AEOLUS PHARMACEUTICALS, INC.
Form 10-K
December 27, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-K

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(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, 2005

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.)

23811 Inverness Place
Laguna Niguel, California 92677
(Address of principal executive offices)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ¨ No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ¨ No ý

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 ý 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 ý

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

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 $3,239,000 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 December 15, 2005, the registrant had outstanding 14,038,259 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company s definitive Proxy Statement to be filed pursuant to Regulation 14A for the registrant s 2006 Annual Meeting of Stockholders are incorporated herein by reference into Part III hereof.

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

Table of Contents

		Page
	PART I	
Item 1.	Business	3
Item 1A.	Risk Factors	18
Item 1B.	Unresolved Staff Comments	27
Item 2.	Properties	27
Item 3.	Legal Proceedings	27
Item 4.	Submission of Matters to a Vote of Security Holders	27
	Executive Officers	28
	PART II	
Item 5.	Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	30
Item 6.	Selected Financial Data	32
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	34
Item 7A.	Quantitative and Qualitative Disclosure About Market Risk	41
Item 8.	Financial Statements and Supplementary Data	41
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	61
Item 9A.	Controls and Procedures	62
Item 9B.	Other Information	62
	PART III	
Item 10.	Directors and Executive Officers of the Registrant	63
Item 11.	Executive Compensation	63
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	63
Item 13.	Certain Relationships and Related Transactions	63

Item 14. Principal Accounting Fees and Services 63

PART IV

Item 15. Exhibits and Financial Statement Schedules 64

PART I

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that relate to future events or our future financial performance. You can identify forward-looking statements by terminology such as may, might, will, could, should, would, expect, plan, anticipate, believe, estimate, predict, continue or the negative of these terms or other comparable terminology. Our actual results might differ materially from any forward-looking statement due to various risks, uncertainties and contingencies, including but not limited to the following:

- *our need for, and our ability to obtain, 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;*
- *the acceptance of any future products by physicians and patients;*
- *competition and dependence on collaborative partners;*
- *loss of key management or scientific personnel;*
- *our ability to obtain adequate intellectual property protection and to enforce these rights;*
- *our ability to avoid infringement of the intellectual property rights of others; and*
- *the other factors and risks described under the section captioned Risk Factors.*

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

Item 1. Business.

Business

General

Aeolus Pharmaceuticals, Inc. (we or the Company), a San Diego-based biopharmaceutical company, is developing a new class of catalytic antioxidant compounds for diseases and disorders of the central nervous system, respiratory system, autoimmune system and oncology. Our lead drug candidate is AEOL 10150 and is the first in our class of catalytic antioxidant compounds to enter human clinical evaluation. AEOL 10150 is a small molecule catalytic antioxidant that has shown the ability to scavenge a broad range of reactive oxygen species, or free radicals. As a catalytic antioxidant, AEOL 10150 mimics and thereby amplifies the body s natural enzymatic systems for eliminating these damaging compounds. Because oxygen-derived free radicals are believed to have an important role in the pathogenesis of many diseases, we believe that Aeolus catalytic antioxidants may have a broad range of potential therapeutic uses. In particular, our catalytic antioxidants have been shown to significantly reduce tissue damage in animal models of amyotrophic lateral sclerosis (ALS, also commonly referred to as Lou Gehrig s disease), stroke, chronic obstructive pulmonary disease and mucositis caused by radiation therapy.

We recently announced positive safety results from a completed Phase I single dose study of AEOL 10150 in patients diagnosed with ALS. In addition, in September 2005, we launched a Phase I multiple dose study of AEOL 10150 in patients diagnosed with ALS. We expect to complete this study during the second quarter of fiscal year 2006. The data from these safety studies are not limited to ALS, but can also be utilized to support subsequent efficacy studies of AEOL 10150 in ALS, as well as other indications for which we have developed preclinical efficacy data.

In addition, the Company has launched the Aeolus Pipeline Initiative whereby the Company, in conjunction with a variety of academic collaborators, is focused on identifying between 1-2 compounds evaluated from six disease categories for potential entrance into human clinical evaluation in 2006, and an additional 2-3 compounds in 2007. The Aeolus Pipeline Initiative is an internal development initiative focused on advancing several of the most promising catalytic antioxidant compounds from our proprietary library of 200 compounds. The initial therapeutic focus areas for the Aeolus Pipeline Initiative are: Parkinson s disease; Cystic Fibrosis; Chronic Obstructive Lung Disease; biodefense/radioprotection; tumor suppression/bone marrow transplantation; and stroke. These therapeutic focus areas were selected based upon preliminary data developed using our catalytic antioxidant compounds.

We were incorporated in the State of Delaware in 1994. Our common stock trades on the OTC Bulletin Board under the symbol AOLS. Our principal executive offices are located at 23811 Inverness Place, Laguna Niguel, California 92677, and our phone number at that address is (949) 481-9825. Our website address is www.aeoluspharma.com. However, the information in, or that can be accessed through, our home page is not part of this report. We also make available free of charge through our website our most recent annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC.

Background on the Importance of Antioxidants

Oxygen Stress and Disease

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

Oxygen-derived free radicals can damage DNA, proteins and lipids resulting in inflammation and both acute and delayed cell death. (Figure 1.) The body protects itself from the harmful effects of free radicals and other oxidants through multiple antioxidant enzyme systems such as superoxide dismutase (SOD). These natural antioxidants convert the reactive molecules into compounds suitable for normal metabolism. When too many free radicals are produced for the body s normal defenses to convert, oxidative stress occurs with a cumulative result of reduced cellular function and, ultimately, disease.

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 suggest that oxygen-derived free radicals are an important

factor in the pathogenesis of a large variety of diseases, including neurological disorders such as ALS, Parkinson s disease, Alzheimer s disease and stroke, and in non-neurological disorders such as cancer radiation therapy damage, emphysema, asthma and diabetes.

Antioxidants as Therapeutics

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

Catalytic Antioxidants vs. Antioxidant Scavengers

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

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

Use of antioxidant scavengers, such as thiols or vitamin derivatives, has shown promise of benefit in preclinical and clinical studies. 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 limitations noted above could be overcome. We established our research and development program to explore and exploit the therapeutic potential of small molecule catalytic antioxidants. We have achieved our initial research objectives and have begun to extend our preclinical accomplishments into our clinical trials.

Our catalytic antioxidant program is designed to:

-

Retain the catalytic mechanism and high antioxidant efficiency of the natural enzymes, and

-

Create and develop stable and small molecule antioxidants without the limitations of SOD so that they:

- have broader antioxidant activity,
- have better tissue penetration,
- have a longer life in the body, and
- are not proteins, which are more difficult and expensive to manufacture.

We have created a class of small molecules that consume free radicals catalytically; that is, these molecules are not themselves consumed in the reaction. Our most advanced compound, 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 I clinical trial in ALS patients.

Our class of compounds, created and developed over the past ten years, is a group of manganoporphyrins (an anti-oxidant containing manganese) that retain the benefits of antioxidant enzymes, are active in animal models of disease and, unlike the body s own enzymes, have properties that make them suitable drug development candidates. Like naturally-occurring enzymatic antioxidants, our AEOL 10150 compound could be 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

ALS, commonly referred to as Lou Gehrig s disease, the most common motor neuron disease, results from progressive degeneration of both upper and lower motor neurons. According to the ALS Association, the incidence of ALS was two per 100,000 people. ALS occurs more often in men as women, with typical onset between 40 and 70 years of age. ALS is a progressive disease and approximately 80% of ALS patients die within five years of diagnosis, with only 10% living more than 10 years. The average life expectancy is two to five years after diagnosis, with death from respiratory and/or bulbar muscle failure. The International Alliance of ALS/MND Associations reports there are over 350,000 patients with ALS/MND worldwide and 120,000 cases diagnosed each year worldwide. In the United States, there are approximately 30,000 patients with ALS with 5,600 new patients diagnosed each year per the ALS Association.

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 superoxide dismutase 1 (SOD1) gene. More than 90 point mutations have been identified, all of which appear to associate with ALS, and result in motor neuron disease in corresponding transgenic mice. SOD mutations have been observed in both familial and sporadic ALS patients, although the nature of the dysfunction produced by the SOD1 mutations remains unclear. The clinical and pathological manifestations of familial ALS and sporadic ALS are indistinguishable suggesting common pathways in both types of disease.

The study of ALS has changed in recent years with the development of transgenic mice that express the mutant human SOD1 (the G93A transgenic mice), 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 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.

Twenty-four confirmed transgenic mice were alternately assigned to either a control group or AEOL 10150-treatment on the day of symptom onset, which was defined as a noticeable hind-limb weakness. Treatment began on the day of symptom onset. The initial dose of AEOL 10150 was 5 mg/kg, with continued treatment at a dose of 2.5 mg/kg once a day until death or near death.

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

Figure 2.

Table 1 and Figure 2 above 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.

Dr. Crow has repeated the ALS preclinical experiment a total of four times, in each case with similar results, including most recently using the same route of administration that is being used in our Phase I 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 AEOL 10150 in the G93A mouse model of ALS.

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

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

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

Following administration of single doses of AEOL 10150 (3, 12, 30, 45, 60 and 75 mg), pharmacokinetic analysis demonstrated plasma area under the curve (AUC) values ranging from 354 ng hr/mL in the 3 mg group to 12,167 ng hr/mL in the 75 mg group. Correspondingly, Cmax ranged from 114.8 ng/mL to 1584 ng/mL, and Tmax ranged from 1 to 2 hours in these same groups. The mean half-life of AEOL 10150 ranged from 2.6 (3 mg cohort) to 6.4 hours (75 mg cohort). Linear dose response and dose proportionality were documented. The Cmax test measures peak concentration of a drug in plasma. The Tmax test measures the period of time to the peak plasma concentration noted in the Cmax test. A summary of these results is provided in table form below.

