owners was approximately 2,100.

(c) 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. 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.

In addition, we cannot pay a dividend on our common stock without the prior approval of Goodnow Capital pursuant to the terms of the Debenture and Warrant Purchase Agreement dated September 16, 2003 between us and Goodnow. This restriction will expire on the earliest of:

- the date that Goodnow owns less than 20% of our outstanding common stock on an as converted basis;
- the completion, to the absolute satisfaction of Goodnow, of initial clinical safety studies of AEOL 10150 and analysis of the data developed based upon such studies with the results satisfactory to Goodnow, in its absolute discretion, to initiate efficacy studies of AEOL 10150 in humans; or
  - the initiation of dosing of the first human patient in an efficacy-based study of AEOL 10150.

In addition, we cannot pay a dividend on our common stock without the prior approval of Xmark Opportunity Fund, L.P. and Xmark Opportunity Fund, Ltd. (collectively, the “Xmark Funds”) pursuant to the terms of the Senior Convertible Notes dated

August 1, 2008, September 4, 2008, November 3, 2008 and December 1, 2008 between us and the Xmark Funds. This restriction will expire on the conversion or repayment of all outstanding Senior Convertible Notes.

(d) Equity Compensation Plan and Additional Equity Information as of September 30, 2008

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	2,258,441	\$ 0.70	2,574,895
1994 Stock Option Plan	1,976,840	\$ 4.57	0
Equity compensation plans and securities not approved by our stockholders:			
Warrant to Purchase Common Stock Issued to Brookstreet Securities Corporation	250,000	\$ 1.50	Not applicable
Warrant to Purchase Common Stock Issued to TBCC Funding Trust II (1)	1,759	\$ 19.90	Not applicable
Total – Common Stock	4,487,040		2,574,895
Convertible Promissory Note convertible into shares of Series B Preferred Stock Issued to Elan Pharma International Limited (as of September 30, 2008)(2)(3)			
	59,316	\$ 9.00	2,151
Total – Series B Preferred Stock	59,316		2,151

(1) This Warrant expired unexercised on October 30, 2008.

(2) As of September 30, 2008, each share of Series B preferred stock was convertible into one share of common stock.

(3) The conversion value of the note will increase by its 10% interest rate until its maturity on February 8, 2009.

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

The warrants to purchase shares of our common stock issued to Brookstreet Securities Corporation (“Brookstreet”) have not been approved by our stockholders. In May 2006, we entered into an agreement with Brookstreet to provide us with financial advisory services for a one-year period. For these services, 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 vest on May 24, 2006, August 22, 2006, November 20, 2006, February 18, 2007 and May 19, 2007, respectively. The warrants are exercisable for five years.



The warrant to purchase shares of our common stock issued to TBCC Funding Trust II has not been approved by our stockholders. This warrant was issued in October 2001 in connection with the execution of a Master Loan and Security Agreement with Transamerica Technology Finance Corporation. We borrowed \$565,000 from Transamerica in October 2001. The warrant expired unexercised on October 30, 2008.

(e) Stock Performance Graph

The following graph shows a five-year comparison of cumulative total stockholder returns for Aeolus, the Nasdaq Stock Market (U.S.) Index and the Nasdaq Biotech Index. The graph and data below assume that \$100 was invested on September 30, 2003 in each of Aeolus' Common Stock, the stocks in the Nasdaq Stock Market (U.S.) Index and the stocks in the Nasdaq Biotech Index, and further assumes the reinvestment of all dividends.

	9/30/03	9/30/04	9/30/05	9/30/06	9/30/07	9/30/08
Aeolus Pharmaceuticals, Inc.	\$ 100.00	\$ 50.67	\$ 37.33	\$ 26.67	\$ 17.00	\$ 15.00
Nasdaq Stock Market (U.S.)	\$ 100.00	\$ 106.69	\$ 121.83	\$ 128.92	\$ 155.36	\$ 121.35
Nasdaq Biotech Index	\$ 100.00	\$ 99.20	\$ 109.01	\$ 104.80	\$ 118.78	\$ 116.65

#### (f) Recent Sales of Unregistered Securities

On August 1, 2008, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with three accredited institutional investors (the "Investors") pursuant to which the Company agreed to sell to the Investors units comprised of senior unsecured convertible notes of the Company (the "Notes"), in an aggregate principal amount of up to \$5,000,000, which shall bear interest at a rate of 7% per year and mature on the 30-month anniversary of their date of issuance, and warrants to purchase up to an aggregate of 10,000,000 additional shares of Common Stock (the "Warrant Shares"), each with an initial exercise price of \$0.50 per share, subject to adjustment pursuant to the warrants (the "Warrants") (collectively the "SCN Financing"). Each unit (collectively, the "Units") is comprised of \$1,000 in Note principal and Warrants to purchase up to 2,000 shares of the Company's common stock, par value \$0.01 per share (the "Common Stock"), and has a purchase price of \$1,000.

On August 1, 2008, the Company sold and issued to the Investors 500 Units comprised of Notes in the aggregate principal amount of \$500,000 and Warrants to purchase up to 1,000,000 shares of Common Stock for an aggregate purchase price of \$500,000 (the "Financing").

The Investors have also agreed and completed the purchase of an additional 125 Units on each of September 4, 2008, October 1, 2008, November 3, 2008 and December 1, 2008 (the "Subsequent Financing"), in each case for an aggregate purchase price of \$125,000. Each of the Subsequent Closings has occurred in accordance with the terms of the Purchase Agreement. The Notes issued in the Financing, the Subsequent Financing and at the Subsequent Closings have an initial conversion price of \$0.35 per share, subject to adjustment pursuant to the Notes. In addition, the Investors have the option to purchase up to an additional 4,000 Units, in one or more closings (each, an "Election Closing"), and at their sole option at any time on or before February 1, 2010. Any additional Units sold at an Election Closing would also be sold by the Company at a purchase price of \$1,000 per Unit, except that the initial conversion price of the Notes issued in an Election Closing will equal the volume weighted average closing sale price for the Common Stock for the sixty consecutive trading day period ending on the trading day immediately preceding such Election Closing, provided that such initial conversion price may not be less than \$0.20 per share or greater than \$0.75 per share, in each case subject to adjustment pursuant to the Note.

The Notes are and will be convertible, at the Investors' sole election, into shares of Common Stock at any time and from time to time. The conversion price of the Notes (including the \$0.20 floor and \$0.75 ceiling price with respect to Notes issued at Election Closings) and the exercise price of the Warrants are subject to adjustment in the event of a stock dividend or split, reorganization, recapitalization or similar event. Additionally, the conversion price of the

Notes and the exercise price of the

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Warrants may be reduced in the event the Company issues securities at a price per share lower than the then current conversion price of the Notes. The Notes are due and payable in cash at the aggregate principal value plus accrued interest 30 months from the date of issuance if not converted earlier by the Investors.

Interest on the Notes accrues at the rate of 7.0% per annum from the date of issuance, and is payable semi-annually, on January 31 and July 31 of each year. Interest shall be payable, at the Company's sole election, in cash or shares of Common Stock, to holders of Notes on the record date for such interest payments, with the record dates being each January 15 and July 15 immediately preceding an interest payment date.

The Warrants are exercisable for a five year period from the date of issuance and contain a "cashless exercise" feature that allows the Investors to exercise the Warrants without a cash payment to the Company under certain circumstances.

These 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. The agreements executed in connection with the Financing contain representations to support the Company's reasonable belief that each Investor had access to information concerning the Company's operations and financial condition, each Investor 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 Investor 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; the Company made no solicitation in connection with the Financing other than communications with the Investors; the Company obtained representations from each Investor regarding its investment intent, experience and sophistication; and each Investor either received or had access to adequate information about the Company 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.

(g) Purchase of Equity Securities by the Issuer and Affiliated Purchases

None.

#### Item 6. Selected Financial Data.

You should 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 Form 10-K. We derived the consolidated statements of operations data for the five fiscal years ended September 30, 2008 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, 2005 and 2004 and the consolidated balance sheet data at September 30, 2006, 2005 and 2004, each of these consolidated financial statements are included elsewhere in this Form 10-K. All common stock amounts have been adjusted for a one-for-ten reverse stock split effected in July 2004.

## Statement of Operations Data:

	2008	Year Ended September 30,				2004
		2007	2006	2005		
		(in thousands, except per share data)				
Revenue:						
Grant income and contract revenue	\$ —	\$ —	\$ 92	\$ 252	\$ 305	
Costs and expenses:						
Research and development	977	1,381	3,480	4,515	8,295	
General and administrative	1,540	1,919	2,216	2,674	3,987	
Total costs and expenses	2,517	3,300	5,696	7,189	12,282	
Loss from operations	(2,517 )	(3,300 )	(5,604 )	(6,937 )	(11,977 )	
Other income (expenses), net	(405)	225	(118)	63	23	
Interest income (expense), net	(51)	51	(6)	(31 )	(5,213 )	
Net loss	(2,973 )	(3,024 )	(5,728 )	(6,905 )	(17,167 )	
Preferred stock dividend and accretion	—	—	(81)	—	(135 )	
Net loss attributable to common stockholders	\$ (2,973 )	\$ (3,024 )	\$ (5,809 )	\$ (6,905 )	\$ (17,302 )	
Basic net loss per share attributable to common stockholders	\$ (0.09 )	\$ (0.10 )	\$ (0.31 )	\$ (0.49 )	\$ (2.06 )	
Diluted net loss per share attributable to common stockholders	\$ (0.11 )	\$ (0.10 )	\$ (0.31 )	\$ (0.49 )	\$ (2.06 )	
Weighted average common shares outstanding:						
Basic	31,953	30,239	18,926	13,976	8,388	
Diluted	32,217	30,239	18,926	13,976	8,388	

## Balance Sheet Data:

	2008	2007	September 30,		2004
			2006	2005	
			(in thousands)		
Cash and cash equivalents and marketable securities	\$ 399	\$ 1,727	\$ 3,324	\$ 626	\$ 7,381
Working capital (deficiency)	\$ (1,336)	\$ 1,538	\$ 1,581	\$ (73 )	\$ 6,093
Total assets	\$ 1,120	\$ 1,931	\$ 3,554	\$ 937	\$ 7,856
	\$ 534	\$ 483	\$ —	\$ 867	\$ 787

Long-term portion of capital  
lease obligations and notes  
payable

Total liabilities	\$ 2,157	\$ 751	\$ 1,847	\$ 1,869	\$ 2,324
Total stockholders' equity (deficit)	\$ (1,037)	\$ 1,180	\$ 1,707	\$ (932 )	\$ 5,532

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

### Introduction

You should read the following discussion in conjunction with our consolidated financial statements and the notes appearing elsewhere in this 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 Form 10-K.

### Overview

We are developing a series of catalytic antioxidant molecules to protect against the damaging effects of reactive oxygen derived molecules, commonly referred to as free radicals. Free radicals cause damage in a broad group of diseases and conditions. Our initial target indications are as a protective agent against the effects of mustard gas exposure, as a protective agent against radiation exposure, cancer radiation therapy, as a protective agent against the effects of chlorine gas exposure and amyotrophic lateral sclerosis, also known as "ALS" or "Lou Gehrig's disease." 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 also have a long-term clinical trial underway in a single patient with ALS to test the efficacy and further test the safety of AEOL 10150. However, further development of AEOL 10150 for the treatment of ALS and cancer radiation therapy, if any, will be dependent upon future specific financing for this development or a partnership and the results of our ongoing studies of AEOL 10150 for the treatment of mustard gas exposure and chlorine gas exposure.

We do not have any recurring revenue and therefore we must rely on public or private equity offerings, debt financings, collaboration arrangements or grants to finance our operations.

We had net losses attributable to common stockholders of \$2,973,000 and \$3,024,000 for the fiscal years ended September 30, 2008 and 2007, respectively. We had an accumulated deficit of \$158,899,000 at September 30, 2008. We have not yet generated any revenue from product sales and do not expect to receive any product revenue in the foreseeable future, if at all.

#### Corporate Matters

On November 21, 2005, we completed a private placement of an aggregate of 1,250,000 shares of our Series A Convertible Preferred Stock and warrants to purchase up to an aggregate of 2,500,000 shares of common stock for aggregate net proceeds of approximately \$2,400,000 (the "2005 Financing"). Each share of the Series A preferred stock, which had a stated value of \$2.00 per share, was initially convertible into two shares of common stock at any time at the election of the holders thereof. The warrants had an initial exercise price of \$1.00 per share.

