AEOLUS PHARMACEUTICALS, INC.
Form 424B3
December 17, 2004
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Prospectus Supplement filed pursuant to Rule 424(b)(3)

in connection with Registration Statement No. 333-111382

Aeolus Pharmaceuticals, Inc.

(f/k/a Incara Pharmaceuticals Corporation)

Prospectus Supplement No. 4 dated December 17, 2004

(To Prospectus dated January 14, 2004)

8,107,039 shares of common stock

This Prospectus Supplement supplements information contained in that certain Prospectus, dated January 14, 2004, as amended or supplemented, relating to the offer and sale of up to 8,107,039 shares of common stock of Aeolus Pharmaceuticals, Inc. (f/k/a Incara Pharmaceuticals Corporation) by Goodnow Capital, L.L.C., who is also referred to as the selling stockholder in the Prospectus. This Prospectus Supplement is not complete without, and may not be delivered or used except in connection with, the original Prospectus. We will not receive any proceeds from the sale of the shares of common stock by selling stockholders.

As a result of the name change, which was effective on July 16, 2004, our common stock is traded on the OTC Bulletin Board under the symbol AOLS.

Filing of Annual Report on Form 10-K

On December 17, 2004, we filed our Annual Report on Form 10-K for the fiscal year ended September 30, 2004. That Form 10-K, without exhibits, is attached hereto.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 3 of the original Prospectus.

NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OUR SECURITIES OR DETERMINED THAT THE PROSPECTUS OR THIS PROSPECTUS SUPPLEMENT IS TRUTHFUL OR COMPLETE. IT IS ILLEGAL FOR ANYONE TO TELL YOU OTHERWISE.

The date of this Prospectus Supplement No. 4 is December 17, 2004

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-K

(MARK ONE)

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

For the fiscal year ended September 30, 2004

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 other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

P.O. Box 14287

79 T.W. Alexander Drive

4401 Research Commons, Suite 200

Research Triangle Park, North Carolina

27709

(Address of principal executive offices)

Company s telephone number, including area code: 919-558-8688

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

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 x 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 registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

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 the last business day of the registrant s most recently completed second fiscal quarter was approximately $5,389,000 as of such date. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of

the outstanding common stock have been excluded in that such persons might be deemed to be affiliates. This determination of affiliate status might not be conclusive for other purposes.

As of November 30, 2004, the Registrant had outstanding 13,947,303 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company s Proxy Statement for the 2005 Annual Meeting of Stockholders are incorporated herein by reference into Part III.

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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 that relate to future events or our future financial performance. You can identify forward-looking statements by terminology such as may, might, will, could, should, would, expect, plan, anticipate, believe, estimate, predict, intend, potential or continue or the negative of these terms or other comparable terminology. Our actual results might differ materially from any forward-looking statement due to various risks, uncertainties and contingencies, including:

- *the need for additional funds;*
- *uncertainties relating to clinical trials and regulatory reviews;*
- *our dependence on a limited number of therapeutic compounds;*
- *the early stage of the products we are developing;*
- *competition and dependence on collaborative partners;*
- *our ability to obtain adequate patent protection and to enforce these rights;*
- *our ability to avoid infringement of the patent rights of others; and*
- *the other factors and risks described under the section captioned Business Risks Associated with Our Business .*

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.

Item 1. Business.

BUSINESS

General

Aeolus Pharmaceuticals is developing new classes of disease modifying antioxidant small molecules, initially targeting neurodegenerative disorders. Oxygen-derived free radicals are important contributors to the pathogenesis of many diseases. Our compounds have demonstrated efficacy in tissue culture and animal preclinical models of amyotrophic lateral sclerosis, or ALS, which is also known as Lou Gehrig s disease, stroke and spinal cord injury. We began a Phase 1 clinical trial in patients with ALS in October 2004. We have also demonstrated efficacy for our catalytic antioxidants in preclinical models of cancer. In addition, the role of oxygen-derived free radicals in diabetes, respiratory diseases and neurodegenerative diseases such as Alzheimer s disease and Parkinson s disease has been widely studied and documented.

Our website address is www.aeoluspharma.com. We have adopted a Code of Ethics for our Chief Executive Officer and senior financial officers, a copy of which is available on our website, www.aeoluspharma.com. We make available free of charge through our website our 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.

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. (Figure 1.) The body protects itself from the harmful effects of free radicals and other oxidants through multiple antioxidant enzyme systems such as superoxide dismutases, or SOD. These natural antioxidants convert the reactive molecules into compounds

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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.

Figure 1. Interrelationship of superoxide and other cellular oxidants leading to damage to cellular constituents resulting in dysfunction or cell death.

Free radical biology is one of the most widely studied areas in modern science; over 50,000 papers on the subject have been published in the past 30 years. Increasingly, data point to oxygen-derived free radicals as 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 the body s natural antioxidant enzyme, superoxide dismutase, or SOD, or more recently, studies involving over-expression of SOD in transgenic animals, have shown promise of therapeutic benefit in a broad range of disease therapy. Increased SOD function improves outcome in animal models of conditions including stroke, ischemia-reperfusion injury 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; the latter resulted in withdrawal of Orgotein from the market in all but Spain.

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, thus a many-to-one ratio exists between the reactive oxygen molecules and the antioxidant.

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 up to 10,000 times more potent.

Use of antioxidant scavengers, such as thiols or vitamin derivatives, has shown promise of benefit in preclinical and clinical studies. Ethyol, a thiol-containing antioxidant, is approved for reducing radiation and chemotherapy toxicity during cancer treatment, and clinical studies have suggested benefit of other antioxidants in kidney and neurodegenerative diseases. However, large sustained doses of the compounds are required

as each antioxidant scavenger molecule is consumed by its reaction with the free radical. Toxicities and the inefficiency of scavengers have limited the utility of antioxidant scavengers to very specific circumstances.

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 the noted limitations could be overcome. We established our research and development program to exploit the therapeutic potential of small molecule catalytic antioxidants. We have succeeded in our initial research objectives and are preparing to extend our preclinical accomplishments into clinical trials.

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Our catalytic antioxidant program is designed to:

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

We have created a class of small molecules that consume free radicals catalytically; that is they are not themselves consumed in the reaction. The most advanced compound from this effort, AEOL 10150, has shown efficacy in a variety of animal models, including ALS, stroke, radiation injury, pulmonary diseases, and diabetes. AEOL 10150 is now in a Phase 1 clinical trial in ALS patients.

This class of compounds, created and developed over the past eight years, is a patent protected group of manganoporphyrins that retain the positive 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. Like naturally occurring enzymatic antioxidants, our AEOL 10150 compound is up to 10,000 times more potent than non-enzymatic antioxidant scavengers.

Catalytic Antioxidants in Neurodegenerative Diseases

The body protects itself from the harmful effects of oxygen-derived free radicals through multiple antioxidant enzyme systems. When too many free radicals are produced for the body s normal defenses to detoxify, oxidative stress occurs. It has been experimentally demonstrated in tissue culture and animal models that oxygen stress plays a critical role in neuronal cell death, and oxidative stress is apparent in both acute and chronic neurodegenerative diseases, including ALS, stroke and Parkinson s disease.

The body s natural antioxidants have demonstrated some efficacy in models of neurodegeneration, however delivery and stability issues have reduced enthusiasm to clinically develop these molecules. Our program is designed to create stable small molecule antioxidants without the limitations of the body s natural antioxidants.

Catalytic Antioxidants in ALS

Amylotrophic lateral sclerosis, or ALS, the most common motor neuron disease, results from progressive degeneration of both upper and lower motor neurons. The incidence is 1-2 per 100,000 people. ALS occurs twice as often in men as women, with typical onset between 50 and 70 years of age. ALS is progressive 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 three 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 120,000 cases diagnosed each year. In the United States, there are approximately 30,000 patients with ALS with 5,000 new patients diagnosed each year.

Sporadic (i.e., of unknown origin) ALS is the most common form, accounting for 80-90% of cases. The cause of sporadic ALS is unclear. Familial ALS comprises the remainder of cases and 10-20% of these patients have a mutated 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.

The study of ALS has changed in recent years with the development of transgenic mice that express the mutant human SOD1, facilitating the search for new ALS treatments. These mice exhibit a motor neuron disease that presents initially as hind limb weakness, at about 100-120 days of age, and progresses to respiratory failure within 10-15 days of symptom onset. To date, a large majority of reported studies in this model initiated treatment substantially prior to symptom onset, e.g. at 30-60 days of age. Extension of survival from such studies must be carefully examined, and includes both a delay in symptom onset, and in some cases an extension of survival after symptom onset. The stated goal of these studies is to examine the biology of ALS development, and the clinical relevance of this pre-treatment model must be considered carefully.

John P. Crow, Ph.D., and his colleagues at the University of Alabama at Birmingham have tested Aeolus lead compound AEOL 10150 in an animal model of ALS. 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.

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Twenty-four confirmed transgenic mice were alternately assigned to control, 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.

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

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 and Figure 2 show that AEOL 10150 treatment resulted in a greater than 2.5 times mean survival interval, compared to control. AEOL 10150-teated mice were observed to remain mildly disabled until a day or two before death. In contrast, control mice experienced increased disability daily.

Figure 2.

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Dr. Crow has repeated the ALS preclinical experiment a total of four times with similar results, including most recently using the same route of administration that is being used in our Phase 1 clinical trials. 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. Aeolus is also conducting preclinical studies to determine if intrathecal delivery can produce a more effective and longer lasting result than subcutaneous therapy of its antioxidant mimetic compound, AEOL 10150, in the G93A mouse model of ALS.

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

Stroke

An estimated 600,000 people in the United States annually suffer strokes. In the United States, strokes kill approximately 158,000 people annually and have left more than 1,000,000 people disabled to some extent, according to the American Heart Association. The estimated direct cost of stroke is over $28 billion annually, much of which is attributable to the high expense of rehabilitating and caring for victims.

Stroke is an injury to the brain caused by the blockage of blood flow. The reestablishment of blood flow after blockage can cause further damage, which is called reperfusion injury. Many scientists believe that the damage from stroke and reperfusion injury is caused, at least in part, by free radicals. In animal models of stroke, in which the middle cerebral artery of a rat or mouse is blocked for 60 to 90 minutes and then unblocked, AEOL 10113 and AEOL 10150 significantly reduced damaged brain tissue, even when introduced as late as 7.5 hours after the start of the stroke. AEOL 10150 also significantly reduced damaged brain tissue in a mouse model of severe stroke in which blood flow to a portion of the brain was permanently blocked.

Indications for Catalytic Antioxidants outside Neurodegeneration

Positive preclinical data has been generated by our catalytic antioxidants in applications other than neurodegeneration.

Use in Cancer Therapy

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. A compound that would directly inhibit tumor growth and protect against the therapy-limiting side effects of other cancer treatment could enhance the success of therapy. Preclinical studies have found that our catalytic antioxidants, AEOL 10113 and AEOL 10150, inhibit formation of blood vessels required for tumor growth, and protect normal tissues from damage induced by radiation and chemotherapy. We have obtained outside funding for this program in the form of a National Institutes of Health Small Business Innovation Research grant. AEOL 10113 and AEOL 10150 are our lead candidates in the cancer therapy area.

Antitumor Effect of Catalytic Antioxidants. A drug to protect normal cells will not be useful if it also protects tumor cells. In a model in which breast cancer cells were transplanted into rats, AEOL 10113 did not protect the tumor cells from radiation. Instead, the antitumor effect of radiation was enhanced by administration of the compound. Both AEOL 10113 and the related compound AEOL 10150 have shown antitumor activity following radiation therapy in RP9 prostate cancer in mice and in human HCT116 colon cancers in athymic mice. Both AEOL 10113 and AEOL 10150 have shown some degree of antitumor activity in the absence of radiation therapy in rat models of breast and skin cancers.

Radiation Therapy. It has been recognized for many years that radiation therapy produces oxygen free radicals in the body that react with cellular components to kill cancer cells. These free radicals also harm normal healthy tissue, limiting the dose of radiation that can be given in cancer therapy and causing toxicities such as oral mucositis and lung inflammation and fibrosis. Our catalytic antioxidants have been shown to limit the adverse effects of radiation on normal tissue in the brain, lung and lining of the intestinal tract.

Radiation-Induced Mucositis. Oral ulcerative mucositis is characterized by formation of painful ulcers in the mouth and is a common dose-limiting side effect of drug and radiation therapy for cancer. AEOL 10150 has reduced the extent and duration of severe radiation-induced mucositis in a preclinical animal model. The compound has shown activity both when given topically as an oral rinse and when injected into the abdominal cavity.

Radiation-Induced Lung Toxicity. The ability of radiation therapy to treat tumors involving the chest such as lung or breast cancer is often limited by injury to the normal lung caused by radiation. Currently, radiation-related pulmonary symptoms occur in

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up to 30% of patients irradiated for lung cancer, breast cancer, lymphoma or thymoma. In laboratory experiments, our catalytic antioxidant AEOL 10113 significantly protected the normal lung tissue of rats against damage caused by radiation.

Developmental Research. In August 2003, we were awarded a $100,000 Small Business Innovation and Research, or SBIR, Phase I grant from the National Cancer Institute, a division of the National Institutes of Health, or NIH, and in March 2004, we were awarded a SBIR Phase II grant from the NIH. Pursuant to the grants, we are studying the antitumor and radiation-protective effects of our catalytic antioxidants. We completed Phase I during fiscal 2004. The Phase II grant is payable over two years and will explore the ability of the selected compound to inhibit tumors from becoming channels for further cancerous growth and block damage to normal tissue from radiation therapy. The initial grant amount of $375,000 of Phase II was awarded in March 2004 by the NIH. The $375,000 for the second part of the Phase II grant is expected to be awarded in early 2005 and is contingent upon the NIH s availability of funds and satisfactory progress of the project. The study is a collaboration between us and the Department of Radiation Oncology at Duke University Medical Center.

Aeolus plans to file in fiscal 2005 an IND for Phase 1 safety trials of AEOL 10150 in patients with various types of solid tumors. The goal is to eventually evaluate the efficacy of AEOL 10150 in patients with cancer undergoing radiation therapy. Preclinical work suggests that AEOL 10150 could be an effective radioprotectant and could inhibit tumor regrowth in patients undergoing palliative radiation therapy.

Catalytic Antioxidants in Respiratory Diseases

Chronic obstructive pulmonary disease, or COPD, is a collective term for diseases characterized by difficulty in expelling air from the lungs. The three diseases most commonly labeled COPD are asthma, chronic bronchitis, and emphysema. According to the National Health Interview Survey taken in 1993, approximately 25 million people in the United States had COPD, including approximately 10 million with asthma, 13 million with chronic bronchitis and 2 million with emphysema. COPD is the fourth leading cause of death in the United States.

Asthma is characterized by acute episodes of difficulty in breathing due to reversible constriction of the airways in the lung. These episodes are initiated by allergies to particular substances, physical conditions (e.g. cold, humidity or exercise), or respiratory infections. Reactive oxygen- and nitrogen-derived free radicals are believed to be involved in the inflammation and airway constriction that is characteristic of an asthma attack. When given by inhalation our compounds reduce markers of airway inflammation in an animal model of allergy-induced asthma attacks.

Chronic bronchitis is an inflammatory and degenerative condition in which the ability of the lung to transfer oxygen to the blood stream is gradually decreased by damage to the lung tissue. Cigarette smoking is the major cause. Much of the damage caused by cigarette smoke and other pollutants is believed to be caused by free radicals. AEOL 10150 reduced the extent of lung tissue damage induced by tobacco smoke in an animal model of chronic bronchitis when administered by inhalation.

There are no treatments that have been shown to slow the progression of COPD. Currently most patients are treated to relieve symptoms, using many of the same compounds that are used to treat asthma.

Diabetes

Type I diabetes is caused by the autoimmune destruction of insulin-producing beta cells in the pancreas. A body of evidence suggests that oxygen-derived free radicals contribute to the mechanisms of beta cell destruction. Beta cells genetically engineered to over produce antioxidant enzymes have been shown to be resistant to some oxygen free radical damage. Other scientists have shown that increased production of SOD in pancreatic beta cells of mice provides the mice resistance in experimental models of diabetes.