Pharmacokinetic Parameters for AEOL 10150:
Result Summary, Phase I Single Dose Evaluation

	AEOL 10150						
Pharmacokinetic Parameter	**3 mg N = 3**	**12 mg N = 4**	**30 mg N = 3**	**45 mg N = 4**	**45 mg N = 4 (repeat, different patients)**	**60 mg N = 4**	**75 mg N= 3**
AUC(0-) (hr•ng/mL)	354 ±100	1,494 ±386	4,580 ±1828	7,116 ±1010	5,922 ±1307	9,087 ±2180	12,167 ±1543
Tmax (0-48) (hr)	1 ±0	1 ±1	1 ±0	1 ±0	2 ±1	2 ±0	2 ±1
Cmax (0-48) (ng/mL)	115 ±38	267 ±40	733 ±166	1,245 ±247	962 ±333	1,330 ±226	1,584 ±378
T1/2 (hr)	2.61 ±0.60	3.97 ±1.09	5.25 ±1.65	6.31 ±2.54	5.28 ±1.00	5.93 ±0.90	6.36 ±0.47

The most frequently reported adverse events in this Phase I clinical trial were injection site reactions, followed by dizziness and headache. Adverse events were primarily mild in severity, and approximately one-half of the events were considered to have a possible relationship to the study medication. In addition, no clinically meaningful findings were noted in the safety, laboratory, vital sign, the Unified Parkinson s Disease Rating Scale (UPDRS), functional ALS, or electro cardiogram (ECG) data. All cohorts exhibited dose-related peak plasma drug concentrations and consistent disappearance half-lives.

In September 2005, the Company initiated a Phase I multiple does study of AEOL 10150 in patients diagnosed with ALS. Under the multiple dose protocol, three groups of six ALS patients (four receiving AEOL 10150 and two receiving placebo) will be enrolled, based upon patients who meet the El Escorial criteria for Clinically Definite ALS, Clinically Probable ALS, Clinically Probable-Laboratory Supported ALS, or Definite Familial-Laboratory Supported

ALS (i.e., Clinically Possible ALS with an identified SOD gene mutation). Each patient will receive twice daily subcutaneous injections of AEOL 10150 or placebo, for six consecutive days, followed by a single subcutaneous injection on the seventh day, for a total of 13 injections. In the first cohort, each injection will be 40 mg (i.e., 80 mg daily for six days and 40 mg on the seventh day). In the second cohort, each injection will be 60 mg (i.e., 120 mg/kg daily for six days and 60 mg on the seventh day). In the third cohort, each injection will be 75 mg (i.e., 150 mg daily for six days and 75 mg on the seventh day). Each patient will complete follow-up evaluation by 14 days.

The study is planned to be conducted at six clinical ALS centers, with each center enrolling three patients. Male and female ALS patients, 18 to 70 years of age, will be eligible for study participation. Patients must be ambulatory (with the use of a walker or cane, if needed) and capable of orthostatic blood pressure assessments. Clinical signs/symptoms, laboratory values, cardiac assessments, and pharmacokinetics (PK) will be performed.

On November 30, 2005, the Company announced the completion of dosing of the first cohort (40 mg, twice-a-day dosing) of the three planned multiple-dose cohorts in its Phase I multiple dose evaluation of AEOL 10150 in patients diagnosed with ALS. Human-efficacious dose modeling, based upon use of AEOL 10150 in an accepted model of ALS, suggests that the estimated effective dose of AEOL 10150 in ALS patients (based on a 60 kg, or 132 pound, human) should be about 12 mg/day. Details about the multiple dose study are provided below.

The Data Safety Monitoring Board reviewing the data from the 40 mg multiple dose cohort concluded that no reported adverse events met the definition of a serious adverse event. The most commonly reported adverse events for all study participants being associated with administration of study drug or placebo was injection site irritation, including pain, soreness, burning or stinging at the injection site. These injection site reactions were generally mild to moderate in intensity and of limited duration. There were no clinically significant abnormalities in the ECG patterns in any subject. In addition, there were no QTc interval prolongations (QTc greater than or equal to 450 msec) in any subject at any time. Finally, there were no significant drug-induced changes for vital signs, FVC, neurological exams, UPDRS exams, or ALS/FRS-R examinations.

Based upon a review of the data developed from this first multiple-dose cohort, preliminary pharmacokinetic analysis showed that the mean Cmax for the first 40 mg twice-daily dose was 1216+/-129 ng/ml; and, for the last dose, 1735+/-220 ng/ml. This compares with the highest single dose (75 mg) Cmax of 1584+/-378 ng/ml and the two 45 mg. single dose cohorts of 1245+/-247 ng./ml and 962+/-333 ng/ml from the Phase I single dose evaluation of AEOL 10150 in ALS patients. Tmax from the first multiple-dose cohort was similar to that observed in the single dose study, ranging from between one and two hours. The half life of AEOL 10150 observed from this first multiple dose cohort averaged 9.4+/-3.4 hours, compared to an average of 5.3 to 6.4 from the Phase I single dose study (30 mg to 75 mg).

The second cohort (60 mg) for the multiple dose study began in late November 2005 and is expected to be completed, and the data analyzed, by the end of December 2005. The final cohort (75 mg) is expected to begin in the first quarter of 2006, with dosing and data analysis completed before the end of that quarter.

Catalytic Antioxidants in Other Neurodegenerative Diseases

A goal for our preclinical program is to identify additional manganese porphyrins from our compound library that have enhanced pharmaceutical profiles for use in neurodegenerative diseases. We are focusing these efforts on our AEOL-112 series (which all contain the same manganoporphyrins structure noted above) that are smaller, more lipophilic and lack mutagenicity in the Ames test. Preliminary studies have found that these compounds penetrate the blood brain-barrier better than compounds from the Company s AEOL-101 series and offer some protection in an MPTP-animal model of Parkinson s disease. Because MPTP is a redox active agent that destroys striatal neurons that produce dopamine, it is an often used agent of Parkinson s disease in animal models of the disease. Striatal dopamine (DA) levels, a good measure of MPTP neurotoxicity, were assessed by HPLC-EC following administration of mice with MPTP (15 mg/kg x 3, s.c., 24h intervals). MPTP-induced DA depletion was partially attenuated by AEOL 11207 administration (15 mg x 5, s.c., 24h intervals). Current studies are underway to screen the 112 series of manganese porphyrins for a lead candidate to move forward in this clinical indication.

Parkinson s disease

Parkinson s disease is a common neurodegenerative disorder, second in occurrence among these disorders only to Alzheimer s disease. According to the Parkinson s Disease Foundation, Parkinson s affects as many as one million people in the United States, with approximately 40,000 new cases diagnosed in the United States each year.

According to the National Parkinson Foundation, each patient spends an average of $2,500 a year for medications. After factoring in office visits, Social Security payments, nursing home expenditures and lost income, the total cost to the United States is estimated to exceed $5.6 billion annually.

Parkinson s specifically involves the progressive destruction of the nerves that secrete dopamine and control the basal ganglia, an area of the brain involved in the regulation of movement. Dopamine turnover has been shown to elevate the levels of reactive oxygen species (ROS) in the brain. In addition, a street-drug contaminant has

appeared that can cause parkinsonism in drug abusers. The compound N-methyl-4-phenyl-1, 2, 3, 6tetrahydropyridine (MPTP) has been identified in underground laboratory preparations of a potent analog of meperidine (Demerol). MPTP-containing powder, sometimes sold as a new synthetic heroin, can be dissolved in water and administered intravenously or taken by the intranasal route. MPTP has been documented to produce irreversible chronic Parkinson symptoms in drug abusers. Agents such as MPTP overproduce ROS in the basal ganglia. Therefore, ROS mediated neuronal dysfunction may play a key role in the development of Parkinson s disease. Symptoms of this disease include tremors, rigidity and bradykinesia (i.e., slowness of movement). In the more advanced stages, it can cause fluctuations in motor function, sleep problems and various neuro-psychiatric disorders.

Stroke

An estimated 700,000 people in the United States annually suffer strokes. In the United States, strokes kill approximately 163,000 people annually and have left more than 1,100,000 people fully or partially disabled, according to the American Heart Association in 2005. The estimated direct cost of stroke in the United States is approximately $35 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 the amount of 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 through a National Institutes of Health (NIH) Small Business Innovation Research (SBIR) grant, which is discussed below. 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 up to 30% of patients irradiated for lung cancer, breast cancer, lymphoma or thymoma. In laboratory experiments, 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 SBIR Phase I grant from the National Cancer Institute, a division of the NIH. In March 2004, we were awarded a SBIR Phase II grant from the NIH and in January 2005, the grant was extended for a second year. 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 be used to 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 and an additional $375,000 was awarded in January 2005 for the second part of the Phase II grant. The study is a collaboration between us and the Department of Radiation Oncology at Duke University Medical Center.

Results of this research so far have shown the chronic subcutaneous administration of AEOL 10150 provided a significant protective effect from radiation-induced lung injury, as assessed by breathing frequency, histopathology and immunohistochemistry. These findings support the concept that AEOL 10150 may be useful as a radioprotective adjunct-agent based on its ability to scavenge free radicals and inhibit inflammation. The data further demonstrated that the chronic administration of AEOL 10150 after exposure to ionizing irradiation might be an effective strategy to prevent or treat radiation-induced tissue injury.

Catalytic Antioxidants in Respiratory Diseases

Chronic obstructive pulmonary disease (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 2003, approximately 25 million people in the United States had COPD, including approximately 14 million with asthma, 9 million with chronic bronchitis and 3 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 I 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.

Collaborative and Licensing Arrangements

Duke Licenses

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

National Jewish Medical and Research Center License

In September 1997, we executed a Sponsored Research Agreement with National Jewish Medical and Research Center (the NJM). The NJM Agreement grants Aeolus Sciences an option to negotiate a royalty-bearing exclusive license for technology, patents and inventions resulting from research at the NJM within the field of antioxidant compounds and related discoveries. We have agreed to support the NJM s costs incurred in performance of the research. In November 2000, we obtained an exclusive worldwide license from the NJM to develop, make, use and sell products using proprietary information and technology developed under this Sponsored Research Agreement. We must make milestone payments to the NJM 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 NJM agreement is terminable by the NJM in the event of breach and otherwise expires when the last licensed patent expires. We terminated the Sponsored Research Agreement in June 2005; however, we maintain our rights under the exclusive worldwide license.

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 this collaboration was terminated 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.