On June 5, 2006, we completed a private placement of 10,000,000 shares of our Common Stock, warrants to purchase up to an aggregate of 7,000,000 shares of common stock with an exercise price of \$0.75 per share and a five year term and warrants to purchase up to an aggregate of 4,000,000 shares of common stock with an exercise price of \$0.50 per share and a one year term (which expired on June 5, 2007 without being exercised) for aggregate net proceeds of approximately \$4,754,000 (the "2006 Financing").

In connection with the 2006 Financing, all outstanding shares of the Series A Preferred Stock were converted into an aggregate of 5,000,000 shares of common stock. In addition, the exercise price of the warrants to purchase up to an aggregate of 2,500,000 shares of common stock issued in the 2005 Financing were lowered from \$1.00 per share to \$0.50 per share in accordance with the terms of the warrants.

On May 22, 2007, we completed a private placement of 2,666,667 shares of our Common Stock, warrants to purchase up to an aggregate of 2,000,001 shares of common stock with an exercise price of \$0.75 per share and a five year term for aggregate net proceeds of approximately \$1,761,000 (the "2007 Financing").

On August 1, 2008, we completed a private placement pursuant to which the Company agreed to sell to the Investors units comprised of senior unsecured convertible notes of the Company (the "Notes"), in an aggregate principal amount of up to \$5,000,000, which shall bear interest at a rate of 7% per year and mature on the 30-month anniversary of their date of issuance, and warrants to purchase up to an aggregate of 10,000,000 additional shares of Common Stock, each with an initial exercise price of \$0.50 per share, subject to adjustment pursuant to the warrants. Each unit (collectively, the "Units") is comprised of \$1,000 in Note principal and Warrants to purchase up to 2,000 shares of the Company's common stock, par value \$0.01 per share (the "Common Stock"), and has a purchase price of \$1,000. On August 1, 2008, the Company sold and issued to the Investors 500 Units comprised of Notes in the aggregate principal amount of \$500,000 and Warrants to purchase up to 1,000,000 shares of Common Stock for an aggregate purchase price of \$500,000 (the "Financing"). On September 4, 2008, the Company sold and issued to the Investors 125 Units comprised of Notes in the aggregate principal amount of \$125,000 and Warrants to purchase up to 250,000 shares of Common Stock for an aggregate purchase price of \$125,000 (the "Subsequent Financing").

#### Results of Operations

Fiscal Year Ended September 30, 2008 Compared to Fiscal Year Ended September 30, 2007

We had a net loss attributable to common stockholders of \$2,973,000 for the fiscal year ended September 30, 2008, versus a net loss attributable to common stockholders of \$3,024,000 for fiscal 2007.

We did not generate any revenues through the sale of our drug candidates or grants during fiscal 2008 or fiscal 2007.

#### Research and Development

Research and development (“R&D”) expenses decreased \$404,000, or 29%, to \$977,000 for fiscal 2008 from \$1,381,000 for fiscal 2007. The lower level of R&D expenses during the current period reflects a lower amount of employment, consulting and manufacturing expenses offset by a higher level of pre-clinical and patent expenses. Employment and consulting expenses were \$152,000 during fiscal 2008 versus \$434,000 during fiscal 2007. The decline in employment and consulting expenses reflects that we were completing our multiple dose clinical trial and were in the process of manufacturing bulk quantities of our lead drug candidate, AEOL 10150, during fiscal 2007, whereas during the current year we had restructured our research program to utilize outside research institutions and grants to perform our research activities and therefore had a lower level of employment and consulting expenses. During fiscal 2008, manufacturing costs were \$136,000 compared to \$526,000 during fiscal 2007. Offsetting these declines was an increase of \$335,000 in outside research services as a result of our transition to outsourcing of research activities during the current period and \$130,000 in patent fees as a result of an increase in patent filing activity.



R&D expenses for our antioxidant program have totaled \$34,511,000 from inception through September 30, 2008. 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 2009 will be higher than fiscal 2008 as we may initiate additional studies of AEOL 10150. Our ongoing cash requirements will also depend on numerous factors, particularly the progress of our R&D programs and our ability to negotiate and complete collaborative agreements.

#### General and Administrative

General and administrative 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.

General and administrative (“G&A”) expenses decreased \$379,000, or 20%, to \$1,540,000 for fiscal year 2008 from \$1,919,000 for fiscal year 2007. G&A expenses were lower during fiscal year 2008 versus fiscal year 2007 due to a decline in employment costs, stock compensation expense and investor relations expense. Employment costs declined by \$156,000 during fiscal 2008 compared to fiscal 2007, as the current year reflects employment costs of our sole employee, our Chief Executive Officer, whereas the prior year includes employment costs of two additional executive officers as well as severance and bonus costs to three executive officers. Stock compensation expense decreased by \$216,000 as a result of the lower headcount during the current year. Investor relations expenses declined by \$54,000, as a result of a decrease in the level of activity for our investor relations program. Offsetting these declines were increased consulting expenses in the amount of \$65,000 for market analysis and out-licensing analysis for our drug candidates.

During fiscal 2008, CPEC LLC (“CPEC”) received a milestone payment from ARCA Biopharma, Inc., a privately held cardiovascular-focused company (“ARCA”). In 2003, CPEC, of which we own 35%, out-licensed all rights to a potential therapeutic compound referred to as “bucindolol” to ARCA. During fiscal 2008, CPEC received a milestone payment of \$500,000 as a result of ARCA filing a New Drug Application for bucindolol. We recorded \$175,000 of income during fiscal 2008 as a result of our equity ownership of CPEC LLC. Also as a result of the filing of the New Drug Application with the US Food and Drug Administration, we are obligated to pay \$413,000 in the form of cash or stock at our election to the majority owner of CPEC who will in turn pay the original licensors of bucindolol per the terms of the 1994 Purchase Agreement of CPEC. The obligation is included in our financial statements under the heading “Accounts Payable.”

We incurred net interest expense of \$51,000 during fiscal year 2008 compared to net interest income of \$51,000 for fiscal year 2007. The change reflects higher interest expense as a result of the issuance of the Senior Convertible Note which bear interest at a rate of 7% as well as the related amortization of debt issuance costs and a note issuance discount. Interest expense also increased as a result of a higher average balance of our note payable with Elan and the draws on our margin loan with UBS Financial Services, Inc. Interest income on our investments also decreased due to a lower level of investable assets as well as a lower level of interest rates during fiscal 2008 versus fiscal 2007.

During fiscal 2008 as a result of the issuance of Senior Convertible Notes, we were required to lower the exercise price of 4,687,000 warrants previously issued in our November 2005 Financing and in our 2007 Financing to \$0.35 per share, the conversion price of the Senior Convertible Notes issued on August 1, 2008. As a result of the change in the exercise price, these warrants were revalued resulting in an increase in the value of \$118,000 which was charged to the statement of operations.

During fiscal 2008, we recorded an “other-than-temporary” impairment charge of \$49,000 based upon reduced market values of our auction-rate securities as determined based upon investment statements received from UBS Financial Services, Inc. During fiscal 2008, the auction rate securities which the Company has invested in have experienced auction failures as a result of the current disruptions in the credit markets. This is the first time the Company has experienced this type of event for its holdings of auction-rate securities and the Company believes that prior to February 13, 2008, the Company’s investment advisor, UBS, had not had a failed auction. The Company understands that the failure of auctions is broad based and not limited to those securities held by the Company. As a result of the failed auctions, our auction-rate securities are currently not liquid. Furthermore, the Company cannot predict how long they will remain illiquid.

During fiscal 2007, we recognized \$225,000 in income as a result of the forgiveness of a portion of the principal balance of a note payable from Elan Corporation, plc. (“Elan”). In connection with the termination of a note payable and issuance of a new note payable, we paid \$300,000 in cash to Elan, Elan and the Company entered into a new note payable in the amount of \$453,000 for a period of two years under substantially the same terms as the original note and Elan forgave \$225,000 of the original note payable.

Fiscal Year Ended September 30, 2007 Compared to Fiscal Year Ended September 30, 2006

We had a net loss attributable to common stockholders of \$3,024,000 for the fiscal year ended September 30, 2007, versus a net loss attributable to common stockholders of \$5,809,000 for fiscal 2006.

In August 2003, we were awarded a \$100,000 Small Business Innovation and Research (“SBIR”) Phase I grant from the National Cancer Institute, a division of the NIH. In March 2004, we were awarded up to \$375,000 for the first year of a SBIR Phase II grant and received approval for a second year of the Phase II grant program in January 2005. Pursuant to the grants, we are studying the antitumor and radiation-protective effects of our catalytic antioxidants. The study is a collaboration between us and the Department of Radiation Oncology at Duke University Medical Center. We recognized zero and \$92,000 of grant income during fiscal year 2007 and 2006, respectively from our SBIR grant from the National Cancer Institute. We do not expect to earn further grant revenues as work under our SBIR grant has been completed.

Research and Development

Research and development (“R&D”) expenses decreased \$2,099,000, or 60%, to \$1,381,000 for fiscal 2007 from \$3,480,000 for fiscal 2006. Our primary operational focus and R&D spending during fiscal year 2007 was on finalizing our Phase I multiple dose clinical trial for the treatment of ALS, planning the future clinical and development plan for AEOL 10150 and AEOL 11207 as well as advancing additional drug candidates in our pipeline, while our primary operational focus and R&D spending during fiscal year 2006 was on conducting our Phase I multiple dose clinical trial for the treatment of ALS and the advancement of the Aeolus Pipeline Initiative. Clinical trial expenses for fiscal year 2007 were \$64,000 compared to \$1,233,000 during fiscal year 2006. Preclinical expenses primarily related to the development of additional drug candidates in our pipeline for fiscal year 2007 were \$72,000, whereas preclinical expenses during fiscal year 2006 were \$585,000. Patent fees also decreased by \$629,000 during the current year as we were in the process of validating several patents internationally during fiscal 2006 while no such activity occurred during fiscal 2007. Offsetting these declines was an increase of \$400,000 in contract manufacturing and chemistry costs.

General and Administrative

General and administrative 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 buildings and equipment, depreciation, utilities, information technology and procurement costs that we need to support the corporate functions listed above.

General and administrative (“G&A”) expenses decreased \$297,000, or 13%, to \$1,919,000 for fiscal year 2007 from \$2,216,000 for fiscal year 2006. G&A expenses were lower during fiscal year 2007 versus fiscal year 2006 due to our efforts to decrease the level of services provided by consultants resulting in a decline of \$160,000 in legal and professional fees and a decline of \$135,000 in employee compensation. Offsetting these decline were increased non-cash stock expenses in the amount of \$132,000.

During fiscal 2007, we recognized \$225,000 in income as a result of the forgiveness of a portion of the principal balance of a note payable from Elan Corporation, plc. (“Elan”). In connection with the termination of a note payable and issuance of a new note payable, we paid \$300,000 in cash to Elan, Elan and the Company entered into a new note payable in the amount of \$453,000 for a period of two years under substantially the same terms as the original note and Elan forgave \$225,000 of the original note payable.

During fiscal 2006, CPEC LLC, received a milestone payment and equity consideration from ARCA Discovery, Inc., a privately held cardiovascular-focused company ("ARCA"). In 2003, CPEC LLC ("CPEC"), of which we own 35%, out-licensed all rights to a potential therapeutic compound referred to as "bucindolol" to ARCA. During fiscal 2006, CPEC agreed to modify the license agreement between CPEC and ARCA and received 400,000 shares of ARCA common stock as consideration for the amendment. In addition, during fiscal 2006, CPEC received a milestone payment of \$1,000,000 as a result of ARCA completing a financing. We recorded \$433,000 of income during fiscal 2006 as a result of our equity ownership of CPEC LLC.

In accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock," and the terms of the warrants and the transaction documents in our 2005 Financing and 2006 Financing, at the closing dates, November 21, 2005 and June 5, 2006, respectively, the fair value of the warrants issued in the financings were initially accounted for as liabilities until the date the applicable registration statement registering the shares underlying the warrants was declared effective by the Securities and Exchange Commission. The warrant liabilities were revalued at each balance sheet date until the EITF 00-19 equity classification requirements were satisfied and changes in fair value were charged to the statement of operations. Between November 21, 2005 and March 1, 2006, the fair value of the 2005 Financing warrants decreased by \$401,000 which was credited to the statement of operations. On March 1, 2006, the Securities and Exchange Commission declared the registration statement registering the shares underlying the warrants in the 2005 Financing effective and

accordingly the warrant liability was reclassified to additional paid in capital. During the period from June 5, 2006 to July 31, 2006, the fair value of the 2006 Financing warrants increased by \$901,000 which was charged to the statement of operations. On July 31, 2006, the Securities and Exchange Commission declared the registration statement registering the shares underlying the warrants issued in the 2006 Financing effective and accordingly the warrant liability was reclassified to additional paid in capital. No such liability was required during the current year for the May 2007 financing. The warrant liability and revaluations have not and will not have any impact on the Company's working capital, liquidity, or business operations.

In connection with the 2006 Financing, we were required to reduce the exercise price of the 2005 Financing warrants to purchase 2,500,000 shares of common stock from \$1.00 per share to \$0.50 per share, the purchase price of the common stock issued in the 2006 Financing. As a result of the change in the exercise price, these warrants were revalued resulting in an increase in their value of \$105,000 which was charged to the statement of operations.

We accreted \$81,000 of dividends on our Series A preferred stock during fiscal 2006. All of the outstanding Series A Convertible Preferred Stock was converted into common stock in fiscal 2006 and we no longer accrete dividends on the Series A Convertible Preferred Stock.

#### Liquidity and Capital Resources

At September 30, 2008, we had \$399,000 of cash, a decrease of \$1,328,000 from September 30, 2007. The decrease in cash from September 30, 2007 to 2008 was primarily due to our fiscal 2008 operating expenses offset by the Senior Convertible Note financing. During fiscal 2008, we sold \$625,000 senior convertible notes with an additional \$375,000 issued between October 1, 2008 and December 1, 2008. The investors also have an option to invest an additional \$4.0 million over the next eighteen months. We believe we have adequate financial resources (not including any possible additional investments of \$4.0 million which are at the option of the investors) to conduct operations into the second quarter of fiscal year 2009. This raises substantial doubt about our ability to continue as a going concern, which will be dependent on our ability to generate sufficient cash flows to meet our obligations on a timely basis, to obtain additional financing and, ultimately, to achieve operating profit.

We incurred operational losses of \$2,517,000 during fiscal 2008. Our ongoing 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 will need to raise additional funds and explore other strategic and financial alternatives, including a merger with another company and the establishment of new collaborations for current research programs that include initial cash payments and ongoing research support, or 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 a 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. It generally is difficult for small biotechnology companies like us to raise funds in the equity markets. Any additional equity financing, if available, would likely 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, 2008 were as follows:

Contractual Obligations	Total	Payments due by period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-term debt	\$ 1,544	\$ 919	\$ 625	\$ —	\$ —
Capital lease obligations	—	—	—	—	—
Operating leases	—	—	—	—	—
Purchase obligations	1,682	1,682	—	—	—
Total	\$ 3,226	\$ 2,601	\$ 625	\$ —	\$ —

#### 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 have operating leases, which are generally for office and laboratory space. In accordance with accounting principles generally accepted in the United States, operating leases are not reflected in the accompanying consolidated balance sheets. We do not have any capital leases.

#### Relationship with Goodnow Capital 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 \$8.0 million in secured bridge financing in the form of convertible promissory notes we issued to Goodnow Capital, L.L.C. 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 its wholly owned subsidiaries. Upon consummation of the merger, a \$3.0 million note held by Goodnow, including accrued interest, converted into 3,060,144 shares of our common stock. On April 19, 2004, we sold \$10.26 million of our common stock in a private placement. In conjunction with the private placement, Goodnow voluntarily converted a \$5.0 million debenture, including accrued interest thereon, into 5,046,875 shares of our common stock, which, along with the 3,060,144 shares issued in the merger and the 20 shares that Goodnow owned before the consummation of the merger, represented 58.1% of the shares of our common stock outstanding on November 30, 2004. As of December 10, 2008, Xmark Opportunity Partners, LLC, through its management of Goodnow and the Xmark Funds, and through the Xmark Voting Trust, had beneficial ownership over 57.0% of our outstanding common stock. As a result of this significant ownership, Goodnow is able to significantly influence, if not control, future actions voted on by stockholders of our company.

As part of the \$8.0 million financing from Goodnow, we agreed:

- to secure the \$8.0 million debt with liens on all of our assets, which liens expired on April 19, 2004 when the remaining debt converted to shares of common stock;
- to spend the financing proceeds only in accordance with a budget and development plan agreed to by Goodnow;
- to not enter into any arrangement with a party other than Goodnow in which we would raise capital through the issuance of our securities other than the raising of up to an aggregate of \$20,000,000 through the issuance of shares of our common stock at a price of greater than \$3.00 per share and which would represent 25% or less of our then outstanding common stock on an as-converted to common and fully diluted basis. If we agree to or consummate a financing transaction with someone other than Goodnow that exceeds these limitations, we will pay Goodnow a break-up fee of \$500,000. Goodnow approved the April 2004 private placement, which exceeded these limitations, and waived the fee. However, the \$20,000,000 limitation was lowered to \$9,740,000 and the 25% limitation was reduced to zero. Goodnow also approved the 2005 Financing, the 2006 Financing, the 2007 Financing and the SCN Financing, each of which exceeded these limitations and waived the fee; and
- to allow Goodnow to appoint one director to our board of directors, provided Goodnow owns at least 10%, but less than 20%, of our outstanding common stock, on an as-converted to common and fully diluted basis, and two directors if Goodnow owns more than 20% of our outstanding common stock.

In addition, without Goodnow's prior approval, we have agreed to not:

- make any expenditure or series of related expenditures in excess of \$25,000, except (i) expenditures pursuant to the SBIR grant from the U.S. Small Business Administration, (ii) specified in a budget approved in writing in advance by Goodnow and our Board, and (iii) directly relating to the development of AEOL 10150 for the treatment of ALS;
  - change our business or operations;
  - merge with or sell or lease a substantial portion of our assets to any entity;
  - incur debt from any third party or place a lien on any of our properties;
    - amend our certificate of incorporation or bylaws;
    - increase the compensation we pay our employees;
    - pay dividends on any class of our capital stock;
    - cancel any debt except for full value; or
  - issue any capital stock except pursuant to agreements with or as agreed to by Goodnow.

The affirmative covenants expire on the earliest of:

- the date that Goodnow owns less than 20% of our outstanding common stock on an as converted basis;
- the completion, to the absolute satisfaction of Goodnow, of initial clinical safety studies of AEOL 10150, and analysis of the data developed based upon such studies with results satisfactory to Goodnow, in its absolute discretion, to initiate



efficacy studies of AEOL 10150; or

- the initiation of dosing of the first human patient in an efficacy-based study of AEOL 10150.

On August 1, 2008, we also entered into a Securities Purchase Agreement with the Xmark Funds pursuant to which we agreed to sell to the Xmark Funds units comprised of senior unsecured convertible notes of the Company (the "Notes"), in an aggregate principal amount of up to \$5,000,000 and warrants to purchase up to an aggregate of 10,000,000 additional shares of Common Stock (collectively the "SCN Financing"). On August 1, 2008, the Company sold and issued to the Investors 500 Units comprised of Notes in the aggregate principal amount of \$500,000 and Warrants to purchase up to 1,000,000 shares of Common Stock for an aggregate purchase price of \$500,000 (the "Financing"). On September 4, 2008, the Company sold and issued to the Investors 125 Units comprised of Notes in the aggregate principal amount of \$125,000 and Warrants to purchase up to 250,000 shares of Common Stock for an aggregate purchase price of \$125,000 (the "Subsequent Financing").

The Notes also provide that the Company shall not perform issue any equity securities other than certain exempt securities as defined in the Notes, incur any indebtedness other than certain exempt indebtedness as defined in the Notes, allow the incurrence of any liens on its assets, repay any indebtedness other than the Notes, pay a dividend on its common stock or make an investment other than ordinary investing activities without the consent of the holders of Notes representing a majority of the then-outstanding principal subject to the Notes.

#### 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.

#### New Accounting Pronouncements

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements ("FAS 157"). FAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. FAS 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability and establishes a fair value hierarchy that prioritizes the

information used to develop those assumptions. For non-financial assets and liabilities, FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008. For financial assets and liabilities, FAS 157 was effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of FAS 157 to significantly affect its financial condition or results of operations.

In February 2007, the Financial Accounting Standards Board (“FASB”) issued Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115 (“FAS 159”). FAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. FAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company’s choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. FAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company does not expect the adoption of FAS 159 to significantly affect its financial condition or results of operations.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements (“FAS

160”). FAS 160 is an amendment of Accounting Research Bulletin (“ARB”) No. 51 and was issued to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements. This Statement applies to all entities that prepare consolidated financial statements, except not-for-profit organizations, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries. FAS 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and that a parent company must recognize a gain or loss in net income when a subsidiary is deconsolidated. FAS 160 is effective for fiscal years beginning after December 15, 2008 and early adoption is prohibited. The Company is currently evaluating the potential impact on its statement of financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141R, “Business Combinations” (“FAS 141R”), which establishes principles and requirements for the reporting entity in a business combination, including recognition and measurement in the financial statements of the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. FAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and interim periods within those fiscal years. The Company must adopt SFAS 141R on September 1, 2009, the beginning of its fiscal year 2010. The Company does not expect the application of FAS 141R to have a material effect on the financial statements.

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

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting of U.S. government treasury and agency notes, corporate debt obligations, municipal debt obligations, auction rate securities and money market funds, directly or through managed funds. Our cash is deposited in and invested through highly rated financial institutions in North America. Our investments are subject to interest rate risk and will fall in value if market interest rates increase. We could be exposed to losses related to these securities should one of our counterparties default. We attempt to mitigate this risk through credit monitoring procedures. At September 30, 2008, we held approximately \$525,000 in auction rate securities with a AAA credit rating upon purchase. In February 2008, we were informed that there was insufficient demand at auction for these securities. As a result, this amount is currently not liquid and may not become liquid unless the issuer is able to refinance it. We have classified our investment in auction rate securities as a long-term investment and included the investment in other assets on our balance sheet.

At September 30, 2008, we had two fixed-rate notes payable and one variable rate note payable.

#### Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors  
Aeolus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Aeolus Pharmaceuticals, Inc. (the “Company”) as of September 30, 2008 and 2007, and the related consolidated statements of operations, stockholders’ equity (deficit), and cash flows for each of the years ended September 30, 2008, 2007 and 2006. 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included 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 consolidated financial position of Aeolus Pharmaceuticals, Inc. as of September 30, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the years ended September 30, 2008, 2007 and 2006, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B of the consolidated financial statements, the Company has suffered recurring losses, negative cash flows from operations and does not currently possess sufficient working capital to fund its operations throughout the next fiscal year. These matters 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 B. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Haskell & White LLP

HASKELL & WHITE LLP

Irvine, California  
December 11, 2008



AEOLUS PHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS  
(Dollars in thousands, except per share data)

	September 30,	
	2008	2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 399	\$ 1,727
Prepays and other current assets	156	79
Total current assets	555	1,806
Investments, available for sale	440	—
Investment in CPEC LLC	125	125
Total assets	\$ 1,120	\$ 1,931
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 991	\$ 268
Margin loan (Note F)	366	—
Current maturity of long-term note payable	534	—
Total current liabilities	1,891	268
Senior convertible notes to related parties, net (redemption value of \$625,000 as of September 30, 2008 (Note F))	266	—
Long-term note payable	—	483
Total liabilities	2,157	751
Commitments and Contingencies (Note E and J)		
Stockholders' equity (deficit):		
Preferred stock, \$.01 par value per share, 10,000,000 shares authorized:		
Series B nonredeemable convertible preferred stock, 600,000 shares authorized; 475,087 shares issued and outstanding as of September 30, 2008 and 2007	5	5
	320	320

Common stock, \$.01 par value per share, 150,000,000 shares authorized; 31,952,749 shares issued and outstanding at September 30, 2008 and 2007			
Additional paid-in capital	157,573		156,781
Unrealized losses on investments, available for sale	(36)		—
Accumulated deficit	(158,899)		(155,926)
Total stockholders' equity (deficit)	(1,037)		1,180
Total liabilities and stockholders' equity (deficit)	\$ 1,120	\$	1,931