Data from an animal model of Type 1 diabetes suggest that treatment of susceptible patients with a catalytic antioxidant might delay or prevent disease. Also, treatment with a catalytic antioxidant could delay the progression or prevent the occurrence of diabetic complications such as vascular disease, kidney disease, blindness, etc. which are mediated, in part, by free radical mechanisms.

Commercialization

Assuming successful development of one or more of our compounds, the effective marketing of a pharmaceutical for treatment of these indications will require the resources of a sales organization. We intend to seek development, marketing and/or licensing arrangements for the uses of our catalytic antioxidant compounds with pharmaceutical companies that have an established marketing presence in the target indications.

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To successfully commercialize our catalytic antioxidant programs, we must seek academic or corporate partners with expertise in areas outside our own or develop this expertise internally. We might not be able to successfully develop our catalytic antioxidant technology, either internally or through collaboration with others.

Collaborative and Licensing Arrangements

Duke Licenses

Through our wholly owned subsidiary, Aeolus Sciences, Inc., we have obtained exclusive worldwide rights from Duke University to products using antioxidant technology and compounds developed by Dr. Irwin Fridovich and other scientists at Duke. These scientists provide research support and advice in the field of free radical and antioxidant research. 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 license to pay patent prosecution, maintenance and defense costs. The Duke licenses are terminable in the event of breach and otherwise expire when the last licensed patent expires.

National Jewish License

In September 1997, we executed a Sponsored Research Agreement with National Jewish Medical and Research Center. The National Jewish Agreement grants Aeolus Sciences an option to negotiate a royalty-bearing exclusive license for technology, patents and inventions resulting from research at National Jewish within the field of antioxidant compounds and related discoveries. We have agreed to support National Jewish s costs incurred in performance of the research. In November 2000, we obtained an exclusive worldwide license from National Jewish to develop, make, use and sell products using proprietary information and technology developed under this sponsored research agreement. We must make milestone payments to National Jewish 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 National Jewish license is terminable in the event of breach and otherwise expires when the last licensed patent expires.

Elan Corporation, plc

In May 2002, we 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 we terminated this collaboration in January 2003, we 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.

Manufacturing

Assuming the successful development of one or more of our catalytic antioxidant compounds, we plan to contract with third parties for manufacturing capabilities.

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. We might not be able to enter into any marketing arrangements for any of our products on satisfactory terms.

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 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 cheaper, safer or more effective than those being developed by us or that would render our technology obsolete.

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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.

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

Antioxidants

Several companies have explored the therapeutic potential of antioxidant compounds in numerous indications. Historically, most of these companies have focused on engineered versions of naturally occurring antioxidant enzymes, but with limited success, perhaps because the large size of these molecules makes delivery into the cells difficult. Antioxidant drug research continues at a rapid pace despite previous clinical setbacks. In October 1998, Metaphore Pharmaceuticals, Inc. reported results from preclinical studies of a small molecule that performs the same chemical reactions as the antioxidant enzyme superoxide dismutase. Metaphore reported that this compound substantially reduced tissue damage due to inflammation and reperfusion in animal models. In April 2004, Metaphore announced positive Phase 2 results with M40403 in the treatment of pain when used in combination with morphine. Also in 2004 Metaphore noted that it had completed a confirmatory Phase 2 study of M40403 in pain in conjunction with opioids and that it had completed a Phase 1 study of M40419. Eukarion, Inc. is also developing similar compounds, which are in preclinical development for conditions associated with damage caused by free radicals. Novia Pharmaceuticals Ltd. also is pursuing antioxidant research in neurodegenerative diseases. Novia currently is testing its compound, AD4, in animal studies of Parkinson s disease and multiple sclerosis.

ALS

Rilutek® (riluzole) is marketed by Aventis SA and is the only 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.

Novartis AG is developing TCH-346, an anti-apoptotic, selegiline derivative for the treatment of neurodegenerative diseases including ALS. A Phase 2b clinical trial with TCH-346 was started in September 2003. Wyeth s product, Minocin, is also in Phase 3 development for ALS. There are an additional seven products reported to be in clinical development for ALS.

Reduction of Radiation or Chemotherapy Induced-Injury in Cancer Therapy

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). Eukarion has initiated the investigation of a small molecule antioxidant to reduce radiation induced skin damage in breast cancer.

Amgen, Inc. has announced that its proprietary recombinant human keratinocyte growth factor (rHuKGF) compound, Kepivance (palifermin), significantly reduced the duration and incidence of severe oral mucositis in a Phase 3 study of patients with blood and lymphatic cancers undergoing high-dose chemotherapy and radiation and total body irradiation followed by bone marrow transplant. Amgen submitted an application for approval of this product to both U.S. and European regulatory officials in 2004 and received FDA approval in December 2004.

Acute Stroke Treatment

Recombinant tissue plasminogen activator, or rTPA, is approved in the United States, Germany and several other countries for acute stroke treatment in selected patients, but because this drug must be given within three hours of stroke onset, only about 1-2 % of stroke patients qualify for and receive rTPA. AstraZeneca plc is developing a nitrone compound with free radical trapping properties for stroke. The compound, licensed from Renovis, Inc., is currently in two Phase 3 clinical trials. The Stroke Trials Directory at Washington University (www.strokecenter.org) lists approximately 60 ongoing clinical studies on a wide variety of acute stroke interventions, including several trials of drugs or biologics. If effective, some of these compounds could be complementary to our compounds or, alternatively, become competitors.

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Respiratory Disease

There are several medications on the market to treat the acute symptoms of COPD, including medications that dilate the airways, steroids that reduce inflammation, and some compounds to reduce mucus. These compounds mainly relieve the acute airway constriction and inflammation. No treatments have been shown to decrease the progression of chronic bronchitis or emphysema.

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 might not issue on any of the pending patent applications owned 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.

Our catalytic antioxidant small molecule technology base is described in 14 issued patents and 41 patent applications that are pending. These patents and patent applications belong in whole or in part to Duke or National Jewish 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 and issued U.S. patent applications include composition of matter claims for several series of compounds. Corresponding international patent applications have been filed as we deem appropriate, two of which have issued.

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. These types of agreements can be difficult to enforce and for some types of breach there is no satisfactory remedy for unauthorized disclosures. It is possible that our trade secrets and proprietary know-how will become known or will be independently discovered by others despite our efforts.

Our commercial success will also depend in part on our ability to commercialize products without infringing patents or other proprietary rights of others or breaching the licenses granted to us. If we are not able to obtain a license to any third-party technology needed for our business at a reasonable cost, we might have to stop developing the product.

As with any pharmaceutical company, our patent and other proprietary rights are uncertain. The patent rights related to our products might conflict with current or future proprietary rights of others. For the same reasons the products of others could infringe our patent or proprietary rights. Litigation or patent interference proceedings, either of which could result in substantial cost, might be necessary to enforce any patents or other proprietary rights issued to us or to determine the scope and validity or enforceability of other parties proprietary rights. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could make us pay damages to third parties, require disputed rights to be licensed from third parties, or require us to cease selling our products.

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

preclinical studies;

the submission to the FDA of a request for authorization to conduct clinical trials on an investigational new drug, which must become effective before human clinical trials may commence;

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adequate and well-controlled Phase 1, 2 and 3 human clinical trials to establish the safety and efficacy of the drug for its intended use;

submission to the FDA of a New Drug Application, or 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 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 good manufacturing practices, or 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 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 Investigational New Drug Application, or IND, which must become effective prior to commencement of human clinical trials. Clinical trials are typically conducted in three sequential phases following submission of an IND. Phase 1 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 2 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 3 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 take care to adhere to good clinical practice, or 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. 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 might 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.

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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 National Institutes of Health terminated the Phase 3 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 Discovery, Inc. of Aurora, Colorado and its academic collaborators have reexamined the 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 of bucindolol.

Discontinued Programs

Our historical financial statements include cash expenditures for the following programs that we no longer operate.

Liver Cell Therapy

We acquired a majority ownership interest in a company, formerly known as Incara Cell Technologies, Inc., in September 1997 and the remaining minority interest in March 2000. Incara Cell Technologies operated a program to advance the state of liver cell transplantation. We sold the operations and substantially all of the assets of the liver cell therapy program in October 2002 for cash and a right to receive royalties on products developed using intellectual property transferred. Net expenses for the liver cell therapy program are presented as discontinued operations on the financial statements.

Incara Development, Ltd.

In January 2001, we entered into a collaborative and financing transaction with Elan. As part of the transaction, Elan and we formed Incara Development, Ltd. to develop deligoparin. In January 2001, Incara Development initiated a Phase 2/3 pivotal clinical trial for deligoparin in patients with ulcerative colitis. The trial enrolled 138 patients at 30 academic and private medical centers. The study was designed to examine the effects of subcutaneous injection of deligoparin in patients with symptoms of active ulcerative colitis who were also receiving standard medical treatment. In September 2002, we announced that the results of the trial did not justify further development of deligoparin for treatment of ulcerative colitis and the development of deligoparin was terminated. Elan and we terminated our collaboration in November 2003 and Incara Development was dissolved in August 2004.

Employees

We had three full-time employees and one part-time employee at November 30, 2004. None of our employees is represented by a labor union. We also utilize consultants and are highly dependent on the services of our executive officers. The loss of any of our executive officers could have a material adverse effect on us. In addition, 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 such personnel from other companies, research and academic institutions, government entities and other organizations. We might not be successful in hiring or retaining the personnel we require.

RISKS ASSOCIATED WITH OUR BUSINESS

You should carefully consider the risk factors discussed below, together with all of the other information included in this Form 10-K and presented elsewhere by us from time to time, including our other SEC filings. If any of the following risks, or other risks not presently known to us or that we currently believe immaterial develop into actual events, then our business, financial condition, results of operations or prospects could be negatively affected.

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Risks Related To Our Business

If we do not obtain additional funding in the near future, we will be unable to fund our research and development activities and will need to eliminate or curtail these programs or cease our operations entirely.

The most significant issue we have recently faced and will continue to face is adequate funding of our existing projects. As of September 30, 2004, we had $7,381,000 of cash. We believe we have adequate financial resources to fund our current operations through fiscal 2005, but in order to fund on-going cash requirements beyond fiscal 2005, or to accelerate our programs, we will need to raise additional funds. We are considering strategic and financial options available to us, including the sale of securities. If we do not receive additional financing to fund operations beyond fiscal 2005, 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 of their investment.

Our cash needs will depend on the success of our research and development activities for additional future funding.

If our catalytic antioxidant program shows scientific progress, we will need significant additional funds to move therapies through the preclinical stages 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.

We expect to continue to incur substantial losses and we might never achieve a profit.

As of September 30, 2004, we had an accumulated deficit of $140.2 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 our company for at least several more years. In the past, most of our revenues have come from previous collaborators who reimbursed us for research and development activities.

We remain contingently liable for IRL obligations.

In connection with the December 1999 sale of IRL, our former anti-infectives drug discovery division, to a private pharmaceutical company, we agreed to remain contingently liable through May 2007 on debt and lease obligations assumed by the purchaser, including primarily the IRL facility lease in Cranbury, New Jersey. If the purchaser were to default, or the lender or landlord otherwise collect from us, our financial condition would be materially adversely affected. This contingent liability was approximately $2.6 million at September 30, 2004 and should decline on an approximately straight-line basis to zero in May 2007.

Our research and development 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 research and development 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 uneconomical to market or do not achieve broad market acceptance;
- third parties hold proprietary rights that preclude us from marketing them; 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. As evidence of the difficulty in commercializing new products, we terminated our clinical trial and development of deligoparin in September 2002. We might have to terminate the development of current or future products and our results of operations could be adversely affected.

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If we do not reach the market with our products before our competitors offer products for the same use, or if we do not compete effectively in marketing our products, the 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 cheaper, safer or more effective than those being developed by us or that would render our technology obsolete.

We expect to remain dependent on collaborations with third parties for the development of new products.

Our current business strategy is to enter into agreements with third parties both to license rights to our potential products and to develop and commercialize new products. We might not be able to enter into or maintain these agreements on terms favorable to us. We currently license from third parties, and do not own, rights under patents and certain related intellectual property for our current development program. If any of these licenses were to expire or terminate, our business could be 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.

We have exclusive worldwide rights to our antioxidant small molecule technology through license agreements with Duke University and National Jewish Medical Center. Our licenses generally may be terminated by the licensor if we fail to perform our obligations, 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. 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 were to be developed out of these licenses, key financial and other terms, such as royalty payments, for the licensing of this future technology might have to be negotiated 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 need to obtain collaborative arrangements for manufacturing and marketing of our potential products, or we will have to develop the expertise, obtain the additional capital and spend the resources to perform those functions.

We do not have the staff or facilities to manufacture or market any of the potential products being developed in our catalytic antioxidant program. We will need to enter into collaborative arrangements in the future to develop, commercialize, manufacture and market products expected to emerge from our catalytic antioxidant program. We might not be successful in entering into third party arrangements on acceptable terms, if at all. If we are unable to obtain or retain third-party manufacturing or marketing on acceptable terms, we might be delayed in our ability to commercialize products. Substantial additional funds and personnel would be required if we needed to establish our own manufacturing or marketing operations. We might not be able to obtain adequate funding or establish these capabilities in a cost-effective or

timely manner.

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.

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 sell products that compete directly with ours, without incurring any liability to us. Patent prosecution, maintenance and enforcement on a global basis is 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 prosecution, a patent application might 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 a majority of U.S. patent applications are maintained in secrecy until a patent issues. Publications in the scientific or patent literature generally do not identify the date of an invention, so it is possible that a competitor could be pursuing the patenting of the same invention in the United States and have an earlier invention date. Outside the United States, priority of invention is determined by the earliest effective filing date, not the date of invention. Consequently, if another person or company 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

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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 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 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. If a patent were invalidated, we could be subject to unfettered competition from latecomers. The cost of litigation can be substantial, even if we prevail and there can be no assurance for recovery of 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 subject to frequent and protracted litigation regarding patent and other intellectual property rights. Most companies have numerous patents that protect their intellectual property rights. These third parties might assert 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 spend significant resources and be distracted from our core business activities, regardless of the outcome. If we did not prevail in the litigation, we could be required to license a third party s technology, which might not be possible on satisfactory terms, or discontinue our own activities and develop non-infringing technology, any of which could prevent or 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 technological advances. 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 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 liability to us.

If our employees, consultants or collaborators were to use information improperly obtained from others (even if unintentional), disputes could arise as to ownership and rights in any resulting know-how or inventions.

If we cannot retain or hire qualified personnel, our programs could be delayed.

As of November 30, 2004, we had three full-time employees and one part-time employee. We also utilize consultants and are highly dependent on the services of our executive officers, including in particular James D. Crapo, M.D., our Chief Executive Officer. We also are dependent on the academic collaborators, one of whom is Dr. Crapo, for our research and development activities. The loss of key executive officers or academic 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. We might not be successful in hiring or retaining the personnel needed for success.

Product liability claims, if asserted against us in the future, could exceed our insurance coverage and use our cash resources.

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

Insurance covering product liability claims becomes increasingly expensive as a product moves through the development pipeline to commercialization. We have limited product liability insurance coverage for our clinical trials for ALS. However, the available insurance coverage might not be sufficient to cover us against all potential losses due to liability, if any, or to the expenses

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associated with defending liability claims. A product liability claim successfully asserted against us could exceed our coverage and require us to use our own cash resources, which would then not be available for our own products.

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, 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 might 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.

Risks Related To Owning Our Stock

Majority ownership and control of our company.

As of November 30, 2004, Goodnow Capital, L.L.C. owned 8,107,039 shares of our common stock, representing 58.1% of our outstanding common stock. In addition, Xmark Asset Management, LLC, the manager of Goodnow, holds of record an additional 1,000,000 shares for which Xmark has the right to vote the shares pursuant to a voting trust agreement. As a result, Xmark and Goodnow are able to significantly influence, if not control, future actions voted on by stockholders, including, for example, the election of directors.

The ownership interest of our stockholders will be substantially diluted by future issuances of stock and exercises of currently outstanding options and warrants.