Research and Development Expenditures

Expenditures for research and development activities related to our continuing operations were $4,515,000, $8,295,000 and $2,780,000 during the years ended September 30, 2005, 2004 and 2003, respectively. Research and development expenses for fiscal 2005 included the cost of our Phase I clinical trial for the treatment of ALS, the launch of our Phase I multiple dose clinical trial for the treatment of ALS, preclinical testing associated with the Aeolus Pipeline Initiative and limited preclinical pharmacology and toxicology tests on AEOL 10150.

Manufacturing

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

Commercialization

Assuming successful development and FDA approval of one or more of our compounds, to successfully commercialize our catalytic antioxidant programs, we must seek corporate partners with expertise in commercialization or develop this expertise internally. However, we may not be able to successfully commercialize our catalytic antioxidant technology, either internally or through collaboration with others.

Marketing

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

Competition

General

Competition in the pharmaceutical industry is intense and we expect it to increase. Technological developments in our field of research and development occur at a rapid rate and we expect competition to intensify as advances in this field are made. We will be required to continue to devote substantial resources and efforts to research and development activities. Our most significant competitors, among others, are fully integrated pharmaceutical companies and more established biotechnology companies, which have substantially greater financial, technical, sales, marketing, and human resources than we do. These companies may succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, competitors may 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 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 may be other competitors of whom we are unaware with products which might be more effective or have fewer side effects than our products and those of our known competitors. The following discussion is a summary of information known to us and is not meant to be an exhaustive list of 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 II results with a compound, M40403, in the treatment of pain when used in combination with morphine. Also in 2004, Metaphore noted that it had completed a confirmatory Phase II study of M40403 in pain in conjunction with opioids and that it had completed a Phase I study of another compound, M40419. Proteome Systems Ltd. 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 commercially approved treatment for ALS in the United States and the European Union. Administration of Rilutek prolongs survival of ALS patients by an average of 60-90 days, but has little or no effect on the progression of muscle weakness, or quality of life. Rilutek was approved in the United States in 1995, and in 2001 in the European Union.

CytRx Corporation has initiated a Phase II clinical trial with its small molecule product candidate, arimoclomol, for the treatment of ALS. Arimoclomol has received Orphan Drug and Fast Track designation from the FDA.

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

Pharmacyclics, Inc. is also pursuing the use of its motexafin gadolinium compound for the treatment of 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 III 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 (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. Mitsubishi Pharma Corporation launched Radicut® (Edavore) for the treatment of stroke in Japan in 2001. 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 III clinical trials. The Stroke Trials Directory at Washington University (www.strokecenter.org) lists approximately 150 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, compete with our compounds.

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 may not issue on any of the pending patent applications owned by us or licensed by us from third parties. Even if patents issue, the claims allowed might not be sufficiently broad to protect our technology or provide us protection against competitive products or otherwise be commercially valuable. Patents issued to or licensed by us could be challenged, invalidated, infringed, circumvented or held unenforceable. Even if we successfully defend our patents for our products, the costs of defense can be significant.

Our catalytic antioxidant small molecule technology base is described in 10 issued United States patents and 6 United States patent applications that are pending. These patents and patent applications belong in whole or in part to Duke or the NJM 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 patent applications and issued U.S. patents include composition of matter claims for several series of compounds. Corresponding international patent applications have been filed as we deem appropriate, 22 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.

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:

- completion of preclinical studies;
- the submission to the FDA of a request for authorization to conduct clinical trials on an investigational new drug (an IND), which must become effective before human clinical trials may commence;
- adequate and well-controlled Phase I, II and III human clinical trials to establish the safety and efficacy of the drug for its intended use;
- submission to the FDA of an NDA; and
- review and approval of the NDA by the FDA before the product may be shipped or sold commercially.

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

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

The process of completing clinical testing and obtaining FDA approval for a new drug is likely to take a number of years and require the expenditure of substantial resources. If an application is submitted, there can be no

assurance that the FDA will review and approve the NDA. Even after initial FDA approval has been obtained, further studies, including post-market studies, might be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested and approved. Also, the FDA will require post-market reporting and might require surveillance programs to monitor the side effects of the drug. Results of post-marketing programs might limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling or a change in manufacturing facility, an NDA supplement might be required to be submitted to the FDA.

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

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

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

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

CPEC, LLC

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

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

ARCA Discovery, Inc. of Aurora, Colorado, and its academic collaborators, have reexamined this clinical trial data and have identified a genetic marker that highly correlates with patients who did not respond to bucindolol. ARCA believes that bucindolol s unique pharmacology is suitable for therapy of most heart failure patients who do not exhibit this genetic marker, in other pharmacogenetically-identified subpopulations that are ideally suited for bucindolol s

novel therapeutic action, and for the treatment of ischemia in the setting of left ventricular dysfunction. In October 2003, CPEC outlicensed bucindolol to ARCA. Terms of the license call for future royalty and milestone payments to CPEC upon the development and commercialization of bucindolol.

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, a product candidate for the treatment of ulcerative colitis. In January 2001, Incara Development initiated a Phase II/III 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

At November 30, 2005, our only employee was Richard Burgoon, our Chief Executive Officer. Mr. Burgoon is not represented by a labor union. Each of our other executive officers and service providers are consultants.

Item 1A. Risk Factors.

You should carefully consider the following information about risks described below, together with the other information contained in this annual report on Form 10-K and in our other filings with the SEC, before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this annual report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

Risks Related to Our Business

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

We have incurred significant losses over the past five years, including net losses of $6.9 million, $17.3 million and $3.9 million for the years ended September 30, 2005, 2004 and 2003, respectively, and we had an accumulated deficit of approximately $147.1 million as of September 30, 2005. Our operating losses have been due primarily to our expenditures for research and development on our product candidates and for general and administrative expenses and our lack of significant revenues. We are likely to continue to incur operating losses until such time, if ever, that we generate significant recurring revenues. We anticipate it will take a minimum of five years (and possibly longer) for us to generate recurring revenues, since we expect that it will take at least that long before the development of any of our licensed or other current potential products is completed, marketing approvals are obtained from the FDA and commercial sales of any of these products can begin.

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

We need to raise substantial additional capital to fund our operations and clinical trials and continue our research and development. In addition, we may need to raise substantial additional capital to enforce our proprietary rights, defend, in litigation or otherwise, any claims that we infringe third party patents or other intellectual property rights; and commercialize any of our products that may be approved by the FDA or any international regulatory authority.

As of September 30, 2005, we had cash of approximately $626,000. In November 2005, we completed a private placement in which we issued to certain investors an aggregate of 1,250,000 shares of Series A Convertible Preferred Stock and warrants to purchase 2,500,000 shares of common stock at an initial exercise price of $1.00 per share for aggregate net proceeds of $2,400,000. We expect to use these funds to continue the development of our product candidates and to expand the development of our drug pipeline.

With this financing, we believe we have adequate financial resources to fund our current operations into the second quarter of fiscal year 2006. However, in order to fund on-going cash requirements beyond that point, or to further accelerate or expand our programs, we will need to raise additional funds. We are considering strategic and financial options available to us, including public or private equity offerings, debt financings and collaboration arrangements. If we raise additional funds by issuing securities, our stockholders will experience dilution. Debt financings, if available, may involve restrictive covenants. If we do not receive additional financing to fund our operations beyond the first quarter of fiscal 2006, we would have to discontinue some or all of our activities, merge with or sell some or all of our assets to another company, or cease operations entirely, and our stockholders might lose all or part of their investments.

In addition, if our catalytic antioxidant program shows scientific progress, we will need significant additional funds to move therapies through the preclinical stages of development and clinical trials. If we are unable to raise the amount

of capital necessary to complete development and reach commercialization of any of our catalytic antioxidant products, we will need to delay or cease development of one or more of these products or partner with another company for the development and commercialization of these products.

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

In its audit opinion issued in connection with our consolidated balance sheets as of September 30, 2005 and our consolidated statements of operations, stockholder s equity and cash flows for the year then ended, our independent registered public accounting firm has expressed a substantial doubt about our ability to continue as a going concern given our recurring net losses, negative cash flows from operations and working capital deficiency. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

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

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

As of September 30, 2005, we had an accumulated deficit of $147.1 million from our research, development and other activities. We have not generated material revenues from product sales and do not expect to generate product revenues sufficient to support us for at least several more years. Most of our revenues to date have come from previous collaborators who reimbursed us for research and development activities.

We remain contingently liable for certain 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 lease obligations assumed by the purchaser, including the IRL facility in Cranbury, New Jersey. If the purchaser were to default under these obligations, which could potentially require significant liability payments by us, or if we are otherwise liable under these obligations, we may need to make substantial payments and our financial condition could be materially adversely affected. Our contingent liability was approximately $1.6 million at September 30, 2005 and should decline on an approximately straight-line basis to zero in May 2007.

Our R&D activities are at an early stage and therefore might never result in viable products.

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

- any or all of these proposed products or procedures are found to be unsafe or ineffective or otherwise fail to receive necessary regulatory approvals;

- the proposed products or procedures are not economical to market or do not achieve broad market acceptance;

-

third parties hold proprietary rights that preclude us from marketing the proposed products or procedures; and

-

third parties market a superior or equivalent product.

Further, the timeframe for commercialization of any product is long and uncertain because of the extended testing and regulatory review process required before marketing approval can be obtained. There can be no assurance that we will be able to successfully develop or market any of our proposed products or procedures.

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

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

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

- Difficulty in securing centers to conduct trials;
- Difficulty in enrolling patients in conformity with required protocols or projected timelines;
- Unexpected adverse reactions by patients in trials;
- Difficulty in obtaining clinical supplies of the product;
- Changes in the FDA s requirements for our testing during the course of that testing;
- Inability to generate statistically significant data confirming the efficacy of the product being tested;
- Modification of the drug during testing; and
- Reallocation of our limited financial and other resources to other clinical programs.

It is possible that none of the products we develop will obtain the regulatory approvals necessary for us to begin commercializing them. The time required to obtain FDA and other approvals is unpredictable but often can take years following the commencement of clinical trials, depending upon the nature of the drug candidate. Any analysis we perform of data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which

could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular drug candidate and we may not have the financial resources to continue to develop our products and, as a result, may have to terminate our operations.