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,		
	2008	2007	2006
Revenue			
Grant income	\$ —	\$ —	\$ 92
Costs and expenses:			
Research and development	977	1,381	3,480
General and administrative	1,540	1,919	2,216
Total costs and expenses	2,517	3,300	5,696
Loss from operations	(2,517 )	(3,300 )	(5,604 )
Equity in income of CPEC LLC (\$175 and \$315 dividend received in 2008 and 2006, respectively)	175	—	433
Interest expense	(93 )	(51)	(89 )
Interest income	42	102	83
Deemed dividend on issuance of Senior Convertible Notes and repricing of warrants	(118 )	—	—
Collaboration expense	(413 )	—	—
Other than temporary impairment on marketable investments	(49 )	—	—
Increase in fair value of common stock warrants	—	—	(604 )
Other income	—	225	53
Net loss	(2,973 )	(3,024 )	(5,728 )
Preferred stock dividend and accretion	—	—	(81)
Net loss attributable to common stockholders	\$ (2,973 )	\$ (3,024 )	\$ (5,809 )
Basic net loss per common share attributable to common stockholders	(0.09 )	(0.10 )	(0.31 )
Diluted net loss per common share attributable to common stockholders	(0.11 )	(0.10 )	(0.31 )
Weighted average common shares outstanding:			
Basic	31,953	30,239	18,926
Diluted	32,217	30,239	18,926

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



AEOLUS PHARMACEUTICALS, INC.  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)  
(Dollars in thousands)

	Series B		Common Stock		Additional			Total
	Preferred Stock		Number of	Par	Paid-in	Unrealized	Accumulated	Stockholders'
	Number of Shares	Par Value	Shares	Value	Capital	Losses	Deficit	Equity (Deficit)
Balance at September 30, 2005	475,087	\$ 5	14,038,259	\$ 140	\$ 146,016	—	\$ (147,093)	\$ (932)
Sale of Series A Preferred Stock, net of issuance costs of \$87,000	—	—	—	—	(87)	—	—	(87)
Conversion of Series A Preferred Stock			5,000,000	50	304	—	—	354
Sale of common stock pursuant to stock offering, net of issuance costs of \$46,000	—	—	40,000,000	100	43	—	—	143
Common stock issued pursuant to a license agreement	—	—	25,000	1	12	—	—	13
Exercise of common stock options	—	—	83,332	1	82	—	—	83
Stock-based compensation and amortization of warrants	—	—	—	—	500	—	—	500
Reclassification of common stock warrant liabilities	—	—	—	—	7,361	—	—	7,361
Series A preferred stock dividends and accretion	—	—	118,658	1	80	—	(81)	—
Net loss for the fiscal year ended September 30, 2006	—	—	—	—	—	—	(5,728)	(5,728)
Balance at September 30, 2006	475,087	5	29,265,249	293	154,311	—	(152,902)	1,707
Sale of common stock pursuant to stock offering, net of issuance costs of \$239,000	—	—	2,666,667	27	1,734	—	—	1,761
Exercise of common stock options	—	—	20,833	—	20	—	—	20
Stock-based compensation and amortization of warrants	—	—	—	—	716	—	—	716
Net loss for the fiscal year ended September 30, 2007	—	—	—	—	—	—	(3,024)	(3,024)
Balance at September 30, 2007	475,087	5	31,952,749	320	156,781	—	(155,926)	1,180

Sale of Senior convertible notes and warrants, net of issuance costs of \$156,000	—	—	—	—	451	—	—	451
Stock-based compensation	—	—	—	—	341	—	—	341
Unrealized loss on marketable securities held for sale	—	—	—	—	—	(36)	—	(36)
Net loss for the fiscal year ended September 30, 2008	—	—	—	—	—	—	(2,973)	(2,973)
Balance at September 30, 2008	475,087	\$ 5	31,952,749	\$ 320	\$ 157,573	\$ (36)	\$ (158,899)	\$ (1,037)

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,		
	2008	2007	2006
Cash flows from operating activities:			
Net loss	\$ (2,973 )	\$ (3,024 )	\$ (5,728 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash compensation	341	716	500
Noncash interest and financing costs	89	52	89
Noncash deemed dividend on warrant repricing	118	—	—
Equity income in CPEC LLC	(175)	—	—
Noncash consulting and license fee	—	—	13
Other than temporary impairment on investments available for sale	49	—	—
(Gain) on forgiveness of note payable	—	(225)	—
Increase in fair value of common stock warrants	—	—	604
Change in assets and liabilities:			
Accounts receivable	—	1	13
Prepaid expenses and other assets	15	24	(247)
Accounts payable and accrued expenses	723	(623 )	(111)
Net cash used in operating activities	(1,813 )	(3,079 )	(4,867)
Cash flows from investing activities:			
Proceeds from dividend from CPEC LLC	175	—	315
Purchase of investments available for sale	(525)	—	—
Net cash (used in) provided by investing activities	(350)	—	315
Cash flows from financing activities:			
Repayment of Note Payable	—	(300)	—
Proceeds from the issuance of Senior Convertible Notes and Warrants	625	—	—
Costs related to the issuance of Senior Convertible Notes and Warrants	(156)	—	—
Proceeds from short term note payable	372	—	—
Repayments of short term note payable	(6)	—	—
Proceeds from the issuance of Series A Preferred Stock	—	—	2,500
Costs related to the issuance of Series A Preferred Stock	—	—	(87)
	—	2,000	5,000

Proceeds from issuance of common stock and warrants			
Costs related to the issuance of common stock and warrants	—	(239)	(246)
Proceeds from exercise of stock options	—	21	83
Net cash provided by financing activities	835	1,482	7,250
Net (decrease) increase in cash and cash equivalents	(1,328 )	(1,597 )	2,698
Cash and cash equivalents at beginning of year	1,727	3,324	626
Cash and cash equivalents at end of year	\$ 399	\$ 1,727	\$ 3,324

Supplemental disclosure of cash flow information:

Cash payments of interest	\$ 4	\$ —	\$ —
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Supplemental disclosure of non-cash investing and financing activities:

Common stock issued in exchange for Series A preferred stock	\$ —	\$ —	\$ 354
Preferred stock dividend accreted	\$ —	\$ —	\$ 81

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

AEOLUS PHARMACEUTICALS, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2008

A. Nature of the Business

Aeolus Pharmaceuticals, Inc. is a biopharmaceutical company that is developing a new class of catalytic antioxidant compounds for diseases and disorders of the central nervous system, respiratory system, autoimmune system and oncology. The Company's initial target indications are as a protective agent against the effects of mustard gas exposure, as a protective agent against radiation exposure, cancer radiation therapy, as a protective agent against the effects of chlorine gas exposure and amyotrophic lateral sclerosis, also known as "ALS" or "Lou Gehrig's disease."

The "Company" or "Aeolus" refers collectively to Aeolus Pharmaceuticals, Inc., a Delaware corporation ("Aeolus") and its wholly owned subsidiary, Aeolus Sciences, Inc., a Delaware corporation ("Aeolus Sciences"). As of September 30, 2008, Aeolus also owned a 35.0% interest in CPEC LLC, a Delaware limited liability company ("CPEC"). The Company's primary operations are located in Laguna Niguel, California.

B. Liquidity

The Company has incurred significant operating losses and cash outflows from operations of \$2,517,000 and \$1,813,000 for the fiscal year ended September 30, 2008, respectively. The Company expects to incur additional losses and negative cash flow from operations in fiscal 2009 and for several more years. Management believes the Company has adequate financial resources to conduct operations into the second quarter of fiscal year 2009. This raises substantial doubt about our ability to continue as a going concern, which will be dependent on our ability to generate sufficient cash flows to meet our obligations on a timely basis, to obtain additional financing and, ultimately, to achieve operating profit.

The Company intends to explore strategic and financial alternatives, including a merger with another company, the sale of shares of stock, the establishment of new collaborations for current research programs that include initial cash payments and on-going research support and the out-licensing of our compounds for development by a third party. The Company believes that without additional investment capital it will not have sufficient cash to fund its activities in the near future, and will not be able to continue operating. As such, the Company's continuation as a going concern is dependent upon its ability to raise additional financing. The Company is actively pursuing additional equity financing to provide the necessary funds for working capital and other planned activities.

If the Company is unable to obtain additional financing to fund operations beyond the second quarter of fiscal year 2009, it will need to eliminate some or all of its activities, merge with another company, sell some or all of its assets to another company, or cease operations entirely. There can be no assurance that the Company will be able to obtain additional financing on favorable terms or at all, or that the Company will be able to merge with another Company or sell any or all of its assets.

C. 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. Actual results could differ from those estimates.

#### Cash and Cash Equivalents

The Company invests available cash in short-term bank deposits, money market funds, commercial paper and U.S. Government securities. 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, 2008 and 2007 due to their short-term nature.



## Investments

Investments consist of auction rate securities, each of investment-grade quality, which have an original maturity dates greater than 90 days. These investments are recorded at fair value and accounted for as available-for-sale securities. The unrealized gain (loss) during the period is recorded within accumulated other comprehensive loss unless it is determined to be other-than-temporary. During the year ended September 30, 2008, the Company recorded a net unrealized loss on investments of \$36,000. During the year ended September 30, 2007, the Company also recorded an other than temporary impairment on the auction-rate securities of \$49,000.

## Revenue Recognition

Grant income is recognized as revenue as work under the grant is performed and the related expenses are incurred.

## Research and Development

Research and development costs are expensed in the period incurred. Payments related to the acquisition of in-process research and development are expensed due to the stage of development of the acquired compound or technology at the date of acquisition.

## Income Taxes

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce net deferred tax assets to the amounts expected to be realized.

## Net Loss Per Common Share

The Company computes basic net loss per weighted share attributable to common stockholders using the weighted average number of shares of common stock outstanding during the period. The Company computes diluted net loss per weighted 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 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 issuable upon conversion of the Senior Convertible Notes and shares expected to be issued to satisfy a payable. Diluted weighted average shares excluded incremental shares of approximately 21,796,000, 18,428,000 and 19,439,000 as of September 30, 2008, 2007 and 2006, respectively, related to stock options, convertible debt, convertible preferred stock and warrants to purchase common stock. These shares are excluded due to their anti-dilutive effect as a result of the Company's net loss.

## Accounting for Stock-Based Compensation

Beginning October 1, 2005, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share-Based Payments" ("SFAS No. 123(R)") on a modified prospective transition method to account for its employee stock options. Under the modified prospective transition method, fair value of new and previously granted but unvested equity awards are recognized as compensation expense in the income statement, and prior period results are not restated.

## Segment Reporting

The Company currently operates in only one segment.

#### New Accounting Pronouncements

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements (“FAS 157”). FAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. FAS 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. For non-financial assets and liabilities, FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008. For financial assets and liabilities, FAS 157 was effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of FAS 157 to significantly affect its financial condition or results of operations.

In February 2007, the Financial Accounting Standards Board (“FASB”) issued Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of SFAS 115 (“FAS 159”). FAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types

of assets and liabilities. FAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. FAS 159 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company does not expect the adoption of FAS 159 to significantly affect its financial condition or results of operations.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements ("FAS 160"). FAS 160 is an amendment of Accounting Research Bulletin ("ARB") No. 51 and was issued to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements. This Statement applies to all entities that prepare consolidated financial statements, except not-for-profit organizations, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries. FAS 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and that a parent company must recognize a gain or loss in net income when a subsidiary is deconsolidated. FAS 160 is effective for fiscal years beginning after December 15, 2008 and early adoption is prohibited. The Company is currently evaluating the potential impact on its statement of financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141R, "Business Combinations" ("FAS 141R"), which establishes principles and requirements for the reporting entity in a business combination, including recognition and measurement in the financial statements of the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. FAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and interim periods within those fiscal years. The Company must adopt SFAS 141R on October 1, 2009, the beginning of its fiscal year 2010. The Company does not expect the application of FAS 141R to have a material effect on the financial statements.