We might need to sell additional shares of our common stock, preferred stock or other securities, or enter into collaborations with third parties to meet our capital requirements. We might not be able to complete these transactions if needed. If these sales of stock were to occur, these issuances of stock would dilute the ownership interests of our stockholders. 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 November 30, 2004, we had 13,947,303 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. As of November 30, 2004, options to purchase 2,017,220 shares were outstanding at exercise prices ranging from $0.40 to $205.00, with a weighted average exercise price of $4.69, and 1,497,500 shares

were reserved for issuance under the 2004 Stock Option Plan. In addition, as of November 30, 2004, warrants to purchase 2,207,402 shares of common stock were outstanding at exercise prices ranging from $1.00 to $20.25, with a weighted exercise price of $4.56, and we had reserved 9,118 shares of common stock for issuance pursuant to our Employee Stock Purchase Plan.

In connection with prior collaboration and financing transactions, we have issued Series B preferred stock, a promissory note convertible into Series B preferred stock and warrants to purchase Series B preferred stock to affiliates of Elan Corporation. These securities generally are convertible at the option of the Elan affiliates. As discussed below, the conversion of all or a portion of these securities would dilute the ownership interests of our stockholders.

Stockholders might experience dilution from the conversion of outstanding Series B preferred stock, warrants and a convertible promissory note held by affiliates of Elan Corporation, which are convertible into shares of our common stock.

At November 30, 2004, affiliates of Elan owned 503,544 shares of Series B preferred stock, which is all of the Series B preferred stock issued and outstanding, as well as a convertible promissory note that Elan may convert at its option into 18,483 shares of Series B preferred stock as of November 30, 2004, and warrants to purchase 22,191 shares of Series B preferred stock, for a total of 544,218 shares of Series B preferred stock. Each share of Series B preferred stock may be converted into one share of our common stock. If the Series B preferred stock, promissory note and warrants were all converted into common stock as of November 30, 2004, the Elan affiliates would own an additional 544,218 shares of our common stock. The perceived risk of dilution by the convertible securities held by the Elan affiliates might cause our stockholders to sell their shares, which would decrease the market

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price of our common stock. Further, any subsequent sale of our common stock by the Elan affiliates would increase the number of our publicly traded shares, which could also lower the market price of our common stock.

Our common stock is not listed on an exchange, is illiquid and is characterized by low and/or erratic trading volume, and the price of our common stock has fluctuated from $0.30 to $10.50 during the last two years.

Our common stock is quoted on the OTC Bulletin Board under the symbol AOLS . Historically, the public market for our common stock has been characterized by low and/or erratic trading volume, often resulting in price volatility. An active public market for our common stock is unlikely to develop as long as we are not listed on Nasdaq or an exchange and, even then might be limited because of the limited number of investors, the significant ownership stake of Goodnow Capital and Xmark Funds and our small market capitalization (which is less than that authorized for investment by many institutional investors).

We have agreed to register with the SEC shares of common stock that might be issued to the Elan affiliates pursuant to the conversion of the Series B preferred stock, warrants and convertible promissory note currently owned by the Elan affiliates. In addition, the shares underlying substantially all warrants outstanding either have been registered or we have agreed to register them and will be freely tradable upon issuance. We would expect that any common stock sold in any future private placements would be registered with the SEC and freely tradable. The sale of a significant amount of shares in a future financing could cause the trading price of our common stock to decline and to be highly volatile.

The market price of our common stock is also 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.

Provisions of our charter documents and Delaware law could lead to entrenchment of management which could discourage or delay offers to acquire us, which might reduce the market price of our common stock and the voting rights of the holders of our common stock.

Several provisions of our charter documents, as well as Delaware law, will make it more difficult for our stockholders to change our directors or for a third party to acquire our company, and might discourage a third party from offering to acquire our company, even if a change in control or in management would be beneficial to our stockholders. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock.

Our Board of Directors has the authority to issue up to 3,000,000 shares of preferred stock in one or more series, and to determine the prices, rights, preferences, privileges and restrictions, including voting rights, of the shares within each series without any further vote or action by the stockholders. The rights of the holders of common stock are subject to, and might be adversely affected by, the rights of the holders of any preferred stock that might be issued in the future. The issuance of preferred stock with voting rights could make it more difficult for a third party

to acquire a majority of our outstanding voting stock. The issuance of preferred stock would require the prior approval of Goodnow pursuant to the terms of the Debenture and Warrant Purchase Agreement dated September 16, 2003 between us and Goodnow.

Further, some provisions of Delaware law could delay or make more difficult a merger, tender offer or proxy contest. Such provisions could reduce the market value of our common stock in the future.

Item 2. Properties.

We currently lease 17,280 square feet of office and laboratory space in Research Triangle Park, North Carolina, which is leased through June 2006, and 3,082 square feet of office space in Greenwood Village, Colorado, which is leased through September 2005. We believe that these facilities are adequate to meet our needs for now and the foreseeable future. We have subleased approximately 2,200 square feet of our laboratory space through June 2006.

Item 3. Legal Proceedings.

We are not a party to any material legal proceedings.

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

No matters were submitted to a vote of security holders during the fourth quarter ended September 30, 2004.

Executive Officers

Our executive officers and their ages as of November 30, 2004 are as follows:

Name	Age	Position
James D. Crapo, M.D.	61	Chief Executive Officer
Shayne C. Gad, Ph.D.	55	President
Richard W. Reichow	54	Executive Vice President, Chief Financial Officer, Treasurer and Secretary
Brian J. Day, Ph.D.	44	Chief Scientific Officer

James D. Crapo, M.D. became Aeolus Chief Executive Officer in July 2004. Dr. Crapo has had an extensive career as a leading research scientist, administrator, practicing physician and clinical investigator. Since 1996, he has been Chairman of the Department of Medicine and Executive Vice President of Academic Affairs at the National Jewish Medical and Research Center in Denver, Colorado. National Jewish is a top-rated private institution in immunology and allergic diseases and has been rated number one nationally in pulmonary medicine by U.S. News and World Report for the past 5 years. In addition to his administrative duties at National Jewish, Dr. Crapo s responsibilities include clinical care of patients and scientific research. Prior to his appointment at National Jewish in 1996, Dr. Crapo was on the faculty of Duke University Medical Center where he served for 17 years as the Chief of the Pulmonary and Critical Care Medicine Division. He is the author of more than 200 original scientific publications, numerous book chapters and seven textbooks. He also has previously been President of the American Thoracic Society and is currently serving as President of the Fleischner Society. Dr. Crapo is one of the scientific co-founders of Aeolus catalytic antioxidant drug development program and has been the program s chief scientific officer since its inception. He is one of the inventors on a majority of the program s patents and is also serving as the Medical Director for Aeolus ALS clinical program.

Shayne C. Gad, Ph.D. is a part-time consultant and was appointed President of Aeolus in May 2004. Dr. Gad is the founder and Principal of Gad Consulting Services, an eleven-year-old consulting firm servicing both domestic and international clients within the life sciences industries. Prior to this, he served in director-level and above positions at Searle, Synergen, Inc. and Becton, Dickinson and Company. His experience includes safety assessment and product development in the contract research, pharmaceutical, biotechnology, medical device and chemical industries. He has published 29 books and more than 300 chapters, articles and abstracts in the fields of toxicology, statistics, pharmacology, drug development and safety assessment, and is on numerous editorial boards. He has served on NIH, NIEHS, Canadian government, and non-governmental organization grant review boards. Dr. Gad is a Past-President of the American College of Toxicology, the Roundtable of Toxicology Consultants and three specialty sections of the Society of Toxicology. He is also a member of the Regulatory Affairs Professional Society, Society of Toxicology, Teratology Society, Biometrics Society, Society of Toxicologic Pathologists, American Statistical Association, Drug Information Association and is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicologic Sciences. Dr. Gad received his Ph.D. from the University of Texas at Austin and holds a B.S. in chemistry and biology from Whittier College.

Richard W. Reichow has been Chief Financial Officer and Treasurer since March 1995, Executive Vice President since July 1998, and Secretary since October 1995. Mr. Reichow was employed by Sphinx Pharmaceuticals Corporation, a biopharmaceutical company that was acquired by Eli Lilly and Company in September 1994, as President and Chief Executive Officer from December 1993 to September 1994, as Vice President, Finance & Administration from August 1991 to September 1994, and as Chief Financial Officer and Treasurer from March 1990 to September 1994. Between September 1994 and March 1995, he was an independent financial consultant. Mr. Reichow was Vice President,

Chief Financial Officer and Treasurer of CRX Medical, Inc. from 1987 to 1990. Mr. Reichow is a Certified Public Accountant (inactive).

Brian J. Day, Ph.D., 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 National Jewish Medical and Research Center since 1997 and currently is an Associate 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 program s patents.

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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 bid and asked 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.

	Asked	Bid
Fiscal Year Ended September 30, 2003		
October 1, 2002 through December 31, 2002	$ 1.40	$ 0.50
January 1, 2003 through March 31, 2003	$ 1.00	$ 0.30
April 1, 2003 through June 30, 2003	$ 2.40	$ 0.30
July 1, 2003 through September 30, 2003	$ 5.10	$ 1.00
Fiscal Year Ended September 30, 2004		
October 1, 2003 through December 31, 2003	$ 5.60	$ 2.00
January 1, 2004 through March 31, 2004	$ 4.70	$ 2.20
April 1, 2004 through June 30, 2004	$ 10.50	$ 2.00
July 1, 2004 through September 30, 2004	$ 2.80	$ 0.95

(b) Approximate Number of Equity Security Holders

As of November 30, 2004, the number of record holders of our common stock was 182 and we estimate that the number of beneficial owners was approximately 3,700.

(c) Dividends

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

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 human 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.

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(d) Equity Compensation Plan Information as of September 30, 2004

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:			
1994 Stock Option Plan	2,012,220	$ 4.69	404,296
1995 Employee Stock Purchase Plan	0	Not applicable	9,118
Equity compensation plans not approved by our stockholders:			
2004 Stock Option Plan	0	Not applicable	1,500,000
1999 Equity Incentive Plan Restricted Stock	0	Not applicable	7,834
Warrant to Purchase Common Stock Issued to TBCC Funding Trust II	1,759	$19.90	Not applicable
Warrants to Purchase Common Stock Issued to Petkevich & Partners, LLC	14,890	$20.25	Not applicable
Warrant to Purchase Common Stock Issued to W. Ruffin Woody, Jr.	35,000	$ 1.00	Not applicable
Total Common Stock	2,063,869		1,921,248
Warrant to Purchase Series B Preferred Stock Issued to Elan Pharmaceutical Investments III, Ltd.[1]	22,191	$72.12	Not applicable
Convertible Promissory Note convertible into shares of Series B Preferred Stock Issued to Elan Pharma International Limited (as of September 30, 2004)[1][2]	18,185	$43.27	4,409
Total Series B Preferred Stock	40,376		4,409

(1) Each share of Series B preferred stock is convertible into one share of common stock.

(2) The conversion value of the note will increase by its 10% interest rate until its maturity on December 21, 2006.

Description of Equity Compensation Plans Not Approved by Our Stockholders

As an integral component of a management and employee retention program designed to motivate, retain and provide incentive to our management, employees, directors and consultants, our Board of Directors adopted the 2004 Stock Option Plan in September 2004. The 2004 Stock Option Plan provides for the granting of stock options to employees, officers, directors or consultants of Aeolus and its subsidiaries. We

intend to present the 2004 Stock Option Plan for approval at the 2005 annual meeting of stockholders.

As an integral component of a management and employee retention program designed to motivate, retain and provide incentive to our management, employees and key consultants, our Board of Directors adopted the 1999 Equity Incentive Plan in September 1999. The Equity Plan, which has not been approved by our stockholders, provides for the grant of restricted stock awards which entitle our employees and consultants to receive shares of common stock upon satisfaction of specified vesting periods. In May 2002, the Equity Plan was amended to increase the common stock reserved for issuance to 200,000 shares. During

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September 1999, an aggregate of 120,991 shares of restricted stock were granted to employees and key consultants in consideration of services rendered, the cancellation of options for an equal number of shares of common stock and payment of the par value of the shares. In May 2002, an additional 71,175 shares were granted to employees and a key consultant in consideration of services rendered. All outstanding shares of restricted stock were fully vested at September 30, 2004.

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 expires on October 30, 2008.

The warrants to purchase shares of our common stock issued to Petkevich & Partners, LLC have not been approved by our stockholders. J. Misha Petkevich, a former director, is the Chairman and Chief Executive Officer of Petkevich & Partners. The following is a summary of the terms of the warrants and the circumstances surrounding their issuance. In August 2001, we sold 432,304 shares of common stock in a stock offering at an aggregate purchase price of $6,977,750. We used Petkevich & Partners, LLC as our exclusive placement agent in the offering, which placed 377,330 of the total shares sold. For its services, we paid Petkevich & Partners a cash fee of $427,892 and also issued to them a warrant to purchase 4,890 shares of our common stock. The warrant is exercisable for five years and has an exercise price of $20.25 per share. In October 2001, we entered into an agreement with Petkevich & Partners to provide us with financial advisory services for a one-year period. For these services, we issued a warrant for 10,000 shares of our common stock to Petkevich & Partners in October 2001 and agreed to pay Petkevich & Partners a cash fee of $140,000. The warrant is exercisable for five years and has an exercise price of $20.25 per share. The warrants expire on August 8, 2006 and October 16, 2006, respectively.

The warrant to purchase shares of our common stock issued to W. Ruffin Woody, Jr. has not been approved by our stockholders. This warrant was issued in July 2003 in connection with the execution of a $35,000 promissory note payable to Mr. Woody. The warrant expires on July 11, 2008.

(e) Recent Sales of Unregistered Securities

On April 19, 2004, pursuant to a $10.26 million private placement of common stock, we issued to investors an aggregate of 4,104,000 shares of common stock and warrants to purchase 1,641,600 shares of common stock at an exercise price of $4.00 per share. In addition, we issued a warrant to purchase 410,400 shares of common stock at an exercise price of $2.50 per share to SCO Securities LLC, the placement agent who assisted in the private placement. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

On April 19, 2004, we issued 5,046,875 shares of common stock to Goodnow Capital in exchange for a note payable in the amount of $5,046,875. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

On January 9, 2004, in connection with the issuance of a note payable, we issued to Goodnow a 2-year warrant to purchase 1,250,000 shares of common stock at an exercise price of $4.00 per share. This warrant expired in connection with the financing on April 19, 2004. This transaction was exempt under Section 4(2) of the Securities Act of 1933, as amended.

On September 16, 2003, we issued to Goodnow a warrant to purchase 5,000,000 shares of common stock at an exercise price of $1.00 per share. The warrant expired on November 20, 2003 upon completion of our corporate reorganization. This transaction was exempt from registration

under Section 4(2) of the Securities Act of 1933, as amended.

On August 31, 2003, we sold 20 shares of common stock to Goodnow at the fair market value price of $1.70 per share. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

On July 11, 2003, we issued a five-year warrant to W. Ruffin Woody, Jr. to purchase 35,000 shares of common stock at an exercise price of $1.00 per share. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

On May 14, 2002, we sold 416,204 shares of Series B preferred stock to Elan for $3,000,000. Each share of Series B stock is convertible into one share of common stock at no additional cost. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, or Regulation S.

On May 7, 2002, we issued 10,000 shares of common stock to Duke University in partial payment of a license fee. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

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On February 13, 2002, we issued 48,000 shares of common stock and 58,883 shares of Series B preferred stock to Elan in exchange for a note payable in the amount of $1,400,000. Each share of Series B stock is convertible into one share of common stock at no additional cost. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, or Regulation S.

On October 31, 2001, we issued a seven-year warrant to TBCC Funding Trust II to purchase 1,759 shares of common stock at an exercise price of $19.90 per share. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

On October 16, 2001, we issued a five-year warrant to Petkevich & Partners, LLC to purchase 10,000 shares of common stock at an exercise price of $20.25 per share. This transaction was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

(f) 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, 2004 and the related consolidated balance sheet data at those dates from our consolidated financial statements. Our consolidated financial statements for the fiscal year ended September 30, 2004 were audited by Grant Thornton LLP, independent registered public accounting firm, and our consolidated financial statements for the four fiscal years ended September 30, 2003 were audited by PricewaterhouseCoopers LLP, independent registered public accounting firm, and, except for the consolidated statements of operations for the fiscal years ended September 30, 2000 and 2001 and the consolidated balance sheet data at September 30, 2000, 2001 and 2002, are included elsewhere in this Form 10-K. The financial results for prior years have been reclassified to present our liver therapy program s operations as discontinued operations. All common stock amounts have been adjusted for a one-for-ten reverse stock split effected in July 2004.