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

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

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

We currently license from third parties, and do not own, rights under patents and certain related intellectual property for the development of our product candidates. In addition, we expect to enter into agreements with third parties both to license rights to our product candidates and to develop and commercialize new products. We might

not be able to enter into or maintain these agreements on terms favorable to us, if at all. Further if any of our current licenses were to expire or terminate, our business, prospects, financial condition and results of operations could be materially and adversely affected.

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

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

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

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

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

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

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

21

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

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

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

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

Even if we expend considerable time and money on patent prosecution, a patent application may never issue as a patent. We can never be certain that we were the first to invent the particular technology or that we were the first to file a patent application for the technology because patent applications in the United States and elsewhere are not typically published for public inspection for at least 18 months from the date when they are filed. It is always possible that a competitor is pursuing a patent for the same invention in the United States as we are and has an earlier invention date. Outside the United States in some jurisdictions, priority of invention is determined by the earliest effective filing date, not the date of invention. Consequently, if a third party pursues the same invention and has an earlier filing date, patent protection outside the United States would be unavailable to us. Also, outside the United States, an earlier date of invention cannot overcome a date of publication that precedes the earliest effective filing date. Accordingly, the patenting of our proposed products would be precluded outside the United States if a prior publication anticipates the claims of a pending application, even if the date of publication is within a year of the filing of the pending application.

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

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

Our business also depends on our ability to develop and market products without infringing on the proprietary rights of others or being in breach of our license agreements. The pharmaceutical industry is characterized by a large number

of patents, patent filings and frequent and protracted litigation regarding patent and other intellectual property rights. Many companies have numerous patents that protect their intellectual property rights. Third parties might assert infringement claims against us with respect to our product candidates and future products. If litigation

were required to determine the validity of a third party s claims, we could be required to spend significant time and financial resources, which could distract our management and prevent us from furthering our core business activities, regardless of the outcome. If we did not prevail in the litigation, we could be required to pay damages, license a third party s technology, which may not be possible on terms acceptable to us, or at all, or discontinue our own activities and develop non-infringing technology, any of which could prevent or significantly delay pursuit of our development activities.

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

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

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

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

As of September 30, 2005, we had one full-time employee, our Chief Executive Officer. We utilize consultants to assist with our operations and are highly dependent on the services of our executive officers. We also are dependent on our collaborators for our research and development activities. The loss of key executive officers or collaborators could delay progress in our research and development activities or result in their termination entirely.

We believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific and managerial personnel. We face intense competition for these kinds of personnel from other companies, research and academic institutions, government entities and other organizations. If we fail to identify, attract and retain personnel, we may be unable to continue the development of our product candidates, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

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

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

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

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

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

As a result, these competitors may:

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Succeed in developing competitive products sooner than us or our strategic partners or licensees;

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Obtain FDA and other regulatory approvals for their products before approval of any of our products;

-

Obtain patents that block or otherwise inhibit the development and commercialization of our product candidates;

-

Develop products that are safer or more effective than our products;

-

Devote greater resources to marketing or selling their products;

-

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

-

Introduce products that render our products obsolete;

•

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

•

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

•

Take advantage of other opportunities more readily.

Currently, Rilutek®, which was developed by Aventis Pharma AG, is the only drug of which we are aware that has been approved by the FDA for the treatment of ALS. Other companies are working to develop pharmaceuticals to treat ALS, including CytRx Corporation and Oxford BioMedica plc. In addition, ALS belongs to a family of diseases called neurodegenerative diseases, which includes Alzheimer s disease, Parkinson s disease and Huntington s disease. Due to similarities between these diseases, a new treatment for one disease potentially could be useful for treating others. There are many companies that are producing and developing drugs used to treat neurodegenerative diseases other than ALS, including Amgen, Inc., Guilford Pharmaceuticals, Inc., Phytopharm plc, Cephalon, Inc. and Ceregene, Inc.

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

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

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the receipt of regulatory approvals for the indications that we are studying;

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the establishment and demonstration in the medical community of the safety, clinical efficacy and cost-effectiveness of our products and their potential advantages over existing therapeutic products;

-

marketing and distribution support;

-

the introduction, market penetration and pricing strategies of competing and future products; and

-

coverage and reimbursement policies of governmental and other third-party payors such as insurance companies, health maintenance organizations and other plan administrators.

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

We may need to implement additional finance and accounting systems, procedures and controls to satisfy new reporting requirements.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including expanded disclosures and accelerated reporting requirements and more complex accounting rules, including pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. Compliance with Section 404, which requires companies to evaluate their internal control over financial reporting, and other requirements will increase our costs and require additional management resources. We are required to be in compliance with Section 404 of the Sarbanes-Oxley Act of 2002 by the end of our fiscal year ending September 30, 2007. In addition, beginning with our fiscal year ending September 30, 2006, we are required to adopt Statement of Financial Accounting Standards No. 123R, Share-Based Payment, which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative.

We will need to continue to implement additional finance and accounting systems, procedures and controls to satisfy new reporting requirements. There is no assurance that we will be able to complete a favorable assessment as to the effectiveness of our internal control over financial reporting for our fiscal year ending September 30, 2007, or that any future assessments of the adequacy of our internal control over financial reporting will be favorable. If we are unable to obtain future unqualified reports as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our internal control over financial reporting, which could adversely affect

our stock price.

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

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

Risks Related to Owning Our Stock

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

As of November 30, 2005, Xmark Asset Management, LLC and Xmark Opportunity Managers, LLC (collectively referred to as Xmark), which are both controlled by a common individual, owned 11,515,311 shares, or 71.1%, of our outstanding common stock, through their management of Goodnow Capital, L.L.C. (Goodnow), Xmark Fund, L.P., Xmark Fund, Ltd., Xmark Opportunity Funds, L.P., Xmark Opportunity Fund, Ltd. and Xmark JV Investment Partners, LLC (collectively, the Xmark Funds) and a voting trust agreement for 1,000,000 shares. As a result, the Xmark affiliates will be able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval and continue to have significant influence over our operations. The interests of the Xmark affiliates may be different than the interests of other stockholders on these and other matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which could reduce the price of our common stock.

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

As of September 30, 2005, we had 14,038,259 shares of common stock outstanding. We may grant to our employees, directors and consultants options to purchase shares of our common stock under our 2004 Stock Option Plan. In addition, as of September 30, 2005, options to purchase 2,394,091 shares were outstanding at exercise prices ranging from $0.40 to $205.00 per share, with a weighted average exercise price of $4.05, and 1,539,200 shares were reserved for issuance under the 2004 Stock Option Plan. In addition, as of September 30, 2005, warrants to purchase 2,207,402 shares of common stock were outstanding at exercise prices ranging from $1.00 to $20.25 per share, with a weighted exercise price of $4.56 per share, and we had reserved 9,118 shares of common stock for issuance pursuant to our Employee Stock Purchase Plan. We have also reserved 497,278 shares for the conversion of our Series B Preferred stock and related warrants. In November 2005, we completed a private placement in which we issued to certain investors an aggregate of 1,250,000 shares of Series A Convertible Preferred Stock and warrants to purchase 2,500,000 shares of common stock for aggregate net proceeds of $2,400,000. Under the terms of our charter, as amended in connection with the financing, a dividend payment in the form of interest at the rate of 6% annually, based on funds used by us, may be paid in either cash or common stock at our option. The Series A preferred shares initially are convertible into 2,500,000 shares of our common stock. In connection with the funding agreement, we also issued warrants to purchase up to 2,500,000 shares our common stock. Each warrant has an initial exercise price of $1.00 per share and has a five-year term. As a result, we have reserved an additional 5,000,000 shares for the issuance of common stock upon the conversion of the Series A preferred stock and the exercise of the common stock warrants, and further shares will be reserved for the payment of any common stock dividends.

In connection with prior collaborations and financing transactions, we also 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 (Elan). These securities generally are exercisable and convertible at the option of the Elan affiliates. The exercise or conversion of all or a portion of these securities would dilute the ownership interests of our stockholders.

Our common stock is not listed on an exchange, is illiquid and is characterized by low and/or erratic trading volume, and the per share price of our common stock has fluctuated from $0.44 to $10.50 during the last two years.

Our common stock is quoted on the OTC Bulletin Board under the symbol AOLS. An active public market for our common stock is unlikely to develop as long as we are not listed on the Nasdaq National or SmallCap Market or a national securities exchange. Even if listed, the market for our stock may be impaired because of the limited number of investors, the significant ownership stake of Xmark through its management of Goodnow and the

Xmark Funds and our small market capitalization, which is less than that authorized for investment by many institutional investors.

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

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

If registration rights that we have previously granted are exercised, then the price of our common stock may be adversely affected.

We have agreed to register with the SEC shares of common stock underlying the Series B preferred stock, warrants to purchase Series B preferred stock and a promissory note held by the Elan affiliates. In addition, we have agreed to register with the SEC the common stock underlying the Series A preferred stock and warrants issued in our November 2005 financing. Once these securities are registered with the SEC, they may be freely sold in the open market. We expect that we also will be required to register any securities sold in future private financings. The sale of a significant amount of shares in the open market, or the perception that these sales may occur, could cause the trading price of our common stock to decline or become highly volatile.

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

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease 16,149 square feet of office and laboratory space in Research Triangle Park, North Carolina, which was formerly used as our principal executive offices. In August 2005, we relocated our principal executive offices to Laguna Niguel, California. Although we no longer occupy any space in North Carolina, our lease in Research Triangle Park will continue through June 2006. We have entered into an agreement to sublease approximately 2,200 square feet of the laboratory space through June 2006.

Item 3. Legal Proceedings.

We are not a party to any material legal proceedings.

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, 2005.