#### D. Investments

##### Investments in Auction-Rate Securities

The Company has invested in auction-rate securities with a par value of \$525,000. The auction-rate securities are debt obligations secured by student loans, which loans are generally guaranteed by the U.S. Government under the Federal Family Education Loan Program (FFELP). In addition to the U.S. Government guarantee on such student loans, many of the securities also have separate insurance policies guaranteeing both the principal and accrued interest. Liquidity for these securities has historically been provided by an auction process that resets the applicable interest rate at pre-determined intervals for up to 35 days. In the past, the auction process has generally allowed investors to obtain immediate liquidity if so desired by selling the securities at their face amounts. However, as has been recently reported in the financial press, the current disruptions in the credit markets have adversely affected the auction market for these types of securities. From February 26, 2008 to September 30, 2008, all auctions scheduled with respect to the Company's auction-rate securities failed to close. This is the first time the Company has experienced this type of event for its holdings of auction-rate securities and the Company believes that prior to February 13, 2008, the Company's investment advisor, UBS Financial Services, Inc. ("UBS"), had not had a failed auction. The Company understands that the failure of auctions is broad based and not limited to those securities held by the Company. The auction-rate securities continue to pay interest.

As a result of the failed auctions, these auction-rate securities held by the Company are currently not liquid. Furthermore, the Company cannot predict how long they will remain illiquid. As such, at least in the near term, the Company believes it may not be able to liquidate some or all of its remaining auction-rate securities prior to

their maturities at prices approximating their face amounts. The final maturity dates of the auction-rate securities which the Company owns is between 2029 and 2038.

The Company has taken an “other-than-temporary” impairment charge during the fiscal year ended September 30, 2008 of \$49,000 based upon reduced market values as determined based upon investment statements received from UBS. The Company also holds these investments as available for sale and accordingly records its value on the balance at market value as determined by investments statements provided by UBS. Our auction-rate securities had an estimated fair value of approximately \$440,000 as of September 30, 2008. The estimated fair value of the auction-rate securities could decrease or increase significantly in the future based on market conditions. Management will continue to assess the fair value of the auction-rate securities based on analysis of account statements and other correspondence from UBS.

In June 2008, the Company filed arbitration and mediation claims against UBS seeking rescission of the purchase transactions of its four auction-rate securities, reimbursement for lost interest income and lost revenue due to delays in the development of its drug candidates and punitive damages. UBS did not agree to mediation and the request for mediation was dismissed. In October 2008, UBS filed a response to our arbitration claim denying all allegations and seeking recovery of legal fees and costs. Also in October 2008, we received notification from UBS that it has entered into a settlement agreement with the

New York Attorney General in which UBS agreed to repurchase certain auction-rate securities of certain of its clients at par value for which all of our auction-rate securities are included in the settlement with the New York Attorney General. UBS indicated that we can exercise the option for UBS to repurchase the auction-rate securities for a two year period beginning January 2, 2009. We have submitted the required documentation and intend to exercise our option to sell the four auction-rate securities to UBS on January 2, 2009. We are currently in the discovery phase of the arbitration proceeding. However there can be no assurance as to the ultimate outcome of these claims.

The current market for the auction-rate securities held by the Company is uncertain and management will continue to monitor and evaluate the market for these securities to determine if further impairment of the carrying value of the securities has occurred due to the loss of liquidity or for other reasons. If the credit ratings of the security issuers deteriorate or if normal market conditions do not return in the near future, the Company may be required to further reduce the value of these securities through an impairment charge against net income.

#### Investments in ARCA Biopharma, Inc.

The Company also holds an investment in equity securities of a privately held company, ARCA BioPharma, Inc. ("ARCA"). The aggregate carrying amount of the holdings in ARCA was \$93,000 as of September 30, 2008. The Company accounts for the investment on cost basis and reviews the investment for impairment whenever there are identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. During fiscal years ended September 30, 2008, 2007 and 2006, the Company did not record an impairment on the investment in ARCA.

#### Investments in CPEC LLC

The Company uses the equity method to account for its 35.0% ownership interest in CPEC. During fiscal 2003, CPEC licensed bucindolol, a drug previously under development by the Company for the treatment of heart failure, to ARCA in return for possible future royalty and milestone payments. During fiscal 2006, CPEC agreed to modify the license agreement between CPEC and ARCA and received 400,000 shares of ARCA common stock as consideration for the amendment. In addition, during fiscal 2006, CPEC received a milestone payment of \$1,000,000 as a result of ARCA completing a financing. During fiscal 2006, CPEC declared and paid a dividend of which the Company received \$315,000. During fiscal 2008, CPEC declared and paid a dividend of which the Company received \$175,000. The dividend was paid upon receipt of a milestone payment by CPEC from ARCA which was triggered upon the filing of a New Drug Application for bucindolol. Also as a result of the filing of the New Drug Application with the US Food and Drug Administration, the Company is obligated to pay \$413,000 in the form of cash or stock at the Company's election to the majority owner of CPEC who will in turn pay the original licensors of bucindolol per the terms of the 1994 Purchase Agreement of CPEC. The obligation is included in our financial statements under the heading "Accounts Payable."

CPEC had \$91,000 of net assets at September 30, 2008 and 2007. 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 buicndolol.

#### E. Commitments

The Company acquires assets still in development and enters into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the arrangement, the Company may

have to make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these payments, they are not included in the table of contractual obligations.

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. Notes Payable

The Company has three debt obligations outstanding as of September 30, 2008. The combined aggregate amounts of maturities for all three debt obligations as of September 30, 2008 are as follows (in thousands):

Fiscal year ending September 30,	Redemption Amount
2009	\$ 919
2010	---
2011	625
Total	\$ 1,544

## Senior Convertible Notes to Related Parties

On August 1, 2008, the Company entered into a Securities Purchase Agreement (the "SCN Purchase Agreement") with three accredited institutional investors (the "Investors") pursuant to which the Company agreed to sell to the Investors units comprised of senior unsecured convertible notes of the Company (the "Notes"), in an aggregate principal amount of up to \$5,000,000, which shall bear interest at a rate of 7% per year and mature on the 30-month anniversary of their date of issuance, and warrants to purchase up to an aggregate of 10,000,000 additional shares of Common Stock (the "Warrant Shares"), each with an initial exercise price of \$0.50 per share, subject to adjustment pursuant to the warrants (the "Warrants") (collectively the "SCN Financing"). Each unit (collectively, the "Units") is comprised of \$1,000 in Note principal and Warrants to purchase up to 2,000 shares of the Company's common stock, par value \$0.01 per share (the "Common Stock"), and has a purchase price of \$1,000.

On August 1, 2008, the Company sold and issued to the Investors 500 Units comprised of Notes in the aggregate principal amount of \$500,000 and Warrants to purchase up to 1,000,000 shares of Common Stock for an aggregate purchase price of \$500,000 (the "Financing").

On September 4, 2008, the Company sold and issued to the Investors 125 Units comprised of Notes in the aggregate principal amount of \$125,000 and Warrants to purchase up to 250,000 shares of Common Stock for an aggregate purchase price of \$125,000 (the "Subsequent Financing").

The Investors have also agreed, upon the satisfaction of certain conditions by the Company pursuant to the Amended Purchase Agreement, to purchase an additional 125 Units on each of October 1, 2008, November 3, 2008 and December 1, 2008 (the "Subsequent Closings"), in each case for an aggregate purchase price of \$125,000. The Notes issued in the Financing, the Subsequent Financing and at the Subsequent Closings have, or will have, an initial conversion price of \$0.35 per share, subject to adjustment pursuant to the Notes. In addition, the Investors have the option to purchase up to an additional 4,000 Units, in one or more closings (each, an "Election Closing"), and at their sole option at any time on or before February 1, 2010. The additional Units sold at an Election Closing would also be sold by the Company at a purchase price of \$1,000 per Unit, except that the initial conversion price of the Notes issued in an Election Closing will equal the volume weighted average closing sale price for the Common Stock for the sixty consecutive trading day period ending on the trading day immediately preceding such Election Closing, provided that such initial conversion price may not be less than \$0.20 per share or greater than \$0.75 per share, in each case subject to adjustment pursuant to the Note.

The Notes will be convertible, at the Investors' sole election, into shares of Common Stock at any time and from time to time. As of September 30, 2008, the Notes would be convertible into 1,786,000 shares of Common Stock with a fair value of \$804,000. The conversion price of the Notes (including the \$0.20 floor and \$0.75 ceiling price with

respect to Notes issued at Election Closings) and the exercise price of the Warrants are subject to adjustment in the event of a stock dividend or split, reorganization, recapitalization or similar event. Additionally, the conversion price of the Notes and the exercise price of the Warrants may be reduced in the event the Company issues securities at a price per share lower than the then current conversion price of the Notes. The Notes are due and payable in cash at the aggregate principal value plus accrued interest 30 months from the date of issuance if not converted earlier by the Investors.

Interest on the Notes accrues at the rate of 7.0% per annum from the date of issuance, and is payable semi-annually, on January 31 and July 31 of each year. Interest shall be payable, at the Company's sole election, in cash or shares of Common Stock, to holders of Notes on the record date for such interest payments, with the record dates being each January 15 and July 15 immediately preceding an interest payment date.

The Warrants are exercisable for a five year period from the date of issuance and contain a "cashless exercise" feature that allows the Investors to exercise the Warrants without a cash payment to the Company under certain circumstances.



The net proceeds to the Company from the sale of 625 Units in the Financing and Subsequent Financing, after deducting for expenses, were approximately \$469,000. The Company intends to use the net proceeds to fund the development of AEOL 10150 and to fund ongoing operations of the Company. Offering costs of the private placement were \$156,000 and were allocated to the Notes and Warrants based upon their respective fair values. The offering costs attributed to the Notes in the amount of \$100,000 were capitalized as Debt Issuance Costs and are included in Prepaid and other current assets in the Consolidated Balance Sheet. The Debt Issuance Costs are being amortized over the 30-month life of the Notes in the Financing.

As of September 30, 2008, the carrying value of the Notes was \$266,000 and the redemption value was \$625,000. In connection with the SCN Financing, the Company recorded a note discount in the amount of \$218,000 as a result of the difference between the value attributed to the Notes and the redemption value of the Notes. In addition, the Company determined that the Notes contained an embedded conversion feature with a fair value of \$171,000 which was also recorded as a discount to the Notes. The note discounts are being amortized to interest expense over the thirty-month term of the Notes. The effective interest rate of the Note including the effect of the amortization of the embedded conversion feature and the note discount is 38.3 percent.

The maturity of the Notes may be accelerated upon the occurrence of an event of default, which includes, subject to certain grace periods, exceptions and qualifications as set forth in the Notes, the failure by the Company to maintain the listing of the Common Stock, the failure of the Company to deliver shares Common Stock in a timely manner following a conversion, the failure of the Company to have reserved a sufficient number shares of Common Stock to issue upon conversion of the Notes, the failure by the Company to make payments on the Notes in a timely manner, payment defaults by the Company or any of its significant subsidiaries on debt or other obligations in excess of \$100,000, the occurrence of certain bankruptcy events with respect to the Company or its significant subsidiaries, judgments rendered against the Company or its significant subsidiaries in excess of \$100,000 and breaches of material representations, warranties or covenants by the Company under the Amended Purchase Agreement or the Notes. Upon the occurrence of an event of default related to a bankruptcy of the Company, the Notes shall immediately become due and payable. Upon the occurrence of any event default other than a bankruptcy event of default, any holder of the Notes, in its sole discretion, may declare this Note to be immediately due and payable and the Company shall pay to the holder in cash the sum of all outstanding principal multiplied by 115%, plus accrued and unpaid interest and late charges, if any, thereon. The Notes are unsubordinated obligations of the Company and all payments due under the Notes rank pari passu with the Elan Note and shall not be subordinated to any other Indebtedness of the Company.

The Notes also provide that the Company shall not issue any equity securities other than certain exempt securities as defined in the Notes, incur any indebtedness other than certain exempt indebtedness as defined in the Notes, allow the incurrence of any liens on its assets, repay any indebtedness other than the Notes, pay a dividend on its common stock or make an investment other than ordinary investing activities without the consent of the holders of Notes representing a majority of the then-outstanding principal subject to the Notes.