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Statement of Operations Data:

(in thousands, except per share data)

	Year Ended September 30,				
	2004	**2003**	**2002**	**2001**	**2000**
Revenue:					
Grant income and contract revenue	$ 305	$	$	$	$ 100
Costs and expenses:					
Research and development	8,295	2,780	3,927	5,032	6,693
Purchase of in-process research and development					6,664
General and administrative	3,987	2,025	2,778	3,057	2,585
Total costs and expenses	12,282	4,805	6,705	8,089	15,942
Loss from operations	(11,977)	(4,805)	(6,705)	(8,089)	(15,842)
Gain on sale of division					9,751
Equity in loss of Incara Development		(76)	(1,040)	(12,650)	
Interest income (expense), net	(5,213)	(192)	(50)	223	406
Other income	23	223	150	767	
Loss from continuing operations	(17,167)	(4,850)	(7,645)	(19,749)	(5,685)
Discontinued operations		(38)	(3,657)	(2,464)	(980)
Gain on sale of discontinued operations		1,912			
Net loss	(17,167)	(2,976)	(11,302)	(22,213)	(6,665)
Preferred stock dividend and accretion	(135)	(949)	(887)	(652)	
Net loss attributable to common stockholders	$ (17,302)	$ (3,925)	$ (12,189)	$ (22,865)	$ (6,665)
Net loss per share from continuing operations available to common stockholders	$ (2.06)	$ (4.25)	$ (6.58)	$ (24.78)	$ (10.30)
Net loss per share attributable to common stockholders	$ (2.06)	$ (2.88)	$ (9.40)	$ (27.77)	$ (12.07)
Weighted average common shares outstanding: Basic and diluted	8,388	1,365	1,296	823	552

Balance Sheet Data:

(in thousands)

	September 30,				
	2004	**2003**	**2002**	**2001**	**2000**

Cash and cash equivalents and marketable securities	$ 7,381	$ 586	$ 209	$ 5,453	$ 6,555
Working capital	$ 6,093	$ (2,242)	$ (1,590)	$ 3,967	$ 4,662
Total assets	$ 7,856	$ 1,080	$ 2,201	$ 8,618	$ 7,348
Long-term portion of capital lease obligations and notes payable	$ 787	$ 714	$ 944	$ 17	$ 43
Redeemable convertible exchangeable preferred stock	$	$ 14,503	$ 13,554	$ 12,667	$
Total liabilities	$ 2,324	$ 18,159	$ 3,127	$ 2,971	$ 2,536
Total stockholders equity (deficit)	$ 5,532	$ (17,079)	$ (14,480)	$ (7,020)	$ 4,812

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

Introduction

You should read the followin g 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 1 Business Risks Associated with Our Business and elsewhere in this Form 10-K.

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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 applications will be the use of our catalytic antioxidants for amyotrophic lateral sclerosis, also known as ALS or Lou Gehrig s disease, and cancer radiation therapy. We began a Phase 1 clinical trial in patients with ALS in October 2004.

We do not have any revenue, other than grant income, and therefore we must rely on outside investors, grants or collaborations to finance our operations.

In October 2003, CPEC, LLC licensed bucindolol, a drug being developed to treat heart failure, to ARCA Discovery, Inc. in return for possible future royalty and milestone payments. We own 35% of CPEC.

On October 31, 2002, we sold substantially all of the assets of our liver cell therapy program for the treatment of liver failure. We recognized a gain of $1,912,000 on the sale. The financial operating results for this program have been restated and are presented as discontinued operations on the statements of operations.

In September 2002, as a result of unsatisfactory clinical trial results, we ended a Phase 2/3 clinical trial and the development of an ultra-low molecular weight heparin, known as deligoparin, for the treatment of ulcerative colitis, which was being developed in collaboration with Elan Corporation, plc, an Irish company, and its subsidiaries through our investee, Incara Development, Ltd. Elan and we terminated this collaboration in November 2003.

We had net losses attributable to common stockholders of $17,302,000 and $3,925,000 for the fiscal years ended September 30, 2004 and 2003, respectively. We had an accumulated deficit of $140,188,000 at September 30, 2004. 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 July 16, 2004, we effected a one-for-ten reverse stock split, decreased the number of authorized shares of common stock from 350,000,000 to 50,000,000 and changed our name from Incara Pharmaceuticals Corporation to Aeolus Pharmaceuticals, Inc. All common stock amounts in this Form 10-K have been adjusted for the reverse stock split.

In April 2004, we completed a private placement of 4,104,000 shares of common stock at $2.50 per share, resulting in net proceeds of $9,359,000. In conjunction with the private placement, we issued warrants to purchase 1,641,600 shares of common stock with an exercise price of $4.00 per share and issued a warrant to the placement agent to purchase 410,400 shares of common stock with an exercise price of $2.50 per share. In addition, a $5,047,000 convertible debenture owed to Goodnow Capital, L.L.C. was converted into 5,046,875 shares of common stock.

On November 20, 2003, our stockholders approved the reorganization and merger of our company with and into one of its wholly owned subsidiaries, pursuant to which our stockholders became stockholders of the subsidiary. The corporate reorganization was completed on November 20, 2003. There was no change in the basis of the assets or liabilities of the consolidated company. In conjunction with the reorganization, notes payable in the amount of $3,095,000 were converted into 3,095,144 shares of common stock and all 12,015 shares of Series C preferred stock were converted into 225,533 shares of common stock.

Transactions with Elan Corporation, plc

In January 2001, we closed on a collaborative and financing transaction with Elan. As part of the transaction, Elan and we formed a Bermuda corporation, Incara Development, Ltd., to develop deligoparin. From inception through September 30, 2003, we owned all of the common stock and 60.2% of the non-voting preferred shares of Incara Development and Elan owned 39.8% of the non-voting preferred shares of Incara Development. As part of the transaction, Elan and we entered into license agreements under which we licensed to Incara Development deligoparin and Elan licensed to Incara Development a proprietary drug delivery technology.

As part of the transaction, Elan purchased 82,500 shares of our common stock, 28,457 shares of our Series B non-voting convertible preferred stock and a five-year warrant to purchase 22,191 shares of Series B preferred stock at an exercise price of $72.12 per share for an aggregate purchase price of $4,000,000. Each share of Series B preferred stock is convertible into one share of our common stock. Elan also purchased 12,015 shares of our Series C convertible exchangeable non-voting preferred stock with a face value of $1,000 per share, or a total of $12,015,000. We contributed to Incara Development the proceeds from the issuance of the Series C preferred stock to Elan in exchange for securities of Incara Development. Elan also contributed $2,985,000 to Incara

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Development for its shares of preferred stock of Incara Development. In addition, Elan granted Incara Development a license to Elan s proprietary drug delivery technology for a license fee of $15,000,000.

The Series C preferred stock carried a mandatory stock dividend of 7%, compounded annually and was convertible at Elan s option into shares of our Series B convertible preferred stock. The Series C preferred stock was also exchangeable at the option of Elan at any time for all of the preferred stock of Incara Development held by us which, if exchanged, would have given Elan ownership of 100% of Incara Development s preferred stock outstanding or 50% of the initial amount of combined common and preferred stock of Incara Development. Because the Series C preferred stock was a redeemable preferred stock, it was classified as a liability at September 30, 2003, pursuant to FASB Statement No. 150. On November 20, 2003, our corporate reorganization resulted in the automatic conversion of the Series C preferred stock into 225,533 shares of our common stock.

As part of the initial transaction, Elan and we intended to fund Incara Development pro rata, based on our respective percentage ownership of the combined outstanding common and preferred stock of Incara Development. Of the outstanding combined common and non-voting preferred shares of Incara Development, we owned 80.1% and Elan owned 19.9% from inception through September 30, 2003. Subject to mutual agreement, Elan agreed to lend us up to $4,806,000 to fund our pro rata share of development funding for Incara Development. In return, we issued a convertible promissory note that bears interest at 10% compounded semi-annually on the amount outstanding thereunder. In October 2001 and February 2002, we borrowed from Elan $857,000 and $518,000, respectively, pursuant to the terms of the note arrangement with Elan. In February 2002, we, with Elan s consent, converted the outstanding principal and accrued interest totaling $1,400,000 into 48,000 shares of our common stock and 58,883 shares of our Series B preferred stock. In August 2002, we borrowed from Elan $638,000 pursuant to the terms of the note arrangement. The outstanding balance of the note payable was $787,000 as of September 30, 2004. The note is convertible at the option of Elan into shares of Series B preferred stock at $43.27 per share. The note will mature on December 21, 2006, when the outstanding principal plus accrued interest will be due and payable. We have the option to repay the note either in cash or in shares of Series B preferred 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.

For financial reporting purposes, the value recorded as our investment in Incara Development was the same as the proceeds we received from Elan to purchase the Series C preferred stock, which was $12,015,000. The acquired technology obtained by Incara Development from Elan for $15,000,000 was expensed at inception because the feasibility of using the acquired technology in conjunction with deligoparin had not been established and Incara Development had no alternative future use for the acquired technology. We immediately expensed as Equity in loss of Incara Development 100% of the write-off of the acquired technology, up to our initial investment. We recognized 100% of the net losses of Incara Development to the extent of our initial investment, and we recognized 80.1% of the subsequent net losses, which was the extent of our commitment to provide further financial support to fund those losses.

While we owned all of the outstanding common stock and 60.2% of the non-voting preferred stock of Incara Development prior to November 2003, Elan retained significant minority investor rights, including 50% control of the management committee which oversaw the deligoparin program, that are considered participating rights as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, we did not consolidate the financial statements of Incara Development during fiscal years 2003, 2002 and 2001, but instead accounted for our investment in Incara Development under the equity method of accounting. Elan and we funded Incara Development on a pro rata basis based on the respective ownership of the combined outstanding common and preferred stock of Incara Development. In accordance with APB 18, we recognized 100% of the losses of Incara Development to the extent of our original investment, plus all subsequent losses of Incara Development to the extent that we have committed to provide further financial support to fund those losses. During the fiscal years ended September 30, 2003 and 2002, our equity in loss of Incara Development was $76,000 and $1,040,000, respectively.

In September 2002, we announced that analysis of the results from the clinical trial of deligoparin for the treatment of ulcerative colitis showed that treatment with deligoparin did not meet the primary or secondary endpoints of the study. Although the drug appeared to be safe, the results of the trial did not justify further development of deligoparin for treatment of ulcerative colitis and the development of deligoparin was terminated. Elan and we terminated this collaboration in November 2003 and we became the sole owner of Incara Development. Incara

Development was dissolved in August 2004.

In May 2002, Elan purchased 416,204 shares of our Series B preferred stock for $3,000,000. Elan agreed that it would make additional equity investments in the future based upon the completion of various financial and clinical milestones related to our program for catalytic antioxidant compounds as adjunctive agents to cancer treatment. Elan received an exclusive option to negotiate commercialization or collaboration terms at a later phase relating to catalytic antioxidants being developed by us in the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage. No milestones were met. Elan and we terminated this collaboration in January 2003. In accordance with the terms of the termination agreement, we will pay Elan a royalty on net sales of

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catalytic antioxidant products sold, if any, for the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage.

Results of Operation

Fiscal Year Ended September 30, 2004 Compared to Fiscal Year Ended September 30, 2003

We had a net loss attributable to common stockholders of $17,302,000 for the fiscal year ended September 30, 2004, versus a net loss attributable to common stockholders of $3,925,000 for fiscal 2003. The net loss for fiscal 2003 was net of a $1,912,000 gain on the sale of our liver cell operations to Vesta Therapeutics, Inc. in October 2002.

In August 2003, we were awarded a $100,000 Small Business Innovation and Research, or SBIR, Phase I grant from the National Cancer Institute, a division of the National Institutes of Health, or NIH, and in March 2004, we were awarded a SBIR Phase II grant from the NIH. Pursuant to the grants, we are studying the antitumor and radiation-protective effects of our catalytic antioxidants. We completed Phase I and recognized $100,000 of Phase I grant income during fiscal 2004. The Phase II grant is payable over two years and will explore the ability of the selected compound to inhibit tumors from becoming channels for further cancerous growth and block damage to normal tissue from radiation therapy. The initial grant amount of $375,000 of Phase II was awarded in March 2004 by the NIH. The $375,000 for the second part of the Phase II grant is expected to be awarded in early 2005 and is contingent upon the NIH s availability of funds and satisfactory progress of the project. The study is a collaboration between us and the Department of Radiation Oncology at Duke University Medical Center. We recognized $205,000 of Phase II grant income during fiscal 2004.

Because of our lack of financial resources during fiscal 2003 we had decreased our spending on research and development, or R&D, activities during most of fiscal 2003. With the financing we received beginning in July 2003, we were able to move forward with our preclinical catalytic antioxidant programs. Our R&D expenses increased $5,515,000, or 198%, to $8,295,000 for fiscal 2004 from $2,780,000 for fiscal 2003. Our primary operational focus and R&D spending during fiscal 2004 was on preclinical pharmacology and toxicology tests on our lead compound for the treatment of ALS. We incurred approximately $4,989,000 of outside drug development costs during fiscal 2004 versus only $626,000 of outside drug development costs during fiscal 2003. In addition, we recognized $947,000 of noncash charges for accelerated vesting of stock options for R&D employees during fiscal 2004 as a result of a change in our Board of Directors in April 2004. R&D expenses for our antioxidant program have totaled $24,158,000 from inception through September 30, 2004. Because of the uncertainty of our research and development and clinical studies, we are unable to predict the level of spending and the anticipated program completion date, if any. We expect substantial expenses in the R&D area during the next several years. Our ongoing cash requirements will depend on numerous factors, particularly the progress of our R&D programs and our ability to negotiate and complete collaborative agreements. We are unable to predict the level of spending until near the end of the various programs because of the uncertainty of our research and development and clinical study programs.

General and administrative, or G&A, expenses increased $1,962,000, or 97%, to $3,987,000 for fiscal 2004 from $2,025,000 for fiscal 2003. We expensed $1,580,000 of noncash G&A expenses for fiscal 2004 for accelerated vesting of stock options for G&A employees as a result of a change in our Board of Directors and the resignation of our former Chief Executive Officer. In addition we incurred $575,000 of severance costs in conjunction with the resignation of our former Chief Executive Officer and other officers. We also incurred $150,000 of retainer fees for an investment advisor hired in fiscal 2004. G&A salaries decreased $424,000 from fiscal 2003 to fiscal 2004.

In January 2004, we closed on a convertible debenture of $5,000,000 with Goodnow Capital. Since the convertible debenture conversion rate of $1.00 per share was less than the market value of our common stock at the time of the advances, the convertible debenture proceeds were

allocated to the beneficial conversion feature. As the convertible debenture was converted to common stock in fiscal 2004, the resulting $5,000,000 of discount on the $5,000,000 that we borrowed under the convertible debenture was recognized as $5,000,000 of noncash interest expense in fiscal 2004.

On October 31, 2002, we sold substantially all the assets and operations of our liver cell program to Vesta and recognized a gain of $1,912,000 on the sale. We received a right to royalties on products developed using intellectual property transferred to Vesta and proceeds of $3,422,000, which consisted of $2,955,000 of cash payments and $467,000 of reduction in our notes payable and capital lease obligations. As part of the transaction, we sold to Vesta property and equipment with a net book value of $572,000 and assigned certain related licenses and other agreements to Vesta. We wrote off $492,000 for impaired laboratory facilities and established a reserve of $446,000 for the future net rent costs of our exited laboratory facility. Net expenses of the liver cell program of $38,000 for fiscal 2003 are shown as discontinued operations on the statements of operations.

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Our expenses associated with Incara Development and development of deligoparin of $76,000 were included in Equity in loss of Incara Development for fiscal 2003. The Phase 2/3 clinical trial of deligoparin for the treatment of inflammatory bowel disease ended in September 2002 along with the development of deligoparin, due to an analysis of the clinical trial results, which showed that treatment with deligoparin did not meet the primary or secondary endpoints of the study. We terminated our collaboration with Elan in November 2003 and we became the sole owner of Incara Development. As a result, we consolidated Incara Development s operations in fiscal 2004. Incara Development was dissolved in August 2004.

Other income of $23,000 and $223,000 for fiscal 2004 and 2003, respectively, related primarily to sublease rental income of our leased laboratory facility.