Executive Officers

At November 30, 2005, our only employee was Richard Burgoon, our Chief Executive Officer. Each of our other executive officers are consultants. Our executive officers and their ages as of November 30, 2005 were as follows:

Name	Age	Position(s)
Richard P. Burgoon, Jr., Esq., MBA	44	Chief Executive Officer
John L. McManus	41	President
Brian J. Day, Ph.D.	45	Chief Scientific Officer
Elaine Alexander, M.D.	53	Executive Vice President and Chief Medical Officer
Michael P. McManus	36	Chief Accounting Officer, Treasurer and Secretary

Richard P. Burgoon, Jr., Esq., MBA. Mr. Burgoon joined the Company as Chief Executive Officer in January of 2005. During 2004 Mr. Burgoon was Vice President, Corporate Development of Targeted Diagnostics & Therapeutics, Inc. During 2003 and 2004, Mr. Burgoon was Director, Business Development in the United States for ChoongWae Pharma Corporation. From 2002 to 2004, Mr. Burgoon was a Principal at the Xmark Funds, LLP. From 1998 to 2001, Mr. Burgoon was Senior Vice President, Operations, General Counsel and Secretary of Arena Pharmaceuticals, Inc. where he was recruited as part of the start-up management team, Mr. Burgoon has been an executive within the biopharmaceutical industry for the majority of his 20-year career. He is a co-founder of Allon Therapeutics, Inc. (Toronto: NPC.TO), a publicly-traded CNS-focused company headquartered in Vancouver BC, and GenSpera, Inc., a privately-held oncology-focused company headquartered in San Diego, California. His prior positions have also included Senior Director to Cephalon, Inc. (Nasdaq: CEPH), Intellectual Property Counsel to IDEC Pharmaceuticals (now, Biogen-IDEC; Nasdaq: BIIB), counsel to Beckman Instruments, Inc. (now Beckman-Coulter) and associate to the law firm of Lyon & Lyon. Mr. Burgoon received his MBA from San Diego State University, earned his J.D. from the Franklin Pierce Law Center and undergraduate degrees in biology, psychology and political science from the University of California, Irvine.

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

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

Elaine Alexander, M.D., Ph.D. Dr. Alexander began as a consultant to the Company in February 2005 as Executive Vice President and Chief Medical Officer. Previously, from 2003 to 2005, Dr. Alexander was a consultant to several pharmaceutical companies. From 1999 to 2003, Dr. Alexander served as Vice President of Experimental and Clinical Research, Chief Medical Officer, and Director of Translational Medicine at Arena Pharmaceuticals, Inc. in San Diego, CA. Dr. Alexander s basic and clinical research has focused on the mechanisms of tissue injury and genetics of autoimmune, inflammatory, rheumatologic, and neurologic disorders. Dr. Alexander received her M.D. degree from the UCLA School of Medicine, Los Angeles, California and her postdoctoral internal medicine training at Johns Hopkins Medical Institutions, Baltimore, MD. Dr. Alexander completed fellowship training in

rheumatology and clinical immunology and joined the faculty at Johns Hopkins in the Department of Internal Medicine, Division of Molecular and Clinical Rheumatology. Her Ph.D. in cell biology and biochemistry was followed by a postdoctoral fellowship in immunology at the NIH, National Cancer Institute, Immunology Division, Bethesda, MD. Dr. Alexander is board certified in Internal Medicine and Rheumatology. Dr. Alexander is internationally recognized for her basic and clinical work in autoimmunity and the neurologic complications of autoimmune and rheumatologic disorders. Dr. Alexander served as Director of Experimental Medicine at Cephalon, Inc., Westchester, PA, where she led exploratory research and clinical development for Myotrophin, recombinant human IGF-1, for the treatment of amyotrophic lateral sclerosis and other neurologicindications, contributed to the development of Modafinil for expanded clinical indications, and participated in preclinical development of pipeline candidates. Dr. Alexander has received numerous academic honors, is a member of Alpha Omega Alpha, is the author of over 70 peer reviewed research articles and numerous book chapters, and has served as a reviewer for journals and NIH study sections. Dr. Alexander also serves on the Board of Directors for the Sjogren s Syndrome Foundation, a non profit autoimmune disease national organization, the NIH Autoimmune Disease Coordinating Committee, and the advisory board for the NIH International Sjogren s Syndrome Registry. She has received, and currently is the co-principal investigator, for NIH grants and is the co-chairman of an NIH/industry sponsored autoimmune international workshop on autoimmunity and lymphoma.

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

PART II

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

(a) Price Range of Common Stock

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

	High	Low
Fiscal Year Ended September 30, 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
Fiscal Year Ended September 30, 2005		
October 1, 2004 through December 31, 2004	$ 1.60	$ 1.04
January 1, 2005 through March 31, 2005	$ 1.25	$ 0.65
April 1, 2005 through June 30, 2005	$ 0.95	$ 0.44
July 1, 2005 through September 30, 2005	$ 1.38	$ 0.75

(b) Approximate Number of Equity Security Holders

As of November 30, 2005, the number of record holders of our common stock was 173 and we estimate that the number of beneficial owners was approximately 3,000.

(c) Dividends

We have never paid a cash dividend on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future. If we pay a cash dividend on our common stock, we also must pay the same dividend on an as converted basis on our Series A and Series B preferred stock. Moreover, any additional preferred stock to be issued and any future credit facilities might contain restrictions on our ability to declare and pay dividends on our common stock. We plan to retain all earnings, if any, for the foreseeable future for use in the operation of our business and to fund future growth.

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

-

the date that Goodnow owns less than 20% of our outstanding common stock on an as converted basis;

-

the completion, to the absolute satisfaction of Goodnow, of initial 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.

Further, we cannot pay a dividend on our common stock without the prior approval of Xmark Opportunity Fund, L.P. and Xmark Opportunity Fund, Ltd. pursuant to the terms of our Certificate of Incorporation, as amended in connection with our November 2005 private placement. This restriction will be in effect as long as any shares of Series A preferred stock are outstanding.

(d) Equity Compensation Plan and Additional Equity Information as of September 30, 2005

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by our stockholders:			
2004 Stock Option Plan	398,301	$0.95	1,539,200
1994 Stock Option Plan	1,995,790	$4.67	0
1995 Employee Stock Purchase Plan	0	Not applicable	9,118
Equity compensation plans and securities not approved by our stockholders:			
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	2,445,740		1,556,152
Warrant to Purchase Series B Preferred Stock Issued to Xmark Fund, 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, 2005)(1)(2)	20,048	$43.27	2,546
Total Series B Preferred Stock	42,239		2,546

(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 and Equity Securities Not Approved by Our Stockholders

Our Board of Directors adopted the 1999 Equity Incentive Plan (the Equity 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 thereunder 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, 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 subject to the Equity Plan were granted to employees and a key consultant in consideration of services rendered. All outstanding shares of restricted stock subject to the Equity Plan were fully vested at September 30, 2005. The Equity Plan was terminated by the Board of Directors in October 2005.

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 of ours, 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 issued 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 November 21, 2005, we entered into a Purchase Agreement with certain institutional accredited investors (the Investors) pursuant to which we sold to the Investors an aggregate of 1,250,000 shares of our Series A Convertible Preferred Stock and warrants to purchase up to an aggregate of 2,500,000 shares of common stock for aggregate gross proceeds of $2,500,000. Each share of the Series A preferred stock, which has a stated value of $2.00 per share, is initially convertible into two shares of common stock. These shares may be converted into shares of common stock at any time at the election of the holders thereof.

The warrants have an initial exercise price of $1.00 per share and may be exercised at any time until November 21, 2010, provided that they may terminate early in the event we consummate a merger, consolidation or similar transaction prior to the expiration date. In addition, the warrants contain a cashless exercise feature that allows the Investors to exercise the warrants without a cash payment to us under certain circumstances.

(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, 2005 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, 2005 were audited by Haskell & White LLP, an independent registered public accounting firm. Our consolidated financial statements for the fiscal year ended September 30, 2004 were audited by Grant Thornton LLP, an independent registered public accounting firm, and our consolidated financial statements for the three fiscal years ended September 30, 2003 were audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm. Except for the consolidated statements of operations for the fiscal years ended September 30, 2002 and 2001 and the consolidated balance sheet data at September 30, 2003, 2002 and 2001, each of these financial statements 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.

Statement of Operations Data:

	Year Ended September 30,				
	2005	**2004**	**2003**	**2002**	**2001**
	(in thousands, except per share data)				
Revenue:					
Grant income and contract revenue	$ 252	$ 305	$	$	$
Costs and expenses:					
Research and development	4,515	8,295	2,780	3,927	5,032
General and administrative	2,674	3,987	2,025	2,778	3,057
Total costs and expenses	7,189	12,282	4,805	6,705	8,089
Loss from operations	(6,937)	(11,977)	(4,805)	(6,705)	(8,089)
Equity in loss of Incara Development			(76)	(1,040)	(12,650)
Interest income (expense), net	(31)	(5,213)	(192)	(50)	223
Other income	63	23	223	150	767
Loss from continuing operations	(6,905)	(17,167)	(4,850)	(7,645)	(19,749)
Discontinued operations			(38)	(3,657)	(2,464)
Gain on sale of discontinued operations			1,912		
Net loss	(6,905)	(17,167)	(2,976)	(11,302)	(22,213)
Preferred stock dividend and accretion		(135)	(949)	(887)	(652)
Net loss attributable to common stockholders	$ (6,905)	$ (17,302)	$ (3,925)	$ (12,189)	$ (22,865)
Net loss per share from continuing operations available to common stockholders	$ (0.49)	$ (2.06)	$ (4.25)	$ (6.58)	$ (24.78)
Net loss per share attributable to common stockholders	$ (0.49)	$ (2.06)	$ (2.88)	$ (9.40)	$ (27.77)
Weighted average commons hares outstanding:					
Basic and diluted	13,976	8,388	1,365	1,296	823

Balance Sheet Data:

	September 30,				
	2005	**2004**	**2003**	**2002**	**2001**
	(in thousands)				

Cash and cash equivalents and marketable securities	$ 626	$ 7,381	$ 586	$ 209	$ 5,453
Working capital (deficiency)	$ (73)	$ 6,093	$ (2,242)	$ (1,590)	$ 3,967
Total assets	$ 937	$ 7,856	$ 1,080	$ 2,201	$ 8,618
Long-term portion of capital lease obligations and notes payable	$ 867	$ 787	$ 714	$ 944	$ 17
Redeemable convertible exchangeable preferred stock	$	$	$ 14,503	$ 13,554	$ 12,667
Total liabilities	$ 1,869	$ 2,324	$ 18,159	$ 3,127	$ 2,971
Total stockholders equity (deficit)	$ (932)	$ 5,532	$ (17,079)	$ (14,480)	$ (7,020)

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

Introduction

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

Overview

We are developing a series of catalytic antioxidant molecules to protect against the damaging effects of reactive oxygen derived molecules, commonly referred to as free radicals. Free radicals cause damage in a broad group of diseases and conditions. Our initial target 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 recently announced positive safety results from a completed Phase I single dose study of AEOL 10150 in patients diagnosed with ALS. In addition, in September 2005, we launched a Phase I multiple dose study of AEOL 10150 in patients diagnosed with ALS. We expect to complete this study during the second quarter of fiscal year 2006. The data from these safety studies is not limited to ALS and may be utilized to support subsequent efficacy studies of AEOL 10150 in ALS, as well as other indications for which we have developed preclinical efficacy data.