Affiliates of Xmark Opportunity Partners, LLC are the sole investors in the SCN Financing. Together with its affiliates, Xmark Opportunity Partners, LLC beneficially owned approximately 52% of the Company's outstanding common stock prior to the Financing. Xmark Opportunity Partners, LLC is the sole manager of Goodnow Capital, L.L.C. and possesses sole power to vote and direct the disposition of all securities of the Company held by Goodnow. Goodnow has the right to designate up to two directors for election to the Company's Board of Directors pursuant to the terms of a purchase agreement between Goodnow and the Company. David C. Cavalier, a current director of the Company, is President of Goodnow. The transaction was evaluated by Management and the Board of Directors for fairness to ensure the terms were reasonable given the related party nature of the SCN Financing by providing an option for non-related party investors to participate in the transaction.

Elan Note Payable

In August 2002, Aeolus borrowed from Elan Corporation, plc. (“Elan”) \$638,000. The note payable accrued interest at 10% compounded semi-annually. The note was convertible at the option of Elan into shares of the Company’s Series B non-voting convertible preferred stock (“Series B Stock”) at a rate of \$43.27 per share. The original note matured on December 21, 2006. However, in February 2007, the Company and Elan terminated the note, the Company paid \$300,000 in cash to Elan, Elan forgave \$225,000 of the note payable and Elan and the Company entered into a new two-year note payable in the amount of \$453,000 under substantially the same terms as the original note.

The remaining principal plus accrued interest will be due and payable in February 2009. During the term of the note payable, Elan has the option to convert the note into shares of Series B Preferred Stock at a rate of \$9.00 per share. Upon the maturity of the note payable, Aeolus has the option to repay the note either in cash or in shares of Series B Stock and warrants having a then fair market value of the amount due; provided that the fair market value used for calculating the number of shares to be issued will not be less than \$13.00 per share. As of September 30, 2008, the outstanding balance, including interest, on the note payable to Elan was \$534,000.

#### Margin Loan with UBS Financial Services, Inc.

Aeolus has entered into a secured credit agreement (the “Margin Agreement”) with UBS Financial Services, Inc and subsequently drew \$368,000 under the Margin Agreement. The Margin Agreement bears interest at the per annum rate of LIBOR plus 0.25 percent. The weighted average interest rate for the loan was 2.4% during the period the loan was outstanding in the fiscal year ended September 30, 2008. The average balance of the loan and the total interest paid on the loan during the period the loan was outstanding in the fiscal year ended September 30, 2008 was \$351,000 and \$4,000, respectively.

Availability of the line of credit is subject to the Company’s compliance with certain financial and other covenants. Borrowings under the Margin Agreement are secured by the Company’s investments held by UBS (Note D). In June 2008, UBS notified the Company that it is in violation of the Margin Agreement and has requested repayment of \$20,000. The Company has not made such payment and informed UBS that no such payment will be made pending the outcome of the arbitration claim as more fully discussed in Note D.

#### G. Stockholders’ Equity (Deficit)

##### Preferred Stock

The Certificate of Incorporation of Aeolus authorizes the issuance of up to 10,000,000 shares of Preferred Stock, at a par value of \$.01 per share. The Board of Directors has the authority to issue Preferred Stock in one or more series, to fix the designation and number of shares of each such series, and to determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock, without any further vote or action by the stockholders of the Company.

In January 2001, Aeolus issued to Elan 28,457 shares of Series B Stock. In February 2002, the Company issued 58,883 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. As of September 30, 2008, 475,087 shares of Series B Stock were outstanding. Each share of Series B Stock is convertible into one share of common stock.

On November 21, 2005, the Company completed a private placement whereby the Company issued to certain accredited investors an aggregate of 1,250,000 shares of Series A Convertible Preferred Stock (the “Series A Preferred Stock”) at a stated price of \$2.00 per share and warrants to purchase up to an aggregate of 2,500,000 shares of common stock at an exercise price of \$1.00 per share and a five year term resulting in net proceeds of \$2,413,000. The Series A Preferred Stock accrued dividends at the rate of 6% of the stated price annually, which were paid in our common stock and were accreted to earnings available to common stockholders on a quarterly basis. Each convertible preferred share was convertible into two shares of our common stock which was subsequently increased to four shares of our common stock and had a liquidation preference of \$3.00 per share. The warrants contain a “cashless exercise” feature that allows the holders, under certain circumstances, to exercise the warrants without making a cash payment to the Company.

The fair value of the warrants on November 21, 2005 was estimated to be \$2,146,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 112%; risk free interest rate of 4.4%; and an expected life of five years. The proceeds from the private placement were first allocated to the fair value of the warrants and the remaining proceeds were attributed to the value of the preferred stock, resulting in a carrying value of the Series A Preferred Stock of \$354,000. The carrying value of the Series A Preferred Stock was

not accreted to its redemption value as the occurrence of the redemption event was not considered probable.

Offering costs of the private placement were \$87,000 which was charged to additional paid in capital.

Pursuant to the terms of the registration rights agreement entered into in connection with the transaction, the Company filed a registration statement with Securities and Exchange Commission which was declared effective on March 1, 2006. The registration rights agreement further provides that if a registration statement is not filed or declared effective within specified time periods, the Company would be required to pay each holder an amount in cash, as liquidated damages, equal to 1.5% per month of the aggregate purchase price paid by such holder in the private placement for the common stock and warrants then held. In accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock," and the terms of the warrants and the transaction documents, at the closing date for the financing, November 21, 2005, the fair value of the warrants issued in the private placement were accounted for as a liability. The warrant liability was reclassified to equity when the Securities and Exchange Commission declared the registration statement effective on March 1, 2006. Through March 1, 2006, the warrant liability was revalued at each balance sheet date and the change in fair value was charged to the statement of operations. Between November 21, 2005 and March 1, 2006, the fair value of the warrant decreased by \$401,000 which was credited to the statement of operations.

In connection with the June 5, 2006 financing, all outstanding shares of the Series A Preferred Stock were converted into an aggregate of 5,000,000 shares of common stock. In addition, the exercise price of the warrants to purchase up to an aggregate of 2,500,000 shares of common stock issued in the November 2005 financing was lowered from \$1.00 per share to \$0.50 per share in accordance with the terms of the warrants. As a result of the change of the conversion terms of the Series A Preferred Stock from two shares of common stock to four shares of common stock, the Company recognized a dividend in the amount of \$900,000. Such amount was determined as the incremental intrinsic value of the beneficial conversion feature that was triggered upon conversion of the Series A Preferred stock and was recorded as additional paid-in capital.

#### Common Stock

On June 5, 2006, Aeolus completed a private placement of 10,000,000 shares of the Company's Common Stock at a purchase price of \$0.50 per share for aggregate gross proceeds of \$5,000,000, issued to the certain investors in the private placement warrants (the "2006 Investor Warrants") to purchase up to an aggregate of 7,000,000 shares of common stock of the Company with an exercise price of \$0.75 per share and issued to Efficacy Biotech Master Fund Ltd. a warrant (the "Efficacy Warrant") to purchase up to an aggregate of 4,000,000 shares of common stock with an exercise price of \$0.50 per share (collectively the "2006 Financing"). The 2006 Investor Warrants are exercisable until June 5, 2011 and may be exercised by the holder only pursuant to a cash payment. The Efficacy Warrant expired unexercised on June 5, 2007. The aggregate net proceeds to the Company from this financing, after deducting for expenses, were approximately \$4,754,000.

The fair value of the warrants issued on June 5, 2006 was estimated to be \$4,716,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; risk free interest rate of 5.0%; expected volatility of 120% for the Investor Warrants and 124% for Efficacy Warrant; and an expected life of five years for the 2006 Investor Warrants and one year for the Efficacy Warrant. The proceeds from the private placement were first allocated to the fair value of the warrants and the remaining proceeds were attributed to the value of the common stock.

Pursuant to the terms of the Subscription Agreement for the 2006 Financing, the Company filed a registration statement with the Securities and Exchange Commission which was declared effective on July 31, 2006. The Subscription Agreement further provides that if a registration statement is not filed or declared effective within specified time periods, the Company would be required to pay each holder an amount in cash, as liquidated damages, equal to 1.0% per month of the aggregate purchase price paid by such holder in the private placement for the common stock and warrants then held. In accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock," and the terms of the warrants and the transaction documents, at the closing date, June 5, 2006, the fair value of the warrants issued in the private placement were accounted for as a liability. The warrant liability was reclassified to equity when the Securities and Exchange Commission declared the registration statement effective. From June 5, 2006 to July 31, 2006, the date in which a registration statement registering the shares underlying the warrants was declared effective, the warrant liability was revalued at each balance sheet date and changes in fair value were charged to the statement of operations. Between June 5, 2006 and July 31, 2006, the fair value of the warrant increased by \$901,000 which was charged to the statement of operations. The warrant liability and revaluations have not and will not have any impact on the Company's working capital, liquidity, or business operations.

On May 22, 2007, Aeolus Pharmaceuticals, Inc. entered into a Securities Purchase Agreement with certain accredited investors (the "Investors") pursuant to which the Company sold to the Investors an aggregate of 2,666,667 shares of the Company's common stock at a purchase price of \$0.75 per share for aggregate gross proceeds of \$2,000,000 and issued to the Investors warrants (the "2007 Investor Warrants") to purchase up to an aggregate of 2,000,001 shares of common stock of the Company with an exercise price of \$0.75 per share (collectively, the "May 2007 Private

Placement"). The 2007 Investor Warrants are exercisable until May 22, 2012. In addition, the Company issued to a placement agent a warrant to purchase up to an aggregate of 186,667 shares of common stock with an exercise price of \$0.75 per share.

The aggregate net proceeds to the Company from the May 2007 Private Placement, after deducting for expenses related to finders fees, legal and accounting fees, were approximately \$1,761,000.

The fair value of the 2007 Investor Warrants on May 22, 2007 was estimated to be \$1,428,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; risk free interest rate of 4.8%; expected volatility of 132%; and an expected life of five years.

Pursuant to the terms of the Securities Purchase Agreement, the Company filed a registration statement which was declared effective on July 19, 2007. The Securities Purchase Agreement further provides that if a registration statement is not filed, declared effective within specified time periods or its effectiveness maintained, the Company is required to pay each holder an amount in cash, as liquidated damages, equal to 1.5% per month of the aggregate purchase price paid by such holder in the private placement for the common stock and warrants then held.

## Dividends

The Company has never paid a cash dividend on its common stock and does not anticipate paying cash dividends on its common stock in the foreseeable future. If the Company pays a cash dividend on its common stock, it also must pay the same dividend on an as converted basis on our Series B preferred stock. In addition, Aeolus cannot pay a dividend on its common stock without the prior approval of Goodnow Capital pursuant to the terms of the Debenture and Warrant Purchase Agreement dated September 16, 2003 between the Company and Goodnow and Xmark Opportunity Partners, LLC pursuant to the SCN Purchase Agreement.

## Warrants

In connection with the SCN Financing (Note F), Aeolus issued warrants to purchase 1,250,000 shares at an exercise price of \$0.50 per share with a five year term. The fair value of the warrants on August 1, 2008 was estimated to be \$282,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 128% risk free interest rate of 3.2%; and an expected life of five years. The fair value of the warrants on September 4, 2008 was estimated to be \$53,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 130% risk free interest rate of 3.0%; and an expected life of five years.

In addition, as a result of the SCN Financing, the Company was required to lower the exercise price of 4,687,000 warrants previously issued in the November 2005 Financing and in the 2007 Financing to \$0.35 per share, the conversion price of the Notes issued in the SCN Financing. As a result of the change in the exercise price, these warrants were revalued resulting in an increase in the value of \$118,000 which was charged to the statement of operations.

In connection with the private placement in June 2006, Aeolus issued to the 2006 Investor Warrants to purchase up to an aggregate of 7,000,000 shares of common stock of the Company with an exercise price of \$0.75 per share and issued the Efficacy Warrant to purchase up to an aggregate of 4,000,000 shares of common stock with an exercise price of \$0.50 per share. The 2006 Investor Warrants are exercisable until June 5, 2011 and may be exercised by the holder only pursuant to a cash payment. The Efficacy Warrant expired on June 5, 2007.

In connection with the 2005 Financing, Aeolus issued warrants to purchase 2,500,000 shares at an exercise price of \$1.00 per share. In accordance with the terms of the Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock, the conversion price of the Company's Series A Convertible Preferred Stock (the "Series A Preferred Stock") and the exercise price of the warrants previously issued to the Series A Preferred Stock holders in November 2005 were each automatically reduced to \$0.50 per share, the purchase price of the common stock issued in the 2006 Financing. As a result of the change in the exercise price, these warrants were revalued resulting in an increase in the value of \$105,000 which was charged to the statement of operations.