We accreted $135,000 and $949,000 of dividends on our Series C preferred stock during fiscal 2004 and 2003, respectively. As part of the reorganization on November 20, 2003, all shares of Series C preferred stock were converted into common stock and we no longer accrete dividends on the Series C preferred stock.

Fiscal Year Ended September 30, 2003 Compared to Fiscal Year Ended September 30, 2002

We had a net loss attributable to common stockholders of $3,925,000 for the fiscal year ended September 30, 2003, versus a net loss attributable to common stockholders of $12,189,000 for fiscal 2002. The net loss for fiscal 2003 includes a $1,912,000 gain on the sale of our liver cell operations in October 2002. The results for fiscal 2003 and 2002 include costs of $38,000 and $3,657,000, respectively, for our discontinued liver cell program operations. Our loss from continuing operations was $4,850,000 and $7,645,000 for fiscal 2003 and 2002, respectively. In conjunction with the July 2003 financing with Goodnow Capital, employees agreed that obligations for deferred employee salaries of $718,000 would be cancelled. Previously accrued bonuses of $520,000 were also cancelled. In July 2003, in connection with the pending reorganization and the forgiveness of salaries by employees, the Board of Directors granted employees options to purchase 12,905,156 shares of common stock. We incurred a noncash expense of $1,120,000 in fiscal 2003 for the fair market value of the stock options granted in connection with salaries and bonuses cancelled.

Because of our lack of financial resources during most of fiscal 2003, we reduced our R&D operating expenses by reducing our R&D staff, by reducing expenditures for sponsored research and consultants and by spending less on compound development. Our ongoing R&D expenses decreased $1,147,000, or 29%, to $2,780,000 for fiscal 2003 from $3,927,000 for fiscal 2002. R&D expenses related to our catalytic antioxidant program, which was in the preclinical stage.

G&A expenses decreased $753,000, or 27%, to $2,025,000 for fiscal 2003 from $2,778,000 for fiscal 2002. G&A expenses were lower because we reduced operating expenses due to our lack of financial resources and because the prior year s expenses included higher costs associated with financing, investor relations activities and employee compensation.

On October 31, 2002, we sold substantially all of the assets of our liver cell therapy program to Vesta and recognized a gain of $1,912,000 on the sale. We received a right to royalties on products developed using intellectual property transferred to Vesta and proceeds of $3,422,000, which consisted of $2,955,000 of cash payments and $467,000 of reduction in our notes payable and capital lease obligations. As part of the transaction, we sold to Vesta property and equipment with a net book value of $572,000 and assigned certain related licenses and other agreements to Vesta. We wrote off $492,000 for impaired laboratory facilities and established a reserve of $446,000 for the future net rent costs of our laboratory facility. Net expenses of the liver cell program of $38,000 and $3,657,000 for fiscal 2003 and 2002, respectively, are shown as discontinued operations on the statements of operations. R&D expenses for the liver cell program totaled $10,509,000 from inception through

September 30, 2003. Vesta assumed responsibility for the liver program s operating expenses beginning in October 2002.

Our expenses associated with Incara Development and development of deligoparin are included in Equity in loss of Incara Development. For fiscal 2003 and 2002, our equity in loss of Incara Development was $76,000 and $1,040,000, respectively. The expenses for fiscal 2002 include costs associated with our Phase 2/3 clinical trial of deligoparin for the treatment of inflammatory bowel disease, which Incara Development ended in September 2002 along with the development of deligoparin, due to an analysis of the clinical trial results, which showed that treatment with deligoparin did not meet the primary or secondary endpoints of the study.

Other income of $223,000 for fiscal 2003 represented sublease rental income related to our laboratory facility. Other income of $150,000 for fiscal 2002 represented proceeds from the sale of trademarks.

We accreted $949,000 and $887,000 of dividends on our Series C preferred stock during fiscal 2003 and 2002, respectively.

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Liquidity and Capital Resources

At September 30, 2004, we had $7,381,000 of cash, an increase of $6,795,000 from September 30, 2003. We believe we have adequate financial resources to conduct operations at least through fiscal 2005. The increase in cash was primarily due to the following financing transactions, offset by fiscal 2004 cash operating expenses.

- During October and November 2003, we borrowed the final $1,000,000 available under a $3,000,000 convertible note arrangement with Goodnow.

- On November 20, 2003, as part of our corporate reorganization, the $3,000,000 convertible note, plus accrued interest, was converted into 3,060,144 shares of common stock and the Series C preferred stock owned by the Elan affiliates was converted into 225,533 shares of common stock.

- In January 2004, we closed on a convertible debenture of $5,000,000 with Goodnow. We borrowed $5,000,000 during the period from January 2004 through April 2004.

- In April 2004, Goodnow converted the $5,000,000 debenture and accrued interest into 5,046,875 shares of common stock at the conversion rate of $1.00 per share.

- In April 2004, we completed a private placement of 4,104,000 shares of common stock at $2.50 per share, resulting in net proceeds of $9,359,000. In conjunction with the private placement, we issued warrants to purchase 1,641,600 shares of common stock with an exercise price of $4.00 per share and issued a warrant to the placement agent to purchase 410,400 shares of common stock with an exercise price of $2.50 per share.

We incurred operational losses of $11,997,000 during fiscal 2004. Due to the nonrecurring noncash charges for stock options recognized in fiscal 2004, we anticipate our operational expenses will be lower in fiscal 2005. Our ongoing cash requirements will depend on numerous factors, particularly the progress of our catalytic antioxidant program and our ability to negotiate and complete collaborative agreements. 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 may sell additional shares of our stock and explore other strategic and financial alternatives, including a merger with another company.

There are uncertainties as to these potential sources of capital. Our access to capital might be restricted because we might not be able to enter into any collaboration on terms acceptable or favorable to us 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 might have to relinquish rights to technologies, product candidates or markets that we might otherwise develop ourselves.

Similarly, due to market conditions, the illiquid nature of our stock, and other possible limitations on stock offerings, we might not be able to sell additional securities or raise other funds on terms acceptable or favorable to us. It can be difficult for small biotechnology companies such as us to raise funds in the equity markets. Any additional equity financing, if available, would likely result in substantial dilution to existing stockholders.

Contractual Obligations

Our contractual obligations (in thousands) as of September 30, 2004 were as follows:

Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt	$ 978	$	$ 978	$	$
Capital lease obligations					
Operating leases	821	494	327		
Purchase obligations	1,636	1,636			
Other long term liabilities					
Total	$ 3,435	$ 2,130	$ 1,305	$	$

The operating lease commitments include $250,000 of lease obligations for our laboratory facilities, which has been accrued as a liability on our balance sheet. In December 1999, we sold IRL, our anti-infectives division, to a private pharmaceutical company. We remain contingently liable through May 2007 for a lease obligation of approximately $2,614,000 assumed by the purchaser on

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the former IRL facility in Cranbury, New Jersey. This contingent lease obligation is not recorded as a liability, nor is it included in the above table.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity or capital resources as defined under the rules of SEC release No. FR-67. We do have operating leases. In accordance with accounting principles generally accepted in the United States, operating leases are not reflected in the accompanying consolidated balance sheets. Our operating leases are generally for office and laboratory space. We do not have any capital leases.

Relationship With Goodnow Capital

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, 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 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 where 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. Consequently, this exemption is no longer available to us; and

to allow Goodnow to appoint one director to our board of directors, provided Goodnow owns at least 10% and 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.

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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 human 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.

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; 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.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

See Index to Financial Statements on page F-1.

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

As previously reported, on August 23, 2004, PricewaterhouseCoopers LLP (PwC) resigned as our independent registered public accounting firm. The resignation was the sole decision of PwC and was not sought, recommended or approved by our audit committee. PwC s reports on our financial statements for the fiscal years ended September 30, 2003 and 2002 contained a statement that the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Other than the going concern explanatory paragraph noted in the immediately preceding sentence, PwC s reports for the fiscal years ended September 30, 2003 and 2002 were not qualified or modified as to uncertainty, audit scope or accounting principle. During the fiscal years ended September 30, 2003 and 2002 and through August 23, 2004, there were no disagreements between us and PwC on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which if not resolved to the satisfaction of PwC, would have caused them to make a reference thereto in their reports on the financial statements for such years. During the fiscal years ended September 30, 2003 and 2002 and through August 23, 2004, there were no reportable events (as defined in Regulation S-K Item 304(a)(1)(v)).

Also as previously reported, on October 13, 2004, we announced the appointment of Grant Thornton LLP as our independent registered public accounting firm for our fiscal year ended September 30, 2004. Our Audit Committee approved this appointment. The engagement began on October 11, 2004. We did not consult Grant Thornton during our last two most recent fiscal years or any subsequent interim period prior to the engagement regarding the application of accounting principles to a specified transaction, whether completed or proposed, or the type of audit opinion that might be rendered on our financial statements, or any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K) or a reportable event (as defined in Item 304(a)(1)(v) of Regulation S-K).

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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 Chief Executive Officer and Chief Financial 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 Chief Executive Officer and Chief Financial Officer have concluded that the Company s disclosure controls and procedures are effective.

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

Item 9B. Other Information

On September 22, 2004, the Compensation Committee and the Board of Directors approved the following compensation program for the outside members of our Board of Directors.

Each outside Board member will receive annual cash compensation of $15,000, which will be paid in equal quarterly payments beginning July 1, 2004. Cash compensation for new and terminating Board members will be prorated for the period of time that they are a Board member during the respective quarter.

Audit Committee members will receive an additional $10,000 of annual cash compensation, which will be paid in equal quarterly payments beginning July 1, 2004. Cash compensation for new and terminating Audit Committee members will be prorated for the period of time that they are members of the Audit Committee during the respective quarter.

Each outside Board member was granted a nonqualified stock option for 20,000 shares on September 22, 2004. The option exercise price was equal to the closing price on the grant date. The options have 10-year terms and vest, as long as the Director remains on the Board, on a monthly basis over the 12-month period beginning July 19, 2004. Vested shares will be exercisable for 10 years from the grant date.

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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 2005 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 and Executive Officers of the Registrant.

The information required by Item 10 of Form 10-K concerning the Registrant s directors is incorporated by reference to the information under the headings Election of Directors and Report of the Audit Committee in the Proxy Statement. The information required by Item 10 of Form 10-K concerning the Registrant s executive officers is set forth under the heading Executive Officers located at the end of Part I of this Form 10-K.

Compliance with Section 16(a) of the Securities Exchange Act of 1934.

In July 2004, a Form 3 for the initial statement of beneficial ownership of securities for a newly elected Board member, Michael E. Lewis, was received by the SEC five days late. To our knowledge, there were no other reports required under Section 16(a) of the Securities Exchange Act of 1934 that were not timely filed during the fiscal year ended September 30, 2004.

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 such code of ethics on our Internet website. Our website address is www.aeoluspharma.com.

Item 11. Executive Compensation.

The information required by Item 11 of Form 10-K is incorporated by reference to the information under the headings Proposal No. 1 Election of Directors Information Concerning the Board of Directors and Its Committees , Other Information Compensation of Executive Officers , Compensation of Directors , Report of the Compensation Committee on Executive Compensation , Compensation Committee Interlocks and Insider Participation and Performance Graph in the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management.

The information required by Item 12 of Form 10-K is incorporated by reference to the information under the heading Other Information Principal Stockholders in the Proxy Statement.

Item 13. Certain Relationships and Related Transactions.

The information required by Item 13 of Form 10-K is incorporated by reference to the information under the heading Other Information Certain Transactions in the Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by Item 14 is incorporated by reference to the information under the heading Independent Registered Public Accounting Firm Fees in the Proxy Statement.

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PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

(1) Financial Statements.

See Index to Consolidated Financial Statements on page F-1.

(2) 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.

(3) Exhibits.

		Incorporated by Reference To			
Exhibit Number	Description of Document	Registrant s Form	Dated	Exhibit Number	Filed Herewith
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	Bylaws, as amended	10-Q	06/30/04	3.2	
4.1	Form of Common Stock Certificate	10-Q	06/30/04	4.1	
4.3	Warrant to Purchase Shares of Series B Preferred Stock issued to Elan International Services, Ltd.	10-Q	12/31/00	4.3	
4.4	Form of Warrant issued to investors in August 2001.	S-1	08/02/01	4.4	
4.5	Warrant to Purchase Common Stock of Incara Pharmaceuticals Corporation dated July 11, 2003 issued to W. Ruffin Woody, Jr.	10-Q	06/30/03	4.5	
4.6	Warrant dated September 16, 2003 issued by Incara, Inc. to Goodnow Capital, L.L.C.	S-4	09/19/03	4.6	
4.7	Warrant dated September 16, 2003 issued by Incara Pharmaceuticals Corporation to Goodnow Capital, L.L.C.	S-4	09/19/03	4.7	
4.8	Form of Series B Preferred Stock Certificate	S-4	09/19/03	4.8	

4.9	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
4.10	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
10.4*	License Agreement between Duke University and Aeolus Pharmaceuticals, Inc., dated July 21, 1995	S-1	12/08/95	10.4
10.12	Incara Pharmaceuticals Corporation 1995 Employee Stock Purchase Plan, as amended	S-8	08/22/02	10.12
10.24	Sponsored Research Agreement between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc., dated September 11, 1997	10-K	09/30/97	10.24
10.31	Lease Agreement dated September 19, 1996, as amended, between Cedar Brook Corporate Center, L.P. and Transcell Technologies, Inc., as assigned to Intercardia, Inc. effective May 8, 1998	10-Q	06/30/98	10.31
10.40	Exchange Agreement dated July 15, 1999, between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc.	8-K	07/23/99	10.40
10.41	Registration Rights Agreement dated July 15, 1999, between Interneuron Pharmaceuticals, Inc. and Intercardia, Inc.	8-K	07/23/99	10.41
10.42	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
10.43	Assignment, Assumption and License Agreement dated July 15, 1999, between CPEC LLC and Intercardia, Inc.	8-K	07/23/99	10.43

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Exhibit Number	Description of Document	Incorporated by Reference To Registrant s Form	Dated	Exhibit Number	Filed Herewith
10.44	Incara Pharmaceuticals Corporation 1999 Equity Incentive Plan, as amended	S-8	09/09/02	10.44	
10.47	Form of Severance Agreement dated September 23, 1999 with Clayton I. Duncan, Richard W. Reichow, David P. Ward, John P. Richert and W. Bennett Love	10-K	09/30/99	10.47	
10.53	Employment Agreement between Clayton I. Duncan and Incara Pharmaceuticals Corporation, dated December 11, 2000	10-K	09/30/00	10.53	
10.55	Securities Purchase Agreement among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited dated as of December 21, 2000	8-K	01/29/01	10.55	
10.56*	License Agreement dated November 17, 2000 between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc.	10-Q	12/31/00	10.56	
10.57	Office Lease between Highwoods Realty Limited Partnership and Incara Pharmaceuticals Corporation, dated January 25, 2001	10-Q	12/31/00	10.57	
10.58*	Subscription, Joint Development and Operating Agreement dated January 19, 2001 among Elan Corporation, plc, Elan Pharma International Ltd., Elan International Services, Ltd., Incara Pharmaceuticals Corporation and Incara Development, Ltd.	10-Q	12/31/00	10.58	
10.59*	License Agreement dated January 19, 2001 between Incara Pharmaceuticals Corporation and Incara Development, Ltd.	10-Q	12/31/00	10.59	
10.60*	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	
10.61	Convertible Promissory Note dated December 21, 2000 issued by Incara Pharmaceuticals Corporation to Elan Pharma International Ltd.	10-Q	12/31/00	10.61	
10.62	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	
10.64	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	
10.65	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	
10.66	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	
10.74	Commencement Agreement and Lease Amendment Number One, dated November 1, 2001, to Office Lease between Highwoods Realty Limited Partnership and Incara Pharmaceuticals Corporation	10-K	09/30/01	10.74	
10.75	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	
10.76	Employment Agreement between W. Bennett Love and Incara Pharmaceuticals Corporation, dated April 1, 2002	10-Q	03/31/02	10.76	
10.77	Employment Agreement between Richard W. Reichow and Incara Pharmaceuticals Corporation, dated April 2, 2002	10-Q	03/31/02	10.77	
10.79	Employment Agreement between John P. Richert and Incara Pharmaceuticals Corporation, dated April 2, 2002	10-Q	03/31/02	10.79	
10.82*	License Agreement dated June 25, 1998 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	03/31/02	10.82	
10.83*	License Agreement dated May 7, 2002 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	03/31/02	10.83	
10.84*	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	
10.85*		8-K	07/03/02	10.85	

Development and Option Agreement dated May 15, 2002, among Elan Pharma International Limited, Incara Pharmaceuticals Corporation and Aeolus Pharmaceuticals, Inc.