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

We had net losses attributable to common stockholders of $6,905,000 and $17,302,000 for the fiscal years ended September 30, 2005 and 2004, respectively. We had an accumulated deficit of $147,093,000 at September 30, 2005. We have not yet generated any revenue from product sales and do not expect to receive any product revenue in the foreseeable future, if at all.

Corporate Matters

On November 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 of the surviving entity and all 12,015 shares of previously outstanding Series C preferred stock were converted into 225,533 shares of common stock of the surviving entity.

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 initial 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 initial exercise price of $2.50 per share. In addition, in April 2004, Goodnow Capital, L.L.C. converted a debenture in the aggregate amount of $5,047,000 into 5,046,875 shares of common stock.

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 to reflect the reverse stock split.

On November 21, 2005, we entered into a Purchase Agreement with certain institutional accredited investors pursuant to which we sold to the investors an aggregate of 1,250,000 shares of our Series A Convertible Preferred Stock and warrants to purchase up to an aggregate of 2,500,000 shares of common stock for aggregate net proceeds of $2,400,000. Each share of the Series A preferred stock, which has a stated value of $2.00 per share, is initially convertible into two shares of common stock. These shares may be converted into shares of common stock at any time at the election of the holders thereof. The warrants have an initial exercise price of $1.00 per share.

Transactions with Elan Corporation, plc

In January 2001, we closed 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 deligoparin to Incara Development and Elan licensed to Incara Development a proprietary drug delivery technology.

In connection with the transaction, Elan purchased 82,500 shares of our common stock, 28,457 shares of our Series B convertible preferred stock and a five-year warrant to purchase 22,191 shares of Series B preferred stock at an initial 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 for a total of $12,015,000. We contributed to Incara Development the proceeds from the issuance of the Series C preferred stock in exchange for securities of Incara Development. Elan also contributed $2,985,000 to Incara Development for 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% per year, compounded annually, and was convertible at Elan s option into shares of our Series B 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 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. We owned 80.1% and Elan owned 19.9% of the outstanding combined common and non-voting preferred shares of Incara Development from inception through September 30, 2003. 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 Elan 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 an additional $638,000 pursuant to the terms of the note arrangement. The outstanding balance of the note payable was $867,000 as of September 30, 2005. The note is convertible at the option of Elan into shares of Series B preferred stock at a rate of $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 $12,015,000, which equaled the proceeds we received from Elan to purchase the Series C preferred stock. 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 Accounting Principles Board Opinion (APB) No. 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 had 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 our collaboration in November 2003, at which time 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 catalytic antioxidant products sold, if any, for the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage.

Results of Operations

Fiscal Year Ended September 30, 2005 Compared to Fiscal Year Ended September 30, 2004

We had a net loss attributable to common stockholders of $6,905,000 for the fiscal year ended September 30, 2005, versus a net loss attributable to common stockholders of $17,302,000 for fiscal 2004.

In August 2003, we were awarded a $100,000 Small Business Innovation and Research (SBIR) Phase I grant from the National Cancer Institute, a division of the NIH. In March 2004, we were awarded up to $375,000 for the first year of a SBIR Phase II grant and received approval for a second year of the Phase II grant program in January 2005. Pursuant to the grants, we are studying the antitumor and radiation-protective effects of our catalytic antioxidants. The study is a collaboration between us and the Department of Radiation Oncology at Duke University Medical Center. We recognized $252,000 of grant income during the fiscal year 2005 versus $305,000 during fiscal year 2004.

Research and Development

Research and development (R&D) expenses decreased $3,780,000, or 46%, to $4,515,000 for fiscal year 2005 from $8,295,000 for fiscal year 2004. Our primary operational focus and R&D spending during fiscal year 2005 was on conducting our Phase I clinical trial for the treatment of ALS, while our primary operational focus and R&D spending during fiscal year 2004 was on preclinical pharmacology and toxicology tests on our lead compound, AEOL 10150. We eliminated our R&D staff during fiscal year 2004 and are currently using consultants to conduct our R&D activities. Therefore, we incurred greater expenses for clinical trial and sponsored research costs in fiscal year 2005, compared with fiscal year 2004, in which we incurred higher expenses associated with preclinical activities and payroll costs. R&D expenses for our antioxidant program have totaled $28,673,000 from inception through September 30, 2005. Because of the uncertainty of our research and development and clinical studies, we are unable to predict the

total level of spending on the program or the program completion date. However, we expect R&D expenses during fiscal year 2006 will be higher than fiscal 2005 as we initiate a multi-dose Phase I study in ALS and as we expand our preclinical testing activities to further develop other compounds in our pipeline. Our ongoing cash requirements will also depend on numerous factors, particularly the progress of our R&D programs and our ability to negotiate and complete collaborative agreements.

General and Administrative

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

General and administrative (G&A) expenses decreased $1,313,000, or 33%, to $2,674,000 for fiscal year 2005 from $3,987,000 for fiscal year 2004. G&A expenses were lower during fiscal year 2005 versus 2004 due to a lower amount of amortization expense related to the accelerated vesting of stock options following a change in the board of directors in 2004 ($270,000 during fiscal year 2005 versus $1,580,000 during fiscal year 2004), and lower salaries and wages as a result of a reduction of staffing levels in 2004 and 2005 ($796,000 during fiscal year 2005 versus $1,182,000 for fiscal year 2004). During June 2005, we did not renew the employment contract with our former Chief Financial Officer and as a result incurred non-recurring severance expenses in the amount of $253,000. In August 2005, we closed our offices in Research Triangle Park, North Carolina, and accrued for all remaining lease payments in the amount of $217,000.

Interest expense decreased to $31,000 in fiscal year 2005 from $5,213,000 in fiscal year 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.

Other income of $63,000 and $23,000 for fiscal 2005 and 2004, respectively, related primarily to sublease rental income of our leased laboratory and office facilities in North Carolina.

We accreted $135,000 of dividends on our Series C preferred stock during fiscal 2004. 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, 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 includes a $1,912,000 gain on the sale of our liver cell operations to Vesta Therapeutics, Inc. in October 2002.

As discussed above, in August 2003, we were awarded a SBIR Phase I grant from the National Cancer Institute, and in March 2004, we were awarded a SBIR Phase II grant from the NIH. We recognized $305,000 of Phase II grant income during fiscal 2004.

Because of our lack of financial resources during fiscal 2003, we had decreased our spending on 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.

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.

As discussed above, we recognized $5,000,000 of noncash interest expense in fiscal 2004 in connection with the conversion of a convertible debenture issued to Elan.

On October 31, 2002, we sold substantially all the assets and operations of our liver cell program to Vesta Therapeutics, Inc. 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.

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.

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 in Research Triangle Park.

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.

Liquidity and Capital Resources

At September 30, 2005, we had $626,000 of cash, a decrease of $6,755,000 from September 30, 2004. The decrease in cash from September 30, 2004 to 2005 was primarily due to fiscal 2005 cash operating expenses. On November 21, 2005, we completed a private placement in which we issued to certain investors an aggregate of 1,250,000 shares of Series A Convertible Preferred Stock and warrants to purchase 2,500,000 shares of common stock at an initial exercise price of $1.00 per share for aggregate net proceeds of $2,400,000. With this financing, we believe we have adequate financial resources to conduct operations into the second quarter of fiscal year 2006. This raises substantial doubt about our ability to continue as a going concern, which will be dependent on our ability to generate sufficient cash flows to meet our obligations on a timely basis, to obtain additional financing and, ultimately, to achieve operating profit.

We incurred operational losses of $6,905,000 during fiscal 2005. Our ongoing cash requirements will depend on numerous factors, particularly the progress of our catalytic antioxidant program and clinical trials and our ability to negotiate and complete collaborative agreements or out-licensing arrangements. In order to help fund our on-going operating cash requirements, we intend to seek new collaborations for our antioxidant research program that include initial cash payments and on-going research support. In addition, we will need to sell additional shares of our stock and explore other strategic and financial alternatives, including a merger with another company and the establishment of new collaborations for current research programs that include initial cash payments and ongoing research support, or the out-licensing of our compounds for development by a third party.

There are significant uncertainties as to our ability to access potential sources of capital. We may not be able to enter into any collaboration on terms acceptable to us, or at all, due to conditions in the pharmaceutical industry or in the economy in general or based on the prospects of our catalytic antioxidant program. Even if we are successful in obtaining a collaboration for our antioxidant program, we may have to relinquish rights to technologies, product candidates or markets that we might otherwise develop ourselves. These same risks apply to any attempt to out-license our compounds.

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

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

Contractual Obligations

Our contractual obligations (in thousands) as of September 30, 2005 were as follows:

		Payments due by period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Long-term debt	$ 867	$	$ 867	$	$
Capital lease obligations					
Operating leases	267	267			
Purchase obligations	1,320	1,320			
Total	$ 2,454	$ 1,587	$ 867	$	$

The operating lease commitments are comprised of lease obligations for our laboratory and office facilities in the Research Triangle Park, North Carolina, which have 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 $1,634,000 assumed by the purchaser on the former IRL facility in Cranbury, New Jersey. This contingent lease obligation is not recorded as a liability and is not included in the above table.

Off Balance Sheet Arrangements

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

Relationship with Goodnow Capital and Xmark

In July 2003, we initiated a series of transactions that led to our corporate reorganization and recapitalization. We obtained an aggregate of $8.0 million in secured bridge financing in the form of convertible promissory notes we issued to Goodnow Capital, L.L.C. A portion of this financing allowed us to pay our past due payables and become current. We used the remainder for our operations, including a toxicology study for our catalytic antioxidant compounds under development as a treatment for ALS.