During fiscal 2006, Aeolus issued to an accredited investor a warrant to purchase up to an aggregate of 250,000 shares of common stock with an exercise price ranging from \$0.50 to \$2.50 per share in accordance with the terms of a consulting agreement. The Company incurred \$28,000 and \$76,000 of expense related to warrants issued in fiscal 2007 and 2006, respectively. No warrant expense was incurred in fiscal 2008.

As of September 30, 2008, warrants for common stock outstanding were as follows:

Number of Shares	Exercise Price	Expiration Date
---------------------	-------------------	--------------------

50,000	\$	0.35	May 2011
2,500,000	\$	0.35	November 2010
2,186,668	\$	0.35	May 2012
1,000,000	\$	0.50	August 2013
250,000	\$	0.50	September 2013
7,000,000	\$	0.75	June 2011
50,000	\$	1.00	May 2011
50,000	\$	1.50	May 2011
50,000	\$	2.00	May 2011
50,000	\$	2.50	May 2011
410,400	\$	2.50	April 2009
1,641,600	\$	4.00	April 2009
1,759	\$	19.90	October 2008
15,240,427	\$	1.02	



## H. Stock Compensation Plans

## Stock Option Plans

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 Option Plan (the "2004 Plan") and reserved 5,000,000 shares of common stock for issuance under the 2004 Plan. As of September 30, 2008, 2,574,895 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, 2008, 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 three years following the date of the grant.

Stock option activity under the 2004 Plan and 1994 Plan were as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	Intrinsic Value
Outstanding at September 30, 2005	2,394,091	4.05	8.0 years	92
		\$		\$
Granted	777,641	\$ 0.81	10.0 years	---
Exercised	(83,332)	\$ 1.00	9.2 years	(13)
Cancelled	(16,594)	\$ 16.84		
Outstanding at September 30, 2006	3,071,806	3.25	7.7 years	22
		\$		\$
Granted	1,315,000	\$ 0.68	10.0 years	---
Exercised	(20,833)	\$ 1.00	8.6 years	(8)
Cancelled	(492,356)	\$ 0.65		
Outstanding at September 30, 2007	3,873,617	2.72	7.3 years	2
		\$		\$
Granted	475,000	\$ 0.35	10.0 years	---
Exercised	----			
Cancelled	(113,336)	\$ 0.87		
Outstanding at September 30, 2008	4,235,281	2.50	6.7 years	46
		\$		\$
	3,924,448	\$ 2.67	6.4 years	\$ 11

Exercisable at  
September 30,  
2008

Stock options granted to consultants during fiscal year 2008, 2007 and 2006 were fully vested when issued or vested over a twelve month period. Stock option expense for stock options granted to consultants was \$77,000, \$248,000 and \$199,000 for fiscal year 2008, 2007 and 2006, respectively. For the fiscal years ended September 30, 2008, 2007 and 2006, all stock options were issued at or above the fair market value of a share of common stock. The weighted-average grant-date fair value of options granted during the fiscal years 2008, 2007 and 2006 was \$0.35, \$0.68 and \$0.81, respectively.

A summary of the status of nonvested shares during the three years ended September 30, 2008 was:

Shares	
Nonvested at September 30, 2005	112,917
Granted	777,641
Vested	(350,972)
Nonvested at September 30, 2006	539,586
Granted	1,315,000
Forfeited	(450,000)
Vested	(867,086)
Nonvested at September 30, 2007	537,500
Granted	475,000
Vested	(701,667)
Nonvested at September 30, 2008	310,833

The total deferred compensation expense for outstanding stock options was \$56,000 as of September 30, 2008, which will be recognized over a weighted average period of five months. The total fair value of shares vested during fiscal years 2008, 2007 and 2006 was \$341,000, \$689,000 and \$424,000, respectively.

The details of stock options outstanding at September 30, 2008 were as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at September 30, 2008	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Number Exercisable at September 30, 2008	Weighted Average Exercise Price
\$0.32 - \$0.40	425,000	\$ 0.34	9.7 years	118,334	\$ 0.36
\$0.45 - \$0.60	476,050	\$ 0.56	8.5 years	471,883	\$ 0.56
\$0.68 - \$0.80	464,161	\$ 0.75	7.8 years	464,161	\$ 0.75
\$0.81 - \$0.90	780,085	\$ 0.88	7.6 years	780,085	\$ 0.88
\$0.91 - \$1.45	224,500	\$ 1.04	7.6 years	224,500	\$ 1.04
\$1.50	1,256,015	\$ 1.50	4.8 years	1,256,015	\$ 1.50
\$1.52 - \$12.85	461,418	\$ 4.24	5.3 years	461,418	\$ 4.24
\$14.50 - \$31.88	99,253	\$ 25.97	2.1 years	99,253	\$ 25.97
\$50.9375	2,999	\$ 50.94	1.5 years	2,999	\$ 50.94
\$51.25	45,800	\$ 51.25	1.5 years	45,800	\$ 51.25
\$0.32 - \$51.25	4,235,281	\$ 2.50	6.7 years	3,924,448	\$ 2.67

Under the principles of APB No. 25, the Company did not recognize compensation expense associated with the grant of stock options to employees unless an option was granted with an exercise price at less than fair market value. SFAS 123 requires the use of option valuation models to recognize as expense stock option grants to consultants and to provide supplemental information regarding options granted to employees.

Beginning October 1, 2005, the Company adopted Statement of Financial Accounting Standards (“SFAS”) No. 123(R), “Share-Based Payments” (“SFAS No. 123(R)”) on a modified prospective transition method to account for its employee stock options. Under the modified prospective transition method, fair value of new and previously granted but unvested equity awards are recognized as compensation expense in the income statement, and prior period results are not restated. As a result of the adoption, the Company’s net loss increased by \$224,000 or \$0.01 per share for fiscal 2006.

For fiscal 2008, 2007 and 2006, stock-based compensation expense recognized in the income statement is as follows (in thousands):

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	For the fiscal year ended September 30,		
	2008	2007	2006
Research and development expenses	\$ 45	\$ 177	\$ 43
General and administrative expenses	296	539	457
Total stock-based compensation expense	\$ 341	\$ 716	\$ 500

The fair value of the options associated with the above compensation expense for fiscal 2008, 2007 and 2006, 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,		
	2008	2007	2006
Dividend yield	0%	0%	0%
Expected volatility	197% - 198%	191% - 195%	189% - 191%
Risk-free interest rate	3.8% - 4.6%	4.5% - 5.1%	4.3% - 5.2%
Expected option life after shares are vested	10 years	10 years	10 years

## I. Income Taxes

As of September 30, 2008 and 2007, the Company had federal net operating loss (“NOL”) carryforwards of \$104,015,000 and \$103,008,000, respectively and state operating loss carryforwards of \$27,429,000 and \$26,424,000, respectively. The use of these federal NOL carryforwards 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 carryforwards will not be completed until the time the Company projects it will be able to utilize such NOLs. The federal net operating losses will begin to expire in 2010. The state net operating losses begin to expire in fiscal year 2009. Additionally, the Company had federal research and development carryforwards as of September 30, 2008 and 2007 of \$3,060,000 and \$3,027,000, respectively. The Company had state research and development carryforwards as of September 30, 2008 and 2007 of \$350,000 and \$315,000, respectively.

Significant components of the Company’s deferred tax assets at September 30, 2008 and 2007 consisted of the following (in thousands):

	2008	2007
Net operating loss carryforwards	\$ 37,790	\$ 36,846
AMT credit carryforwards	—	37
Research and development credit carryforwards	3,410	3,342
Accrued payroll related liabilities	2,420	2,172
Note discount	10	—
Impairment on marketable securities	21	—
Charitable contribution carryforwards	—	1,109
Total deferred tax assets	43,651	43,506
Deferred tax liabilities	—	—
Valuation allowance for deferred assets	(43,651 )	(43,506)
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 carryforwards.

Taxes computed at the statutory federal income tax rate of 34% are reconciled to the provision for income taxes as follows (dollars in thousands):

	2008	2007	2006
Effective income tax rate	0%	0%	0%
	\$ (1,011)	\$ (1,028)	\$ (1,975)

United States Federal income tax at statutory rate			
State income taxes (net of federal benefit)	(142)	(170)	(277)
Warrant expense	40	—	—
Change in valuation reserves	1,145	1,244	2,351
Other	(32)	(46)	(99)
Provision for income taxes	\$ —	\$ —	\$ —

On October 1, 2007, the Company adopted the Financial Accounting Standards Board (“FAS”) issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes (“FIN 48”), which alters the framework for recognizing income tax contingencies. Previously, under Statement FAS No. 5, Accounting for Contingencies, the focus was on the subsequent liability recognition for estimated losses from tax contingencies where such losses were probable and the related amounts could be reasonably estimated. Under this new interpretation, a contingent tax asset (i.e., an uncertain tax position) may only be recognized if it is more likely than not that it will ultimately be sustained upon audit. The Company has evaluated its tax positions for all jurisdictions and all years for which the statute of limitations remains open and, in accordance with the provisions of FIN 48 determined that no additional liability for unrecognized tax benefits and interest was necessary.

## J. Agreements

## Duke Licenses

Aeolus 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 Aeolus 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 (“NJC License”) from National Jewish Medical and Research Center (“NJC”) to develop, make, have made, use and sell products using certain technology developed by certain scientists at NJC. The NJC License requires Aeolus to use commercially reasonable efforts to diligently pursue the development and government approval of products using the licensed technology. Aeolus will pay royalties to NJC on net product sales during the term of the NJC License and a milestone payment upon regulatory approval. In addition, Aeolus is obligated under the NJC License to pay all or a portion of patent prosecution, maintenance and defense costs. Unless earlier terminated, the NJC License continues until the expiration of the last to expire issued patent on the licensed technology. Aeolus also had a sponsored research agreement with NJC that grants Aeolus an option to negotiate a royalty-bearing exclusive license for certain technology, patents and inventions resulting from research by certain individuals at NJC within the field of antioxidant, nitrosylating and related areas. Aeolus terminated this agreement effective June 30, 2005.

## Elan Corporation, plc

In May 2002, the Company entered into a collaboration transaction with affiliates of Elan Corporation, plc for the development of our 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 our catalytic antioxidant products sold, if any, for the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage.

## K. Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in thousands, except per share amounts)				
Fiscal 2008					
Total revenue	\$ —	\$ —	\$ —	\$ —	\$ —
Net loss attributable to common stockholders	\$ (641)	\$ (697)	\$ (580)	\$ (1,055)	\$ (2,973)

Basic net loss per common share attributable to common stockholders	\$	(0.02)	\$	(0.02)	\$	(0.02)	\$	(0.03)	\$	(0.09)
Diluted net loss per common share attributable to common stockholders	\$	(0.02)	\$	(0.02)	\$	(0.02)	\$	(0.05)	\$	(0.11)
Fiscal 2007										
Total revenue	\$	—	\$	—	\$	—	\$	—	\$	—
Net loss attributable to common stockholders	\$	(949)	\$	(544)	\$	(509)	\$	(1,022)	\$	(3,024)
Net loss per common share (basic and diluted):										
Net loss attributable to common stockholders	\$	(0.03)	\$	(0.02)	\$	(0.02)	\$	(0.03)	\$	(0.10)



#### L. Subsequent Events

Subsequent to September 30, 2008, the Company sold and issued to the Investors an additional 375 Units comprised of Notes in the aggregate principal amount of \$375,000 and Warrants to purchase up to 750,000 shares of Common Stock for an aggregate purchase price of \$375,000. The Notes have an initial conversion price of \$0.35 per share, subject to adjustment pursuant to the Notes, and are convertible, at the Investors' sole election, into shares of Common Stock at any time and from time to time. The conversion price of the Notes and the exercise price of the Warrants are subject to adjustment in the event of a stock dividend or split, reorganization, recapitalization or similar event. Additionally, the conversion price of the Notes and the exercise price of the Warrants may be reduced in the event the Company issues securities at a price per share lower than the then current conversion price of the Notes. The Notes are due and payable in cash at the aggregate principal value plus accrued interest 30 months from the date of issuance if not converted earlier by the Investors.