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Exhibit Number	Description of Document	Incorporated by Reference To Registrant s Form	Dated	Exhibit Number	Filed Herewith
10.86	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	
10.87	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	
10.88	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	
10.89	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	
10.91*	Asset Purchase Agreement dated October 21, 2002 between Incara Cell Technologies, Inc. and Vesta Therapeutics, Inc.	8-K	10/24/02	10.91	
10.92	Amendment No. 1 dated October 30, 2002 to Asset Purchase Agreement between Incara Cell Technologies, Inc. and Vesta Therapeutics, Inc.	8-K	11/11/02	10.92	
10.94	Severance Agreement between Richard E. Gammans, Sr., Ph.D. and Incara Pharmaceuticals Corporation, dated September 29, 2000	10-Q	12/31/02	10.94	
10.95	Employment Agreement between Richard E. Gammans, Sr., Ph.D. and Incara Pharmaceuticals Corporation, dated March 7, 2003	10-Q	03/31/03	10.95	
10.96	Secured Convertible Promissory Note dated July 11, 2003 issued by Incara Pharmaceuticals Corporation to W. Ruffin Woody, Jr.	10-Q	06/30/03	10.96	
10.97	Convertible Secured Promissory Note dated July 28, 2003 issued by Incara, Inc. to Goodnow Capital, Inc.	10-Q	06/30/03	10.97	
10.98	Guaranty dated July 28, 2003 issued by Incara Pharmaceuticals Incorporation to Goodnow Capital, Inc.	10-Q	06/30/03	10.98	
10.99	Security Agreement dated July 28, 2003 issued by Incara Pharmaceuticals Incorporation to Goodnow Capital, Inc.	10-Q	06/30/03	10.90	
10.100	Debenture and Warrant Purchase Agreement dated September 16, 2003 among Incara Pharmaceuticals Corporation, Incara, Inc. and Goodnow Capital, L.L.C.	S-4	09/19/03	10.100	
10.101	Registration Rights Agreement dated September 16, 2003 among Incara Pharmaceuticals Corporation, Incara, Inc. and Goodnow Capital, L.L.C.	S-4	09/19/03	10.101	
10.102	Purchase Agreement dated April 19, 2004 among Incara Pharmaceuticals Corporation and certain investors	8-K	04/21/04	10.102	
10.103	Registration Rights Agreement dated April 19, 2004 among Incara Pharmaceuticals Corporation, certain investors and SCO Securities LLC	8-K	04/21/04	10.103	
10.104	Amendment No. 1 to Debenture and Warrant Purchase Agreement dated September 16, 2003 among Incara Pharmaceuticals Corporation, Incara, Inc. and Goodnow Capital, L.L.C.	8-K	04/21/04	10.104	
10.105	Separation Agreement dated May 4, 2004 between Clayton I. Duncan and Incara Pharmaceuticals Corporation	10-Q	03/31/04	10.105	
10.106	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	
10.107	Consulting Agreement between Incara Pharmaceuticals Corporation and Shayne C. Gad, Ph.D., dated June 8, 2004	10-Q	06/30/04	10.107	
10.108	Employment Agreement between James D. Crapo, M.D. and Incara Pharmaceuticals Corporation, dated June 22, 2004	10-Q	06/30/04	10.108	
10.109	Aeolus Pharmaceuticals, Inc. 1994 Stock Option Plan, as amended	10-Q	06/30/04	10.109	
10.110	Aeolus Pharmaceuticals, Inc. 2004 Stock Option Plan, as amended on December 13, 2004	8-K	12/15/04	10.110	
10.111	Amendment to Employment Agreement between Aeolus Pharmaceuticals, Inc. and Richard W. Reichow, dated December 2, 2004	8-K	12/03/04	10.111	
10.112		8-K	12/14/04	10.112	

Consulting Agreement between Aeolus Pharmaceuticals, Inc. and Shayne C. Gad, Ph.D., dated December 14, 2004

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Exhibit Number	Description of Document	Incorporated by Reference To Registrant s Form	Dated	Exhibit Number	Filed Herewith
10.113	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	
10.114	Terms of Outside Director Compensation				X
21.1	List of Subsidiaries				X
23.1	Consent of Grant Thornton, LLP, Independent Registered Public Accounting Firm				X
23.2	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm				X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)				X
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)				X
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X

* confidential treatment granted

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and 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/ JAMES D. CRAPO
James D. Crapo, M.D.

Chief Executive Officer

Date: December 17, 2004

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.

Name	Title	Date
/s/ JAMES D. CRAPO **James D. Crapo, M.D.**	Chief Executive Officer (Principal Executive Officer)	December 17, 2004
/s/ RICHARD W. REICHOW **Richard W. Reichow**	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	December 17, 2004
/s/ DAVID C. CAVALIER **David C. Cavalier**	Chairman of the Board of Directors	December 16, 2004
/s/ JOSEPH J. KRIVULKA **Joseph J. Krivulka**	Director	December 17, 2004
/s/ AMIT KUMAR **Amit Kumar, Ph.D.**	Director	December 17, 2004
/s/ MICHAEL E. LEWIS	Director	December 17, 2004

Michael E. Lewis, Ph.D.		
/s/ Chris A. Rallis	Director	December 17, 2004
Chris A. Rallis		
/s/ Peter D. Suzdak	Director	December 17, 2004
Peter D. Suzdak, Ph.D.		

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Report of Independent Registered Public Accounting Firm

To the Board of Directors of

Aeolus Pharmaceuticals, Inc. and Subsidiaries:

We have audited the accompanying consolidated balance sheet of Aeolus Pharmaceuticals, Inc. (a Delaware corporation) and Subsidiaries (the Company) as of September 30, 2004, and the related consolidated statements of operations, stockholders equity, and cash flows for the year then ended. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Aeolus Pharmaceuticals, Inc. and Subsidiaries as of September 30, 2004, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Raleigh, North Carolina

November 19, 2004

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Aeolus Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Aeolus Pharmaceuticals, Inc. (formerly Incara Pharmaceuticals Corporation) and its subsidiaries (the Company) at September 30, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2003, in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit 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, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The financial statements for September 30, 2003 were prepared assuming that the Company would continue as a going concern. As discussed in Note B to the September 30, 2003 financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raised substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters were also described in Note B to the September 30, 2003 financial statements. The financial statements did not include any adjustments that might result from the outcome of this uncertainty.

PricewaterhouseCoopers LLP

Raleigh, North Carolina

December 5, 2003

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AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Dollars in thousands, except per share data)

	September 30,	
	2004	**2003**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,381	$ 586
Accounts receivable	131	
Prepaids and other current assets	118	114
Total current assets	7,630	700
Property and equipment, net	15	25
Other assets	211	355
Total assets	$ 7,856	$ 1,080
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,185	$ 461
Accrued expenses	102	45
Liabilities of discontinued operations	250	388
Current portion of notes payable		2,048
Total current liabilities	1,537	2,942
Long-term note payable	787	714
Series C redeemable convertible exchangeable preferred stock		14,503
Total liabilities	2,324	18,159
Stockholders equity (deficit):		
Preferred stock, $.01 par value per share, 3,000,000 shares authorized:		
Series B nonredeemable convertible preferred stock, 600,000 shares authorized; 503,544 shares issued and outstanding as of September 30, 2004 and 2003	5	5
Common stock, $.01 par value per share, 50,000,000 shares authorized; 13,947,303 and 1,413,383 shares issued and outstanding at September 30, 2004 and 2003, respectively	139	14
Additional paid-in capital	145,576	105,892
Unvested restricted stock		(104)
Accumulated deficit	(140,188)	(122,886)
Total stockholders equity (deficit)	5,532	(17,079)

Total liabilities and stockholders equity (deficit)	$ 7,856	$ 1,080

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

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AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Fiscal Year Ended September 30,		
	2004	2003	2002
Revenue			
Grant income	$ 305	$	$
Costs and expenses:			
Research and development	8,295	2,780	3,927
General and administrative	3,987	2,025	2,778
Total costs and expenses	12,282	4,805	6,705
Loss from operations	(11,977)	(4,805)	(6,705)
Equity in loss of Incara Development		(76)	(1,040)
Interest expense, net	(5,213)	(192)	(50)
Other income	23	223	150
Loss from continuing operations	(17,167)	(4,850)	(7,645)
Discontinued operations		(38)	(3,657)
Gain on sale of discontinued operations		1,912	
Net loss	(17,167)	(2,976)	(11,302)
Preferred stock dividend and accretion	(135)	(949)	(887)
Net loss attributable to common stockholders	$ (17,302)	$ (3,925)	$ (12,189)
Net loss per common share (basic and diluted):			
Loss from continuing operations available to common stockholders	$ (2.06)	$ (4.25)	$ (6.58)
Discontinued operations	$	$ (0.03)	$ (2.82)
Gain on sale of discontinued operations	$	$ 1.40	$
Net loss attributable to common stockholders	$ (2.06)	$ (2.88)	$ (9.40)
Weighted average common shares outstanding:			
Basic and diluted	8,388	1,365	1,296

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

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AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(Dollars in thousands)

	Series B Preferred Stock		Common Stock					Total Stockholders
	Number of Shares	Par Value	Number of Shares	Par Value	Additional Paid-in Capital	Restricted Stock	Accumulated Deficit	Equity (Deficit)
Balance at September 30, 2001	28,457	$ 1	1,271,709	$ 13	$ 99,850	$ (112)	$ (106,772)	$ (7,020)
Sale of Series B preferred stock to Elan, net of issuance costs of $20	416,204	4			2,976			2,980
Conversion of note payable to Elan to common stock and Series B preferred stock	58,883		48,000		1,400			1,400
Series C preferred stock dividends and accretion							(887)	(887)
Proceeds from offerings of Employee Stock Purchase Plan			8,649		37			37
Restricted stock sold to employees and consultant			71,175	1	252	(252)		1
Stock-based compensation and amortization of restricted stock			10,000		164	147		311
Net loss for the fiscal year ended September 30, 2002							(11,302)	(11,302)
Balance at September 30, 2002	503,544	5	1,409,533	14	104,679	(217)	(118,961)	(14,480)
Series C preferred stock dividends and accretion							(949)	(949)
Proceeds from offerings of Employee Stock Purchase Plan			3,830		2			2
Sale of common stock			20					
Warrants issued in conjunction with notes payable					91			91
Stock-based compensation and amortization of restricted stock					1,120	113		1,233
Net loss for the fiscal year ended September 30, 2003							(2,976)	(2,976)
Balance at September 30, 2003	503,544	5	1,413,383	14	105,892	(104)	(122,886)	(17,079)
Series C preferred stock dividends and accretion							(135)	(135)
Common stock issued in exchange of Series C preferred stock			225,533	2	14,635			14,637

Common stock issued in exchange for notes payable and accrued interest		8,141,979	81	8,061			8,142
Beneficial conversion feature of convertible debt				5,000			5,000
Proceeds from offerings of Employee Stock Purchase Plan		652		2			2
Sale of common stock pursuant to stock offering, net of issuance costs of $901		4,104,000	41	9,318			9,359
Exercise of common stock options		61,756	1	75			76
Stock-based compensation and amortization of restricted stock				2,593	104		2,697
Net loss for the fiscal year ended September 30, 2004						(17,167)	(17,167)
Balance at September 30, 2004	503,544	$ 5	13,947,303	$ 139	$ 145,576	$	$ (140,188)	$ 5,532

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

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AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Fiscal Year Ended September 30,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	$ (17,167)	$ (2,976)	$ (11,302)
Loss from discontinued operations		38	3,657
Gain on sale of discontinued operations		(1,912)	
Loss from continuing operations	(17,167)	(4,850)	(7,645)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	10	160	381
Loss from discontinued operations		(38)	(3,657)
Noncash compensation	2,569	1,218	147
Noncash interest and financing costs	5,153	186	112
Noncash consulting and license fee	128	15	87
Equity in loss of Incara Development		112	1,288
Amortization of debt issuance costs	15		
Gain on sale of equipment		(21)	
Change in assets and liabilities:			
Accounts receivable	(131)	(64)	854
Prepaids and other assets	140	(22)	90
Accounts payable and accrued expenses	642	(1,298)	(215)
Net cash used in operating activities	(8,641)	(4,602)	(8,558)
Cash flows from investing activities:			
Proceeds from sale of discontinued operations		3,422	
Distribution from CPEC LLC			140
Investment in Incara Development			(2,013)
Proceeds from sale of equipment		25	
Purchases of property and equipment			(260)
Net cash provided by (used by) investing activities		3,447	(2,133)
Cash flows from financing activities:			
Proceeds from notes payable, net of issuance costs	6,000	2,020	2,578
Proceeds from issuance of common stock and warrants, net of issuance costs	9,436	2	38
Proceeds from issuance of Series B preferred stock and warrants			2,980
Principal payments on notes payable		(441)	(124)
Principal payments on capital lease obligations		(49)	(25)

Net cash provided by financing activities	15,436	1,532	5,447
Net increase (decrease) in cash and cash equivalents	6,795	377	(5,244)
Cash and cash equivalents at beginning of year	586	209	5,453
Cash and cash equivalents at end of year	$ 7,381	$ 586	$ 209
Supplemental disclosure of cash flow information:			
Cash payments of interest	$ 1	$ 10	$ 59
Supplemental disclosure of non-cash investing and financing activities:			
Common stock issued in exchange for Series C preferred stock	$ 14,637	$	$
Common stock issued in exchange for notes payable and accrued interest	$ 8,142	$	$
Beneficial conversion feature of convertible debt	$ 5,000	$	$
Series C preferred stock dividend accreted	$ 135	$ 949	$ 887
Issuance of restricted stock	$	$	$ 252
Equity issued in exchange for note payable and interest	$	$	$ 1,400
Property and equipment acquired through financing arrangements	$	$	$ 33

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

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. NATURE OF THE BUSINESS

The Company is developing a series of catalytic antioxidant molecules to protect against the damaging effects of reactive oxygen-derived molecules, commonly referred to as free radicals. In October 2004, the Company initiated a Phase 1 clinical trial for amyotrophic lateral sclerosis (ALS , also known as Lou Gehrig s disease).

In October 2002, the Company sold its program that was conducting research and development on liver cell therapy for the treatment of liver failure. In September 2002, the Company ended its Phase 2/3 clinical trial and the development of an ultra-low molecular weight heparin for the treatment of ulcerative colitis, which was being developed in collaboration with Elan Corporation, plc, an Irish company, and its subsidiaries (Elan).

The Company 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, 2004, Aeolus also owned a 35.0% interest in CPEC LLC, a Delaware limited liability company (CPEC). The Company s primary operations are located in Research Triangle Park, North Carolina. On July 16, 2004, the Company effected a one-for-ten reverse stock split of its common stock and changed its name from Incara Pharmaceuticals Corporation to Aeolus Pharmaceuticals, Inc. All common stock amounts in these financial statements have been adjusted for the reverse stock split. On November 20, 2003, the Company s stockholders approved a reorganization and merger (see Note H).

B. LIQUIDITY

The Company had an accumulated deficit of $140,188,000 at September 30, 2004, incurred a net loss of $17,167,000 for the year then ended, and expects to incur additional losses in fiscal 2005 and for several more years.

Management believes it has adequate financial resources to fund its operations through fiscal 2005, but in order to fund on-going operating cash requirements beyond fiscal 2005, or to accelerate its programs, the Company needs to raise significant additional funds. The Company intends to explore strategic and financial alternatives, including the sale of shares of stock, and the establishment of new collaborations for current research programs that include initial cash payments and on-going research support.

If the Company is unable to obtain additional financing to fund operations beyond fiscal 2005, 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.

C. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation: The consolidated financial statements include the accounts of Aeolus and its wholly owned subsidiaries. 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. From the inception of Incara Development Ltd., a Bermuda corporation (Incara Development) through September 30, 2003, Aeolus owned 100% of the outstanding common stock and 60.2% of the preferred stock of Incara Development and Elan owned 39.8% of the preferred stock. Elan retained significant minority investor rights, including 50% control of the management committee which oversaw the research program, that are considered participating rights as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Aeolus did not consolidate the financial statements of Incara Development during fiscal years 2003 and 2002, but instead accounted for its investment in Incara Development under the equity method of accounting. Aeolus and Elan ended their collaboration in Incara Development in November 2003 and Aeolus became the sole owner of Incara Development. As a result, Incara Development s limited operations were consolidated with the Company s operations during fiscal 2004. Incara Development was dissolved in August 2004.

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.

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2004 and 2003 due to their short-term nature.

Accounts Receivable: The accounts receivable at September 30, 2004 was comprised of amounts due under the Company s Small Business Innovation and Research grant from the National Cancer Institute, a division of the National Institutes of Health. All amounts recorded as accounts receivable were unbilled as of September 30, 2004.

Property and Equipment: Property and equipment are stated at cost. Depreciation and amortization are provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements and equipment under capital leases, over the lesser of the estimated useful lives or the lease terms. The estimated useful lives are two years for computers and five years for equipment. No impairments of property and equipment were required to be recognized during the fiscal years ended September 30, 2004 or 2002. As a result of the sale of its liver cell therapy program in October 2002, the Company wrote off impaired laboratory facilities utilized by that business with a net book value of $492,000 in fiscal 2003.

Expenses for repairs and maintenance are charged to operations as incurred. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are removed from the accounts, and any resulting gain or loss is credited or charged to operations.

Revenue Recognition: Grant income is recognized as income is earned 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. During fiscal years 2003 and 2002, research and development expenses incurred on behalf of Incara Development and billed to Incara Development were recognized as a reduction of research and development expenses, net of intercompany profits.

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, restricted common stock, convertible debt, warrants and convertible

preferred stock using the treasury stock method and are excluded if their effect is antidilutive. Diluted weighted average common shares excluded incremental shares of approximately 4,764,000, 9,674,000 and 1,253,000 as of September 30, 2004, 2003 and 2002, respectively, related to stock options, unvested shares of restricted common stock, convertible debt, convertible preferred stock and warrants to purchase common and preferred stock. These shares are excluded due to their antidilutive effect as a result of the Company s loss from operations.

Accounting for Stock-Based Compensation: The Company accounts for stock-based compensation based on the provisions of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25), as amended by the Financial Accounting Standards Board (the FASB) Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation (FIN 44). APB No. 25 and FIN 44 state that no compensation expense is recorded for stock options or other stock-based awards to employees that are granted with an exercise price equal to or above the estimated fair value per share of the Company s common stock on the grant date. The Company has adopted the disclosure requirements of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation (SFAS 123), which requires compensation expense to be disclosed based on the fair value of the options granted at the date of the grant.

In December 2002, the FASB issued FASB Statement No. 148, Accounting for Stock-Based Compensation Transition and Disclosure - an amendment of FASB Statement No. 123 (SFAS 148). This Statement amends SFAS 123, to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for stock-based employee compensation. It also amends the disclosure provisions of SFAS 123 to require prominent disclosure about the effects on reported net income of an entity s accounting policy decisions with respect to stock-based employee compensation. The transition and annual disclosure provisions of SFAS 148 were effective December 15, 2002. The Company did not voluntarily change to the fair value based method of accounting for stock-based employee compensation, therefore, the adoption of SFAS 148 did not have a material impact on the Company s operations and/or financial position. The Company has complied with the disclosure provisions.

Had compensation expense, assuming it was recognized on a straight-line basis over the vesting period for awards under the 1994 Stock Option Plan been determined based on the fair value at the grant date, consistent with the provisions of SFAS 123 and SFAS 148, the Company s results of operations on a pro forma basis would have been as follows:

	2004	2003	2002
Net loss attributable to common stockholders (in thousands):			
As reported	$ (17,302)	$ (3,925)	$ (12,189)
Less: pro forma adjustment for stock-based compensation expense	(1,081)	(316)	(1,425)
Pro forma	$ (18,383)	$ (4,241)	$ (13,614)
Basic and diluted net loss per weighted share attributable to common stockholders:			
As reported	$ (2.06)	$ (2.88)	$ (9.40)
Effect of pro forma adjustment	(0.13)	(0.23)	(1.10)
Pro forma	$ (2.19)	$ (3.11)	$ (10.50)

The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect market conditions and experience. The fair value of each option grant for employees and consultants is estimated on the date of the grant using the Black-Scholes option valuation model with the following weighted-average assumptions used for grants:

	2004	2003	2002
Dividend yield	0%	0%	0%
Expected volatility	274%	233%	139%
Risk-free interest rate	1.2% - 4.7%	1.2% - 3.8%	1.5% - 4.9%
Expected option life after shares are vested	3 years	3 years	3 years

Segment Reporting: The Company currently operates in only one segment.

Recent Accounting Pronouncements: In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46), which requires the assets, liabilities and results of operations of variable interest entities (VIE) to be consolidated into the financial statements of the company that has controlling financial interest. FIN 46 also provides the framework for determining whether a VIE should be consolidated based on voting interest or significant financial support provided to the VIE. The implementation and disclosure requirements of this interpretation were effective December 15, 2003. The adoption of FIN 46 did not have a material impact on the Company s operations or financial position.

In April 2003, the FASB issued FASB Statement No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities (SFAS 149). FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133), and No. 138, Accounting for Certain Derivative Instruments and Certain Hedging Activities , establish accounting and reporting standards for derivative instruments including derivatives embedded in other contracts (collectively referred to as derivatives) and for hedging activities. SFAS 149 amends SFAS 133 for certain decisions made by the FASB as part of the Derivatives Implementation Group process. SFAS 149 contains amendments relating to FASB Concepts Statement No. 7, Using Cash Flow Information and Present Value in Accounting Measurements , and FASB Statements No. 65, Accounting for Certain Mortgage Banking Activities , No. 91 Accounting for Nonrefundable Fees and Costs Associated with Originating or Acquiring Loans and Initial Direct Costs of Leases , No. 95, Statement of Cash Flows , and No. 126, Exemption from Certain Required Disclosures about Financial Instruments for Certain Nonpublic Entities . The adoption of SFAS 149 did not have a material impact on the Company s operations or financial position.

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In May 2003, the FASB issued FASB Statement No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS 150). SFAS 150 changes the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity and requires that those instruments be classified as liabilities (or assets in certain circumstances) in statements of financial position. This statement affects the issuer s accounting for three types of freestanding financial instruments including (1) mandatorily redeemable shares that are required to be redeemed at a specified or determinable date or upon an event certain to occur, (2) put options and forward purchase contracts, which involves financial instruments embodying an obligation that the issuer must or could choose to settle by issuing a variable number of its shares or other equity instruments based solely on something other than the issuer s own equity shares and (3) certain obligations that can be settled with shares, the monetary value of which is (i) fixed, tied solely or predominantly to a variable such as a market index, or (ii) varies inversely with the value of the issuers shares. SFAS 150 also requires disclosures about alternative ways of settling the instruments and the capital structure of entities all of whose shares are mandatorily redeemable. For public companies, SFAS 150 became effective at the beginning of the first interim period beginning after June 15, 2003. As a result of SFAS 150, the Company classified its Series C redeemable convertible exchangeable preferred stock (Series C Stock) as a liability at September 30, 2003. All shares of Series C Stock were exchanged for common stock on November 20, 2003.

In 2003, the FASB Emerging Issues Task Force (EITF) reached a tentative conclusion on Issue 03-06, Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share that the two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders, but does not require the presentation of basic and diluted EPS for securities other than common stock. However, the EITF observed that the presentation of basic and diluted earnings per share for a participating security other than common stock is not precluded. The Company is currently evaluating the effect that this EITF conclusion would have on its current presentation of earnings per share.

D. CPEC LLC

The Company uses the equity method to account for its 35.0% ownership interest in CPEC. During fiscal 2004, CPEC licensed bucindolol, a drug previously under development by the Company for the treatment of heart failure, to ARCA Discovery, Inc. in return for possible future royalty and milestone payments and it incurred $13,000 of legal and administrative expenses. During fiscal 2003, CPEC s only activity was $1,000 of interest income. CPEC s activities for fiscal 2002 were $5,000 of interest income and $154,000 of gain from the sale of a trademark jointly owned with Aeolus. In fiscal 2002, Aeolus recorded as other income its portion of the gain on the trademark sale ($96,000) along with its pro rata gain from CPEC ($54,000). Aeolus received cash distributions of $140,000 from CPEC during fiscal 2002. CPEC had $24,000 and $37,000 of net assets at September 30, 2004 and 2003, respectively. Aeolus share of CPEC s net assets is included in other current assets.

E. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30, 2004 and 2003 (in thousands):

	2004	2003

Office equipment	$ 172	$ 425
Laboratory equipment	265	275
Leasehold improvements	51	51
	488	751
Less: accumulated depreciation and amortization	(473)	(726)
	$ 15	$ 25

Depreciation and amortization expense was $10,000, $142,000 and $381,000 for the fiscal years ended September 30, 2004, 2003 and 2002, respectively.

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

F. ACCRUED EXPENSES

At September 30, 2004 and 2003, accrued expenses consisted of the following (in thousands):

	2004	2003
Payroll-related liabilities	$ 91	$ 12
Other	11	33
	$ 102	$ 45

G. COMMITMENTS

The Company leases office and laboratory space under non-cancelable operating leases that expire in September 2005 and in June 2006. Rent expense under non-cancelable operating leases was $282,000, $338,000 and $378,000 for the fiscal years ended September 30, 2004, 2003 and 2002, respectively. At September 30, 2004, the Company s non-cancelable future minimum payments under lease arrangements were as follows (in thousands):

Fiscal Year	
2005	$ 494
2006	327
Total minimum lease payments	$ 821

The Company has accrued $250,000 of these non-cancelable future minimum payments as a reserve for discontinued operations related to future rent costs for its laboratory facilities that are no longer in use.

The Company has subleased a portion of its laboratory space and is entitled to receive sublease rent payments of $17,000 and $6,000 for the fiscal years ending September 30, 2005 and 2006, respectively.

In December 1999, Aeolus sold IRL, its anti-infectives division, to a pharmaceutical company. Aeolus remains contingently liable through May 2007 for a lease obligation of approximately $2,614,000 assumed by the purchaser on the former IRL facility in Cranbury, New Jersey. The Company has not recorded any liability for this lease obligation, as the lease is currently under a sublease arrangement and the Company does not expect to incur any additional expenses.

H. REORGANIZATION

On July 28, 2003, the Company entered into a $3,000,000 secured bridge loan facility (the $3M Note) with Goodnow Capital, L.L.C. (Goodnow). Through September 30, 2003, the Company borrowed $2,000,000 of the $3M Note. The remaining $1,000,000 was borrowed in October and November 2003. On November 20, 2003, the Company s stockholders approved a reorganization and merger (the Reorganization) of the Company with and into its wholly owned subsidiary, pursuant to which the Company s stockholders became stockholders of the subsidiary. The Reorganization was accounted for at historical cost and there was no change in the basis of the Company s assets and liabilities. Pursuant to the terms of the respective agreements, the Reorganization also resulted in the conversion of the $3M Note into 3,060,144 shares of common stock and a $35,000 note payable owed to another party into 35,000 shares of common stock. Pursuant to the terms of the Company s Certificate of Incorporation, the Reorganization also resulted in the conversion of all 12,015 shares of outstanding Series C Stock into 225,533 shares of common stock.

I. $5,000,000 DEBENTURE

In January 2004, the Company closed on a secured convertible debenture facility of $5,000,000 with Goodnow (the Debenture). The Debenture had a due date of December 24, 2004, an interest rate of 10% and was secured by all of the assets of the Company. The Debenture, including interest, was convertible into common stock at a price of $1.00 per share. In connection with the issuance of the $3M Note and the Debenture, the Company agreed to various covenants and restrictions on its operations. The Company borrowed $5,000,000 under the Debenture during the period from January 2004 through April 16, 2004. Since the conversion rate of the Debenture of $1.00 per share was less than the market value of the Company s common stock at the time of the advances, a portion of the proceeds were allocated to additional paid-in-capital for this beneficial conversion feature. As the amount of the beneficial conversion feature exceeded the proceeds of the

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Debenture, the amount of the beneficial conversion feature recorded was limited to the $5,000,000 proceeds from the Debenture. On April 19, 2004, Goodnow voluntarily converted the principal and interest into 5,046,875 shares of the Company s common stock at a price of $1.00 per share. As the Debenture was terminated early and converted to common stock in April 2004, the $5,000,000 beneficial conversion feature of the Debenture was recognized as noncash interest expense during fiscal 2004.

J. OTHER NOTES PAYABLE

In August 2002, Aeolus borrowed from Elan $638,000 pursuant to the terms of a note arrangement with Elan. The note payable accrues interest at 10% compounded semi-annually. The note is convertible at the option of Elan into shares of the Company s Series B non-voting convertible preferred stock (Series B Stock) at $43.27 per share. The note will mature on December 21, 2006, when the outstanding principal plus accrued interest will be due and 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, 2004, the outstanding balance on the note payable to Elan was $787,000.

In July 2003, the Company borrowed $35,000 from an individual, issued a note payable and issued a warrant to purchase 35,000 shares of common stock at $1.00 per share. The note was converted into 35,000 shares of common stock upon completion of the Reorganization.

In October 2001, the Company executed a Master Loan and Security Agreement with Transamerica Technology Finance Corporation (Transamerica) to finance equipment purchases. In October 2001, the Company borrowed $565,000 from Transamerica and pledged equipment with a cost of $681,000 as collateral. All amounts owed to Transamerica were paid in full in October 2002.

K. STOCKHOLDERS EQUITY (DEFICIT)

Preferred Stock: The Certificate of Incorporation of Aeolus authorizes the issuance of up to 3,000,000 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 12,015 shares of Series C redeemable convertible exchangeable non-voting preferred stock. The Series C Stock had liquidation preferences in advance of common stock and the Series B Stock, which is on par with common stock upon a liquidation. The Series C Stock carried a mandatory stock dividend of 7%, compounded annually. At September 30, 2003, the Series C Stock was exchangeable at the option of Elan for all of the preferred stock of Incara Development held by Aeolus which, if exchanged, would have given Elan ownership of 50% of the initial amount of combined common and preferred stock of Incara Development on an as-converted basis. The Series C Stock was convertible by Elan into shares of Series B Stock at the rate of $64.90 per share. Because the exchange feature allowed the Series C Stock to be redeemed for certain assets of Aeolus, the value of the Series C Stock, including accrued dividends, was classified as a liability at September 30, 2003. Pursuant to the terms of the Company s Certificate of Incorporation, the Reorganization resulted in the

conversion of all 12,015 shares of outstanding Series C Stock into 225,533 shares of common stock in November 2003.

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 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. All issued shares of Series B Stock were outstanding at September 30, 2004. Each share of Series B Stock is convertible into one share of common stock.

Common Stock: On April 19, 2004, Aeolus completed a private placement sale of 4,104,000 shares of common stock at $2.50 per share, resulting in net proceeds of $9,359,000 (after deducting costs of the sale) (the Private Placement). The Company issued warrants to the investors to purchase an aggregate of 1,641,600 shares of common stock with an exercise price of $4.00 per share and issued a warrant to the placement agent to purchase 410,400 shares of common stock with an

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

exercise price of $2.50 per share. All common stock amounts in these financial statements have been adjusted for a one-for-ten reverse stock split effected on July 16, 2004.

Warrants: In connection with the Private Placement in April 2004, Aeolus issued warrants to purchase 1,641,600 shares at an exercise price of $4.00 per share and 410,400 shares at an exercise price of $2.50 per share. In connection with the Debenture, Aeolus issued a warrant to Goodnow in January 2004 to purchase 1,250,000 shares of common stock at $4.00 per share. Pursuant to its terms, the warrant expired unexercised as a result of the Private Placement. During fiscal 2003, Aeolus issued two warrants to purchase an aggregate of 5,035,000 shares of common stock at $1.00 per share in connection with the issuance of notes payable. The warrant to purchase 5,000,000 shares expired upon the completion of the Reorganization. The warrant to purchase 35,000 shares expires in July 2008. The Company incurred $92,000 and $112,000 of expense related to warrants issued in fiscal 2003 and 2002, respectively. No warrant expense was incurred in fiscal 2004.