We completed our corporate reorganization on November 20, 2003. The reorganization involved the merger of our former parent company into one of its wholly owned subsidiaries. Upon consummation of the merger, a $3.0 million note held by Goodnow, including accrued interest, converted into 3,060,144 shares of our common stock. On April 19, 2004, we sold $10.26 million of our common stock in a private placement. In conjunction with the private placement, Goodnow voluntarily converted a $5.0 million debenture, including accrued interest thereon, into 5,046,875 shares of our common stock, which, along with the 3,060,144 shares issued in the merger and the 20 shares that Goodnow owned before the consummation of the merger, represented 58.1% of the shares of our common stock outstanding on November 30, 2004. As a result of this significant ownership, Goodnow is able to significantly

influence, if not control, future actions voted on by stockholders of our company.

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

- to secure the $8.0 million debt with liens on all of our assets, which liens expired on April 19, 2004 when the remaining debt converted to shares of common stock;

- to spend the financing proceeds only in accordance with a budget and development plan agreed to by Goodnow;

- to not enter into any arrangement with a party other than Goodnow in which we would raise capital through the issuance of our securities other than the raising of up to an aggregate of $20,000,000 through the issuance of shares of our common stock at a price of greater than $3.00 per share and which would represent 25% or less of our then outstanding common stock on an as-converted to common and fully diluted basis. If we agree to or consummate a financing transaction with someone other than Goodnow that exceeds these limitations, we will pay Goodnow a break-up fee of $500,000. Goodnow approved the April 2004 private placement, which exceeded these limitations, and waived the fee. However, the $20,000,000 limitation was lowered to $9,740,000 and the 25% limitation was reduced to zero. Goodnow also approved the November 2005 private placement, which exceeded these limitations and waived the fee; and

- to allow Goodnow to appoint one director to our board of directors, provided Goodnow owns at least 10%, but less than 20%, of our outstanding common stock, on an as-converted to common and fully diluted basis, and two directors if Goodnow owns more than 20% of our outstanding common stock.

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

- make any expenditure or series of related expenditures in excess of $25,000, except (i) expenditures pursuant to the SBIR grant from the U.S. Small Business Administration, (ii) specified in a budget approved in writing in advance by Goodnow and our Board, and (iii) directly relating to the development of AEOL 10150 for the treatment of ALS;

- change our business or operations;

- merge with or sell or lease a substantial portion of our assets to any entity;

- incur debt from any third party or place a lien on any of our properties;

- amend our certificate of incorporation or bylaws;

- increase the compensation we pay our employees;

- pay dividends on any class of our capital stock;

-

cancel any debt except for full value; or

-

issue any capital stock except pursuant to agreements with or as agreed to by Goodnow.

The affirmative covenants expire on the earliest of:

-

the date that Goodnow owns less than 20% of our outstanding common stock on an as converted basis;

-

the completion, to the absolute satisfaction of Goodnow, of initial 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.

In addition, as a result of the financing completed in November 2005, in which Xmark Opportunity Fund, L.P. and Xmark Opportunity Fund, Ltd. (the Xmark Opportunity Funds) were the lead investors, we have agreed to not, without Xmark Opportunity Funds prior approval:

-

amend our certificate of incorporation or bylaws;

-

issue or sell any class or series of capital stock which is senior to or pari passu with the Series A Preferred Stock;

-

increase the number of authorized shares of Series A Preferred Stock;

-

increase or decrease the number of authorized shares of any class of our capital stock;

-

declare or pay any dividend on shares of our capital stock;

- consummate an acquisition or enter into an agreement with respect to an acquisition;
- materially change the nature or scope of our business;
- sell, transfer, assign, pledge, lease, license any of our intellectual property;
- approve our annual budget or any changes thereto; or
- incur any indebtedness in excess of $50,000 other than trade payables incurred in the ordinary course of business or indebtedness provided for in and consistent with the approved current annual budget;
- create, incur, assume or suffer to exist, any material lien, charge or other encumbrance on any of our properties or assets; or
- increase the compensation or benefits payable to our directors or executive officers.

These covenants shall remain in effect as long as long as any shares of Series A Preferred Stock are outstanding. In addition, so long as Xmark Opportunity Funds own any shares of Series A Preferred Stock, Xmark Opportunity Funds shall have the right to elect a majority of the Company s Board of Directors at any time.

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.

INDEX TO FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	43
Report of Independent Registered Public Accounting Firm	44
Report of Independent Registered Public Accounting Firm	45
Consolidated Balance Sheets As of September 30, 2005 and 2004	46
Consolidated Statements of Operations For the fiscal years ended September 30, 2005, 2004 and 2003	47
Consolidated Statements of Stockholders Equity (Deficit) For the fiscal years ended September 30, 2005, 2004 and 2003	48
Consolidated Statements of Cash Flows For the fiscal years ended September 30, 2005, 2004 and 2003	49
Notes to Consolidated Financial Statements	50

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Aeolus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Aeolus Pharmaceuticals, Inc. (a Delaware corporation) and Subsidiaries (the Company) as of September 30, 2005, and the related consolidated statements of operations, stockholders equity (deficit), 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our 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 consolidated financial position of Aeolus Pharmaceuticals, Inc. and Subsidiaries as of September 30, 2005, and the consolidated 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.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B to the consolidated financial statements, the Company has suffered recurring losses from operations, has a stockholders deficit, and has a working capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note B. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ HASKELL & WHITE LLP

HASKELL & WHITE LLP

Irvine, CA
December 8, 2005

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

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Aeolus Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated statements of operations, of stockholders equity (deficit) and of cash flows present fairly, in all material respects, the results of operations and cash flows of Aeolus Pharmaceuticals, Inc. (formerly Incara Pharmaceuticals Corporation) and its subsidiaries (the Company) for the year 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 audit. We conducted our audit 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 audit provides a reasonable basis for our opinion.

The financial statements for the year ended 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, except for the reverse stock split

described in Note A, as to which the date is July 16, 2004

AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
(Dollars in thousands, except per share data)

	September 30, 2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 626	$ 7,381
Accounts receivable	14	138
Prepaids and other current assets	289	111
Total current assets	929	7,630
Property and equipment, net		15
Other assets	8	211
Total assets	$ 937	$ 7,856
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 712	$ 1,185
Accrued expenses	290	102
Liabilities of discontinued operations		250
Total current liabilities	1,002	1,537
Long-term note payable	867	787
Total liabilities	1,869	2,324
Commitments and Contingencies (Note G and N)		
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; 475,087 and 503,544 shares issued and outstanding as of September 30, 2005 and 2004, respectively	5	5
Common stock, $.01 par value per share, 50,000,000 shares authorized; 14,038,259 and 13,947,303 shares issued and outstanding at September 30, 2005 and 2004, respectively	140	139

Additional paid-in capital	146,016	145,576
Accumulated deficit	(147,093)	(140,188)
Total stockholders' equity (deficit)	(932)	5,532
Total liabilities and stockholders' equity (deficit)	$ 937	$ 7,856

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

AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Fiscal Year Ended September 30,		
	2005	**2004**	**2003**
Revenue			
Grant income	$ 252	$ 305	$
Costs and expenses:			
Research and development	4,515	8,295	2,780
General and administrative	2,674	3,987	2,025
Total costs and expenses	7,189	12,282	4,805
Loss from operations	(6,937)	(11,977)	(4,805)
Equity in loss of Incara Development			(76)
Interest expense, net	(31)	(5,213)	(192)
Other income	63	23	223
Loss from continuing operations	(6,905)	(17,167)	(4,850)
Discontinued operations			(38)
Gain on sale of discontinued operations			1,912
Net loss	(6,905)	(17,167)	(2,976)
Preferred stock dividend and accretion		(135)	(949)
Net loss attributable to common stockholders	$ (6,905)	$ (17,302)	$ (3,925)
Net loss per common share (basic and diluted):			
Loss from continuing operations available to common stockholders	$ (0.49)	$ (2.06)	$ (4.25)
Discontinued operations	$	$	$ (0.03)
Gain on sale of discontinued operations	$	$	$ 1.40
Net loss attributable to common stockholders	$ (0.49)	$ (2.06)	$ (2.88)

Weighted average common shares outstanding:			
Basic and diluted	13,976	8,388	1,365

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

AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Dollars in thousands)

	Series B Preferred Stock		Common Stock					
	Number of Shares	Par Value	Number of Shares	Par Value	Additional Paid-in Capital	Restricted Stock	Accumulated Deficit	Total Stockholders Equity (Deficit)
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							(17,167)	(17,167)

the fiscal year ended September 30, 2004								
Balance at September 30, 2004	503,544	5	13,947,303	139	145,576		(140,188)	5,532
Common stock issued in exchange of Series B preferred stock	(28,457)		28,457					
Compensation expense on the accelerated vesting of employee stock options					293			293
Exercise of common stock options			62,499	1	62			63
Stock-based compensation					85			85
Net loss for the fiscal year ended September 30, 2005							(6,905)	(6,905)
Balance at September 30, 2005	475,087	$ 5	14,038,259	$ 140	$ 146,016	$	$ (147,093)	$ (932)

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

AEOLUS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Fiscal Year Ended September 30,		
	2005	**2004**	**2003**
Cash flows from operating activities:			
Net loss	$ (6,905)	$ (17,167)	$ (2,976)
Loss from discontinued operations			38
Gain on sale of discontinued operations			(1,912)
Loss from continuing operations	(6,905)	(17,167)	(4,850)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	9	10	160
Loss from discontinued operations			(38)
Noncash compensation	293	2,569	1,218
Noncash interest and financing costs	81	5,153	186
Noncash consulting and license fee	85	128	15
Equity in loss of Incara Development			112
Amortization of debt issuance costs		15	
(Gain) Loss on sale or disposal of equipment	(19)		(21)
Change in assets and liabilities:			
Accounts receivable	124	(131)	(64)
Prepaids and other assets	25	140	(22)
Accounts payable and accrued expenses	(535)	642	(1,298)
Net cash used in operating activities	(6,842)	(8,641)	(4,602)
Cash flows from investing activities:			
Proceeds from sale of discontinued operations			3,422
Proceeds from sale of equipment	25		25
Net cash provided by investing activities	25		3,447
Cash flows from financing activities:			
Proceeds from notes payable, net of issuance costs		6,000	2,020
Proceeds from issuance of common stock and warrants, net of issuance costs		9,436	2
Proceeds from exercise of stock options	62		
Principal payments on notes payable			(441)