Interest on the Notes accrues at the rate of 7.0% per annum from the date of issuance, and is payable semi-annually, on January 31 and July 31 of each year. Interest shall be payable, at the Company's sole election, in cash or shares of Common Stock, to holders of Notes on the record date for such interest payments, with the record dates being each January 15 and July 15 immediately preceding an interest payment date.

The Warrants are exercisable for a five year period from the date of issuance and contain a "cashless exercise" feature that allows the Investors to exercise the Warrants without a cash payment to the Company under certain circumstances.

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

None

#### Item 9A. Controls and Procedures.

(a) As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's President and Chief Executive Officer (the Company's Principal Executive Officer) and Chief Financial Officer (the Company's Principal Financial and Accounting Officer), of the effectiveness of the Company's disclosure controls and procedures required by Exchange Act Rule 13a-15. Based upon that evaluation, the Company's Principal Executive Officer and Principal Financial and Accounting Officer have concluded that the Company's disclosure controls and procedures were not effective as of September 30, 2008 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 because of the material weakness discussed below.

(b) During the most recent fiscal quarter, there were no significant changes in the Company's internal control over financial reporting or in other factors that materially affected or are reasonably likely to materially affect the Company's internal control over financial reporting.

#### (c) Management's Report on Internal Control over Financial Reporting

Management of Aeolus Pharmaceuticals, Inc. ("Aeolus" or the "Company") 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 Securities and Exchange Act of 1934, as amended. The Company's internal control over financial reporting is a process designed to provide reasonable assurance to the Company's 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 the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the 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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of September 30, 2008. In making this assessment, management used criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in an Internal Control Integrated Framework. As a result of the lack of segregation of duties, management has determined that a material weakness in internal control over financial reporting related to the segregation of duties existed as

of September 30, 2008, and based on the criteria set forth by COSO, concluded that the Company's internal control over financial reporting was not effective as of September 30, 2008.

A "material weakness," as defined by the Public Company Accounting Oversight Board (PCAOB) is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. This material weakness has not resulted in an adjustment or misstatements to the financial statements.

To address the material weakness, management has established mitigating controls to minimize the potential for material misstatements in the financial statements. Management has determined that given the Company's size, level of operations and financial resources, it is not practicable for the Company to eliminate the segregation of controls weakness and therefore management has established mitigating controls to minimize the impact of the lack of segregation of duties.

This annual report does not include an attestation report of the company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only management's report in this annual report.

#### Item 9B. Other Information.

None.

### PART III

Certain information required by Part III is omitted from this report because the Registrant expects to file a definitive proxy statement for its 2009 Annual Meeting of Stockholders (the "Proxy Statement") within 120 days after the end of its fiscal year pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended, 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 "Proposal No. 1: Election of Directors," "Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive Proxy Statement for the 2009 Annual Meeting of Stockholders is incorporated herein by reference. The information required by this Item 10 concerning the Registrant's executive officers is set forth under the heading "Executive Officers" located at the end of Part I Item 1 of this 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](http://www.aeoluspharma.com). A copy of the Code of Ethics can also be obtained free of charge by writing to Michael P. McManus, Corporate Secretary, Aeolus Pharmaceuticals, Inc., 26361 Crown Valley Parkway, Suite 150 Mission Viejo, CA 92691.

#### Item 11. Executive Compensation.

The information set forth under the headings "Compensation Discussion and Analysis," "Compensation Committee Report," "Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and "Director Compensation" in our definitive Proxy Statement for the 2009 Annual Meeting of Stockholders is incorporated herein by reference.

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

The information set forth under the headings "Other Information — Principal Stockholders" and "Equity Compensation Plan Information" in our definitive Proxy Statement for the 2009 Annual Meeting of Stockholders 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 definitive Proxy Statement for the 2009 Annual Meeting of Stockholders is incorporated herein by reference.

## Item 14. Principal Accountant Fees and Services.

The information set forth under the heading “Independent Registered Public Accounting Firm — Fees” in our definitive Proxy Statement for the 2009 Annual Meeting of Stockholders 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	Dated	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	
3.1	Certificate of Incorporation, as amended	10-Q	06/30/04	3.1	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation	8-K	3/27/06	3.1	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation	8-K	10/27/06	3.1	
3.4	Bylaws, as amended	8-K	10/25/05	3.1	
3.5	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of the Company dated November 18, 2005	8-K	11/23/05	3.1	
4.1		10-Q	06/30/04	4.1	

	Form of Common Stock Certificate			
	Form of Series B Preferred Stock Certificate	S-4	09/19/03	4.8
4.2				
4.3	Form of Warrant to Purchase Common Stock of Incara Pharmaceuticals Corporation dated April 19, 2004 issued to investors in April 2004	8-K	04/21/04	4.9
4.4	Warrant to Purchase Common Stock of Incara Pharmaceuticals Corporation dated April 19, 2004 issued to SCO Securities LLC	8-K	04/21/04	4.10
4.5	Registration Rights Agreement dated November 21, 2005 by and among the Company and each of the Purchasers whose names appear on the Schedule attached thereto	8-K	11/23/05	4.1
4.6	Form of Warrant to Purchase Common Stock dated November 21, 2005	8-K	11/23/05	10.2
4.7	Form of Warrant to Purchase Common Stock dated June 5, 2006.	8-K	6/5/06	10.3
4.8	Warrant to Purchase Common Stock dated June 5, 2006 issued to Efficacy Biotech Master Fund Ltd.	8-K	6/5/06	10.4
4.9	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	5/22/07	4.1
4.10	Form of Warrant to Purchase Common Stock dated May 22, 2007.	8-K	5/22/07	10.2
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	12/31/00	10.59
10.5*	License Agreement dated January 19, 2001 between Elan Corporation, plc, Elan Pharma International Ltd. and Incara Development, Ltd.	10-Q	12/31/00	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	12/31/00	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	03/31/01	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	03/31/01	10.65

10.9	Third Agreement and Amendment, effective as of January 22, 2001, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited	8-K	06/01/01	10.66
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	12/31/01	10.75
10.11*	License Agreement dated June 25, 1998 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	03/31/02	10.82
10.12*	License Agreement dated May 7, 2002 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	03/31/02	10.83
10.13*	License Agreement dated November 17, 2000 between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc.	10-Q	12/31/00	10.56
10.14*	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	07/03/02	10.84
10.15*	Development and Option Agreement dated May 15, 2002, among Elan Pharma International Limited,	8-K	07/03/02	10.85



Incara Pharmaceuticals Corporation and Aeolus Pharmaceuticals, Inc.				
10.16	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	07/03/02	10.86
10.17	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	07/03/02	10.87
10.18	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	07/03/02	10.88
10.19	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	07/03/02	10.89
10.20	Convertible Secured Promissory Note dated July 28, 2003 issued by Incara, Inc. to Goodnow Capital, Inc.	10-Q	06/30/03	10.97
10.21	Guaranty dated July 28, 2003 issued by Incara Pharmaceuticals Incorporation to Goodnow Capital, Inc.	10-Q	06/30/03	10.98
10.22	Security Agreement dated July 28, 2003 issued by Incara Pharmaceuticals	10-Q	06/30/03	10.90

	Incorporation to Goodnow Capital, Inc.			
10.23	Debenture and Warrant Purchase Agreement dated September 16, 2003 among Incara Pharmaceuticals Corporation, Inc. and Goodnow Capital, L.L.C.	S-4	09/19/03	10.100
10.24	Registration Rights Agreement dated September 16, 2003 among Incara Pharmaceuticals Corporation, Inc. and Goodnow Capital, L.L.C.	S-4	09/19/03	10.101
10.25	Registration Rights Agreement dated April 19, 2004 among Incara Pharmaceuticals Corporation, certain investors and SCO Securities LLC	8-K	04/21/04	10.103
10.26	Amendment No. 1 to Debenture and Warrant Purchase Agreement dated September 16, 2003 among Incara Pharmaceuticals Corporation, Inc. and Goodnow Capital, L.L.C.	8-K	04/21/04	10.104
10.27	Letter dated May 17, 2004 from Elan International Services, Limited and Elan Pharma International Limited to Incara Pharmaceuticals Corporation	10-Q	06/30/04	10.106
10.28+	Aeolus Pharmaceuticals, Inc. 1994 Stock Option Plan, as amended	10-Q	06/30/04	10.109
10.29+	Aeolus Pharmaceuticals, Inc. Amended and Restated 2004 Stock Incentive Plan	S-8 POS	3/31/08	99.1
10.30+	Employment Agreement dated July 14, 2006 between Aeolus	8-K	7/14/06	10.1

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Pharmaceuticals, Inc. and John L. McManus				
10.31+	Letter Agreement dated July 10, 2006 between Aeolus Pharmaceuticals, Inc. and McManus & Company, Inc.	8-K	7/10/06	10.2
10.32+	Form of Indemnity Agreement	8-K	2/18/05	10.118
10.33	Terms of Outside Director Compensation	10-K	12/17/04	10.114
10.34+	Form of Incentive Stock Option Agreement	10-Q	2/8/05	10.115
10.35+	Form of Nonqualified Stock Option Agreement	10-Q	2/8/05	10.116
10.36	Purchase Agreement dated November 21, 2005 by and among the Company and the investors whose names appear on the signature pages thereof	8-K	11/23/05	10.1
10.37	Subscription Agreement dated June 5, 2006 by and between the Company and the investors whose names appear on the signature pages thereof.	8-K	6/5/06	10.1
10.38	Right of First Offer Agreement dated June 5, 2006 by and among the Company and Efficacy Biotech Master Fund Ltd.	8-K	6/5/06	10.5
10.39	Board Observer Letter dated June 5, 2006 by and among the Company and Efficacy Biotech Master Fund Ltd.	8-K	6/5/06	10.6
10.40	Securities Purchase Agreement dated May 22, 2007 by and among the Company and the investors whose names appear on the signature pages thereof.	8-K	5/22/07	10.1
10.41	Letter Agreement dated April 30, 2007 by and between the Company and Rodman and Renshaw, LLC	8-K	5/22/07	10.3
10.42		S-1	6/4/07	10.43

	Convertible Promissory Note dated February 7, 2007 issued by Aeolus Pharmaceuticals, Inc. to Elan Pharma International Ltd.				
10.43	Securities Purchase Agreement dated August 1, 2008 by and among the Company and the investors whose names appear on the signature pages thereof, as amended by Amendment No. 1 thereto dated August 4, 2008 by and among the Company and the investors whose names appear on the signature pages thereof.	8-KA	8/1/08	10.1	
10.44	Form of Senior Convertible Note issued by the Company on August 1, 2008	8-K	8/1/08	10.2	
10.45	Form of Warrant to Purchase Common Stock	8-KA	8/1/08	10.3	
10.46	Form of Senior Convertible Note	8-KA	8/1/08	10.4	
10.47+	Form of Restricted Share Award Agreement	S-8 POS	3/31/08	99.2	
14.1	Aeolus Pharmaceuticals, Inc. Code of Ethics for Chief Executive Officer and Senior Financial Officers, as amended on December 13, 2004	8-K	12/14/04	10.113	
21.1	List of Subsidiaries				X
23.1	Consent of Haskell & White, LLP, Independent Registered Public Accounting Firm				X
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a)				X
31.2	Certification of the Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) and 15d-14(a)				X
32.1					X

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

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\* 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 pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

+ Indicates management contract or compensatory plan or arrangement.

# 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 12, 2008

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.

Signatures	Title	Date
/s/ John L. McManus John L. McManus	President and Chief Executive Officer (Principal Executive Officer)	December 12, 2008
/s/ Michael P. McManus Michael P. McManus	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	December 12, 2008
/s/ David C. Cavalier David C. Cavalier	Chairman of the Board of Directors	December 12, 2008
/s/ John M. Farah, Jr. John M. Farah, Jr., Ph.D.	Director	December 12, 2008
/s/ Joseph J. Krivulka Joseph J. Krivulka	Director	December 12, 2008
/s/ Amit Kumar Amit Kumar, Ph.D.	Director	December 12, 2008

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/s/ Michael E. Lewis Michael E. Lewis, Ph.D.	Director	December 12, 2008
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/s/ Chris A. Rallis Chris A. Rallis	Director	December 12, 2008
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/s/ Peter D. Suzdak Peter D. Suzdak, Ph.D.	Director	December 12, 2008
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