As of September 30, 2004, warrants to purchase 2,207,402 whole shares of common stock and 22,191 shares of Series B Stock were outstanding. The warrants for the Series B Stock are exercisable at $72.12 per share and expire in December 2005. Details of the warrants for common stock outstanding at September 30, 2004 were as follows:

Number of Shares	Exercise Price	Expiration Date
1,860	$ 16.125	August 2006
106,783	$ 20.25	August 2006
10,000	$ 20.25	October 2006
1,759	$ 19.90	October 2008
35,000	$ 1.00	July 2008
410,400	$ 2.50	April 2009
1,641,600	$ 4.00	April 2009
2,207,402		

The Company has the option, upon 30 days notice, to redeem warrants to purchase 103,753 shares of common stock that expire in August 2006 at a price of $0.10 per warrant share, if, and only if, at the time notice of such redemption is given, the closing price for the stock for each of the 30 consecutive trading days immediately preceding the date that the redemption notice is given exceeded approximately $60.75 per share.

L. STOCK COMPENSATION PLANS

Restricted Stock: 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 Company s Board of Directors adopted the 1999 Equity Incentive Plan (the Equity Plan) in September 1999. The Equity Plan provides for the grant of restricted stock (Restricted Stock) awards which entitle employees

and consultants of the Company (the Participants) to receive shares of common stock upon satisfaction of specified vesting periods. In May 2002, the Equity Plan was amended to increase the common stock reserved for issuance to 200,000 shares. During September 1999, an aggregate of 120,991 shares of Restricted Stock were granted to employees and key consultants in consideration of services rendered by the Participants to the Company, the cancellation of options for an equal number of shares of common stock and payment of the par value of the shares. In May 2002, an additional 71,175 shares were granted to employees and a key consultant in consideration of services rendered by the Participants to the Company. The value of the Restricted Stock awards granted in May 2002 totaled $252,000, which was amortized over the vesting period. The Company recognized $104,000, $113,000 and $147,000 of expenses related to Restricted Stock awards during the fiscal years ended September 30, 2004, 2003 and 2002, respectively. There were no unvested shares of Restricted Stock at September 30, 2004.

Employee Stock Purchase Plan: In October 1995, Aeolus adopted the Employee Stock Purchase Plan (the ESPP). In March 2002, the stockholders approved an amendment to increase the common stock reserved for issuance under the ESPP to 60,000 shares. Offerings are for one-year periods beginning on October 1 of each year (an Offering) and are divided into two six-month Purchase Periods (the Purchase Periods). Employees may contribute up to ten percent (10%) of gross wages, with certain limitations, via payroll deduction, to the ESPP. Common stock is purchased at the end of each Purchase Period with employee contributions at the lower of 85% of the closing price of Aeolus common stock on the first day of an Offering or the last day of the related Purchase Period. As of September 30, 2004, Aeolus had sold 50,882 shares of common stock pursuant to the ESPP and 9,118 shares were reserved for future issuances.

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Option Plans: In September 2004, the Board of Directors approved the 2004 Stock Option Plan (the 2004 Plan) and reserved 1,500,000 shares of common stock for issuance under the 2004 Plan. No stock options had been granted under the 2004 Plan at September 30, 2004.

Under the Company s 1994 Stock Option Plan (the Option Plan), incentive stock options (ISOs) 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, 2004, 404,296 shares were available to be granted under the Option Plan. The exercise price of the ISOs granted under the Option 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.

During fiscal 2004, the Company recognized noncash charges totaling $2,559,000 for accelerated vesting of stock options as a result of a change in the Board of Directors and the resignation of the Company s former Chief Executive Officer.

In July 2003, in connection with the pending Reorganization and the forgiveness of salaries by employees, the Board of Directors granted employees stock options to purchase 1,290,516 shares of common stock at an exercise price of $1.50 per share, which price was greater than the fair market value of the stock on the grant date. The Company incurred a noncash expense of $1,120,000 for the fair market value of the stock options granted in connection with salaries and bonuses cancelled.

Stock option activity under the Option Plan was as follows:

	Shares	Weighted Average Exercise Price
Outstanding at September 30, 2001	225,315	$ 28.80
Granted	103,102	$ 9.86
Cancelled	(573)	$ 24.02
Outstanding at September 30, 2002	327,844	$ 22.85
Granted	1,406,915	$ 1.45
Cancelled	(59,074)	$ 12.21
Outstanding at September 30, 2003	1,675,685	$ 5.25
Granted	406,324	$ 2.62
Exercised	(61,756)	$ 1.22
Cancelled	(8,033)	$ 43.26

Outstanding at September 30, 2004	2,012,220	$ 4.69

The details of stock options outstanding at September 30, 2004 were as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at September 30, 2004	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Number Exercisable at September 30, 2004	Weighted Average Exercise Price
$0.40 - $0.85	80,558	$ 0.84	8.2 years	80,558	$ 0.84
$1.13	30,000	$ 1.13	9.8 years	30,000	$ 1.13
$1.50	1,256,015	$ 1.50	8.8 years	1,256,015	$ 1.50
$1.52 - $1.85	222,500	$ 1.84	10.0 years	37,498	$ 1.80
$2.10 - $2.50	5,000	$ 2.26	9.7 years	416	$ 2.26
$2.80 - $3.60	78,245	$ 3.06	7.5 years	78,245	$ 3.06
$5.00	84,167	$ 5.00	9.7 years	42,083	$ 5.00
$5.10 - $10.00	40,065	$ 6.90	4.4 years	40,065	$ 6.90
$11.50 - $20.00	105,357	$ 14.47	7.0 years	105,357	$ 14.47
$22.50 - $205.00	110,313	$ 41.51	5.7 years	110,313	$ 41.51
$0.40 - $205.00	2,012,220	$ 4.69	8.6 years	1,780,550	$ 4.99

Under the principles of APB No. 25, the Company does not recognize compensation expense associated with the grant of stock options to employees unless an option is 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

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

supplemental information regarding options granted to employees. Stock options granted to consultants during fiscal 2004 were fully vested when issued, and $138,000 was expensed upon issuance. For the fiscal years ended September 30, 2004, 2003 and 2002, all stock options were issued at or above the fair market value of a share of common stock. The weighted average fair value of the options granted during fiscal years 2004, 2003 and 2002 were approximately $2.62, $1.45 and $9.86 per share, respectively.

M. INCOME TAXES

As of September 30, 2004 and 2003, the Company had federal net operating loss (NOL) carryforwards of $87,013,000 and $79,021,000, respectively, and North Carolina state operating loss carryforwards of $36,396,000 and $39,503,000, 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; 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 began to expire in 2003. Additionally, the Company had federal research and development carryforwards as of September 30, 2004 and 2003 of $2,651,000 and $2,527,000, respectively.

Significant components of the Company s deferred tax assets at September 30, 2004 and 2003 consisted of the following (in thousands):

	2004	2003
Net operating loss carryforwards	$ 33,500	$ 28,692
AMT credit carryforwards	37	37
Research and development credit carryforwards	2,651	2,527
Accrued payroll related liabilities	1,779	1,016
Charitable contribution carryforwards	1,042	976
Other		736
Total deferred tax assets	39,009	33,984
Deferred tax liabilities	(102)	
Valuation allowance for deferred assets	(38,907)	(33,984)
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):

	2004	2003	2002
Effective tax rate	0%	0%	0%
United States Federal tax at statutory rate	$ (5,837)	$ (996)	$ (3,843)
State taxes (net of federal benefit)	(773)	(132)	(412)
Change in valuation reserves	4,923	1,301	4,218
Loss in foreign subsidiary		26	354
Other	1,687	(199)	(317)
Provision for income taxes	$	$	$

N. ELAN CORPORATION TRANSACTIONS

On January 22, 2001, Aeolus closed on a collaborative transaction with Elan. As part of the transaction, Elan and Aeolus formed a Bermuda corporation, Incara Development, Ltd., to develop a compound being investigated as a drug

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

treatment for inflammatory bowel disease (deligoparin). Aeolus owned all of the common stock and 60.2% of the non-voting preferred shares of Incara Development and Elan owned 39.8% of the non-voting preferred shares of Incara Development from inception through September 30, 2003. As part of the transaction, Elan and Aeolus entered into license agreements under which Aeolus licensed to Incara Development rights to deligoparin and Elan licensed to Incara Development proprietary drug delivery technology.

As part of the transaction, Elan also purchased 82,500 shares of Aeolus common stock, 28,457 shares of Series B Stock and a five-year warrant to purchase 22,191 shares of Series B Stock at an exercise price of $72.12 per share for an aggregate purchase price of $4,000,000. Each share of Series B Stock is convertible into one share of common stock. Elan also purchased 12,015 shares of Series C Stock with a face value of $1,000 per share, or a total of $12,015,000. Aeolus contributed to Incara Development the proceeds from the issuance of the Series C Stock in exchange for securities of Incara Development. Elan also contributed $2,985,000 to Incara Development for its shares of preferred stock of Incara Development. In addition, Elan granted Incara Development a license to Elan s proprietary drug delivery technology for a license fee of $15,000,000.

The Series C Stock carried a mandatory stock dividend of 7%, compounded annually. The Series C Stock was exchangeable at the option of Elan at any time for all of the preferred stock of Incara Development held by Aeolus which, if exchanged, would have given Elan ownership of 50% of the initial amount of combined common and preferred stock of Incara Development. The Series C Stock was convertible by Elan into shares of Series B Stock at the rate of $64.90 per share. If the Series C Stock was outstanding as of December 21, 2006, Aeolus would have had the option to exchange the Series C Stock and accrued dividends, for either cash or shares of stock and warrants of Aeolus having a then fair market value of the amount due.

As part of the transaction, Elan and Aeolus funded Incara Development pro rata, based on their respective percentage ownership of the combined outstanding common and preferred stock of Incara Development. Of the outstanding combined common and non-voting preferred shares of Incara Development, Elan owned 19.9% and Aeolus owned 80.1%. Subject to mutual agreement, Elan agreed to lend Aeolus up to $4,806,000 to fund Aeolus pro rata share of development funding for Incara Development. In return, Aeolus issued a convertible promissory note that bears interest at 10% compounded semi-annually on the amount outstanding thereunder. The note is convertible at the option of Elan into shares of Series B Stock at $43.27 per share. The note will mature on December 21, 2006, when the outstanding principal plus accrued interest will be due and 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. In October 2001 and February 2002, Aeolus borrowed from Elan $857,000 and $518,000, respectively, pursuant to the terms of the note arrangement with Elan. In February 2002, Aeolus, with Elan s consent, converted the outstanding principal and accrued interest of $1,400,000 into 48,000 shares of common stock and 58,883 shares of Series B Stock. In August 2002, Aeolus borrowed from Elan $638,000 pursuant to the terms of the note arrangement. The outstanding balance on the note payable to Elan was $787,000 as of September 30, 2004.

For financial reporting purposes, the value recorded as Aeolus initial investment in Incara Development was the same as the fair value of the Series C Stock issued, which was $12,015,000. The technology obtained by Incara Development from Elan was expensed at inception because the feasibility of using the contributed technology in conjunction with deligoparin had not been established and Incara Development had no alternative future use for the contributed technology. Aeolus immediately expensed as Equity in loss of Incara Development its initial investment in Incara Development, reflective of Aeolus pro rata interest in Incara Development. Aeolus accreted a 7% dividend on the Series C Stock.

While Aeolus owned all of the outstanding common stock and 60.2% of the non-voting preferred stock of Incara Development, Elan retained significant minority investor rights, including 50% control of the management committee which oversaw the deligoparin program, that were considered to be participating rights as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Aeolus did not consolidate the financial statements of Incara Development, but instead accounted for its investment in Incara Development under the equity method of accounting. Elan and Aeolus funded Incara Development on a pro rata basis based on their respective ownership of the combined outstanding common and preferred stock of Incara Development. In accordance with APB 18, the Company recognized 100% of the losses of Incara Development to the extent of its original investment, plus all subsequent losses of Incara Development to the extent that it has committed to provide further financial support to fund those losses.

Incara Development was a development stage company with no revenue. During the fiscal year ended September 30, 2003 and 2002, Incara Development had operating expenses of approximately $141,000 and $1,593,000, which included $138,000 and $1,454,000, respectively, for expenses and management services invoiced to Incara Development by Aeolus.

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

During fiscal 2003 and 2002, Aeolus invoiced Incara Development for research and development expenses that Aeolus incurred on behalf of Incara Development. These expenses were recognized as a reduction of Aeolus research and development expenses, net of intercompany profits. The following table is a reconciliation of the net loss of Incara Development to the Equity in loss of Incara Development included in the Company s statements of operations (in thousands).

	2003	2002
Incara Development net loss	$ 141	$ 1,593
Incara Pharmaceuticals portion of net loss (80.1%)	$ 113	$ 1,276
Profit on services provided to Incara Development	(38)	(256)
Other	1	20
Equity in loss of Incara Development	$ 76	$ 1,040

In September 2002, Incara Development ended its Phase 2/3 clinical trial and the development of deligoparin due to an analysis of the clinical trial results, which showed that treatment with deligoparin did not meet the primary or secondary endpoints of the study. Elan and Aeolus ended their collaboration in the joint venture in November 2003 and Aeolus became the sole owner of Incara Development. As a result, Incara Development s limited operations during fiscal 2004 were consolidated with the Company s operations. Incara Development was dissolved in August 2004. No gain or loss was recognized on the disposition of Incara Development.

In May 2002, Elan purchased 416,204 shares of Series B Stock for $3,000,000. Elan received an exclusive option to negotiate commercialization or collaboration terms at a later phase relating to catalytic antioxidants being developed by Aeolus in the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage (the Antioxidant Agreement). In January 2003, the Company and Elan terminated the Antioxidant Agreement. In accordance with the terms of the termination agreement, the Company will pay Elan a royalty on net sales of catalytic antioxidant products sold, if any, for the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage.

O. DISCONTINUED OPERATION - LIVER CELL PROGRAM

On October 31, 2002, Aeolus sold substantially all of the assets of one of its subsidiaries and its liver cell program to Vesta Therapeutics, Inc. (Vesta) and recognized a gain of $1,912,000 on the sale. The Company received a right to royalties on products developed using intellectual property transferred to Vesta and proceeds of $3,422,000, which consisted of $2,955,000 of cash payments and $467,000 of reduction in the Company s notes payable and capital lease obligations. As part of the transaction, the Company sold to Vesta property and equipment with a net book value of $572,000 and assigned certain related licenses and other agreements to Vesta. The Company wrote off $492,000 for impaired laboratory facilities and established a reserve of $446,000 for the future net rent costs of the laboratory facility. Net expense and the net pretax loss of the liver cell program was $38,000 and $3,657,000 for fiscal years 2003 and 2002, respectively. These net amounts are shown as discontinued operations on the statements of operations.

P. 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,

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AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 has 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 has agreed to support certain of NJC s costs incurred in performance of the research.

Q. QUARTERLY FINANCIAL DATA (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in thousands, except per share amounts)				
Fiscal 2004					
Total revenue	$ 47	$ 55	$ 72	$ 131	$ 305
Net loss attributable to common stockholders	$ (2,478)	$ (2,308)	$ (10,468)	$ (2,048)	$ (17,302)
Net loss per common share (basic and diluted):					
Net loss attributable to common stockholders	$ (0.86)	$ (0.49)	$ (0.81)	$ (0.15)	$ (2.06)
Fiscal 2003					
Total revenue	$	$	$	$	$
Loss from continuing operations attributable to common stockholders	$ (1,788)	$ (1,480)	$ (1,216)	$ (1,315)	$ (5,799)
Discontinued operations	$ (38)	$	$	$	$ (38)
Gain on sale of discontinued operations	$ 1,912	$	$	$	$ 1,912
Net income (loss) attributable to common stockholders	$ 86	$ (1,480)	$ (1,216)	$ (1,315)	$ (3,925)
Net income (loss) per common share (basic and diluted):					
Loss from continuing operations attributable to common stockholders	$ (1.33)	$ (1.08)	$ (0.89)	$ (0.96)	$ (4.25)
Discontinued operations	$ (0.03)	$	$	$	$ (0.03)
Gain on sale of discontinued operations	$ 1.42	$	$	$	$ 1.40
Net income (loss) attributable to common stockholders	$ 0.06	$ (1.08)	$ (0.89)	$ (0.96)	$ (2.88)