Principal payments on capital lease obligations			(49)
Net cash provided by financing activities	62	15,436	1,532
Net (decrease) increase in cash and cash equivalents	(6,755)	6,795	377
Cash and cash equivalents at beginning of year	7,381	586	209
Cash and cash equivalents at end of year	$ 626	$ 7,381	$ 586
Supplemental disclosure of cash flow information:			
Cash payments of interest	$	$ 1	$ 10
Supplemental disclosure of non-cash investing and financing activities:			
Common stock issued in exchange for Series B preferred stock	$ 28	$	$
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

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

AEOLUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2005

A. Nature of the Business

Aeolus Pharmaceuticals, Inc. is a San Diego based biopharmaceutical company that is developing a new class of catalytic antioxidant compounds for diseases and disorders of the central nervous system, respiratory system, autoimmune system and oncology. The Company recently announced positive safety results from a completed Phase I single dose study of its lead product, AEOL 10150, in patients diagnosed with amyotrophic lateral sclerosis (ALS). The data from this safety study is not limited to ALS, but rather can be utilized to support subsequent efficacy studies of AEOL 10150 in ALS, as well as other indications for which the Company has developed preclinical efficacy data. In addition, the Company recently announced the Aeolus Pipeline Initiative whereby the Company, in conjunction with a variety of academic collaborations, is focused on identifying between 1-2 compounds evaluated from six disease categories for potential entrance into human clinical evaluation in 2006.

The Company or Aeolus refers collectively to Aeolus Pharmaceuticals, Inc., a Delaware corporation (Aeolus) and its wholly owned subsidiary, Aeolus Sciences, Inc., a Delaware corporation (Aeolus Sciences). As of September 30, 2005, Aeolus also owned a 35.0% interest in CPEC LLC, a Delaware limited liability company (CPEC). The Company s primary operations are located in San Diego, California.

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 has incurred significant operating losses and cash outflows from operations of $6,905,000 and $6,842,000 for the fiscal year ended September 30, 2005, respectively. The Company expects to incur additional losses and negative cash flow from operations in fiscal 2006 and for several more years.

On November 21, 2005, the Company completed a private placement in which it issued to certain investors an aggregate of 1,250,000 shares of Series A Convertible Preferred Stock and warrants to purchase 2,500,000 shares of common stock at an initial exercise price of $1.00 per share for aggregate net proceeds of $2,400,000. With this financing, management believes the Company has adequate financial resources to conduct operations into the second quarter of fiscal year 2006. This raises substantial doubt about our ability to continue as a going concern, which will be dependent on our ability to generate sufficient cash flows to meet our obligations on a timely basis, to obtain additional financing and, ultimately, to achieve operating profit.

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

financing to provide the necessary funds for working capital and other planned activities.

If the Company is unable to obtain additional financing to fund operations beyond the second quarter of fiscal year 2006, it will need to eliminate some or all of its activities, merge with another company, sell some or all of its assets to another company, or cease operations entirely. There can be no assurance that the Company will be able to obtain additional financing on favorable terms or at all, or that the Company will be able to merge with another Company or sell any or all of its assets.

C. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Aeolus and its wholly owned 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.

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, 2005 and 2004 due to their short-term nature.

Accounts Receivable

The accounts receivable at September 30, 2005 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 as well as reimbursements due from its sub-lease tenants. All amounts recorded as accounts receivable were unbilled as of September 30, 2005.

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. As a result of the closure of the Company s offices in the Research Triangle Park, North Carolina in August 2005, the Company wrote off impaired office and laboratory facilities leasehold improvements no longer utilized with a net book value of $6,000 in fiscal 2005. There were no other impairments in

fiscal year 2005.

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 as work under the grant is performed and the related expenses are incurred.

Research and Development

Research and development costs are expensed in the period incurred. Payments related to the acquisition of in-process research and development are expensed due to the stage of development of the acquired compound or technology at the date of acquisition. During fiscal year 2003, 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 5,119,000, 4,764,000 and 9,674,000 as of September 30, 2005, 2004 and 2003, 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 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 and the 2004 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:

	2005	2004	2003
Net loss attributable to common stockholders (in thousands):			
As reported	$ (6,905)	$ (17,302)	$ (3,925)
Add: APB 25 compensation expense on the accelerated vesting of employee stock options	294	1,394	
Less: pro forma adjustment for stock-based compensation expense	(676)	(1,081)	(316)
Pro forma	$ (7,287)	$ (16,989)	$ (4,241)
Basic and diluted net loss per weighted share attributable to common stockholders:			
As reported	$ (0.49)	$ (2.06)	$ (2.88)
Effect of pro forma adjustment	(0.03)	0.03	(0.23)
Pro forma	$ (0.52)	$ (2.03)	$ (3.11)

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:

	2005	2004	2003
Dividend yield	0%	0%	0%
Expected volatility	195%	274%	233%
Risk-free interest rate	2.9% - 4.3%	1.2% - 4.7%	1.2% - 3.8%
Expected option life after shares are vested	10 years	3 years	3 years

Segment Reporting

The Company currently operates in only one segment.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (the FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R), which establishes standards for transactions in which an entity exchanges its equity instruments for goods or services. SFAS 123R requires companies to expense the value of employee stock options and similar awards. Share-based payments will be measured at fair

value on the grant date, based on the estimated number of awards that are expected to vest. SFAS 123R applies to all unvested share-based awards outstanding at the Company s adoption date. SFAS 123R eliminates the exception to account for such awards using the intrinsic method previously allowable under Accounting Principals Board Opinion No. 25 Accounting for Stock Issued to Employees (APB 25). SFAS 123R will be effective for the Company s fiscal year beginning October 1, 2005. The adoption of this Statement is expected to result in significantly higher reported operating expenses in our future financial statements. Had we adopted the provisions of Statement No. 123(R) as of October 1, 2004, our reported loss for the year ended September 30, 2005 would have been approximately $382,000 higher, or $7,287,000, as disclosed above in this Note C, Accounting for Stock-Based Compensation.

In April 2005, the FASB issued Interpretation No. 47, Accounting for Conditional Asset Retirement Obligations (Interpretation No. 47), which clarifies that an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability s fair value can be reasonably estimated. The fair value of a liability for the conditional asset retirement obligation should be recognized when incurred, which is generally upon acquisition, construction, or development and (or) through the normal operation of the asset. Uncertainty about the timing and (or) method of settlement of a conditional asset retirement obligation should be factored into the measurement of the liability when sufficient information exists. Interpretation No. 47 is

effective no later than the end of fiscal years beginning after December 15, 2005. The Company does not expect the adoption of Interpretation No. 47 to have a material impact on the Company s operations or financial position.

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 had $24,000 of net assets at September 30, 2004 and 2005. 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, 2005 and 2004 (in thousands):

	2005	2004
Office equipment	$ 35	$ 172
Laboratory equipment		265
Leasehold improvements		51
	35	488
Less: accumulated depreciation and amortization	(35)	(473)
	$	$ 15

Depreciation and amortization expense was $9,000, $10,000 and $160,000 for the fiscal years ended September 30, 2005, 2004 and 2003, respectively. During fiscal year 2005, the Company wrote off impaired office and laboratory facilities leasehold improvements no longer utilized with a net book value of $6,000 as a result of the closure of the Company s offices in the Research Triangle Park, North Carolina in August 2005.

F. Accrued Expenses

At September 30, 2005 and 2004, accrued expenses consisted of the following (in thousands):

	2005	2004
Lease reserve (Note G)	$ 267	$
Payroll-related liabilities	10	91
Other	13	11
	$ 290	$ 102

G. Commitments

The Company leases office and laboratory space under a non-cancelable operating lease that expires in June 2006. Rent expense under non-cancelable operating leases was $563,000, $282,000 and $338,000 for the fiscal years ended September 30, 2005, 2004 and 2003, respectively. At September 30, 2005, the Company s non-cancelable future

minimum payments under lease arrangements were $267,000 payable during fiscal 2006, for which the Company has accrued the entire amount as a reserve related to future rent costs for its office and laboratory facilities that are no longer in use. The Company is also obligated at the end of the lease to remove the leasehold improvements and to restore the laboratory space to its original condition.

The Company has subleased a portion of its laboratory space and is entitled to receive sublease rent payments of $19,000 for the fiscal year ending September 30, 2006.

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 $1,634,000 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 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, 2005, the outstanding balance on the note payable to Elan was $867,000.

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.

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. On January 14, 2005, Elan converted 28,457 shares of the Series B Stock in 28,457 shares of common stock. As of September 30, 2005, 475,087 shares of Series B Stock were outstanding. 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 exercise price of $2.50 per share.

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 of expense related to warrants issued in fiscal 2003. No warrant expense was incurred in fiscal 2004 and

fiscal 2005.

As of September 30, 2005, 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, 2005 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 $60.75 per share.

L. Stock Compensation Plans

Stock Option Plans

As an integral component of a management and employee retention program designed to motivate, retain and provide incentive to the Company s management, employees and key consultants, the Board of Directors approved the 2004 Stock Option Plan (the 2004 Plan) and reserved 2,000,000 shares of common stock for issuance under the 2004 Plan. As of September 30, 2005, 1,539,200 shares were available to be granted under the 2004 Plan. The exercise price of the ISOs granted under the 2004 Plan must not be less than the fair market value of the common stock as determined on the date of the grant. The options may have a term up to 10 years. Options typically vest immediately or up to one year following the date of the grant.

Under the Company s 1994 Stock Option Plan (the 1994 Plan), incentive stock options (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, 2005, there were no shares available to be granted under the 1994 Plan. The exercise price of the ISOs granted under the 1994 Plan must not be less than the fair market value of the common stock as determined on the date of the grant. The options may have a term up to 10 years. Options typically vest over three years following the date of the grant.

During fiscal 2005 and 2004, the Company recognized noncash charges totaling $293,000 and $2,569,000, respectively, 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 2004 Plan and 1994 Plan were as follows:

	Shares	Weighted Average Exercise Price
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
Granted	463,300	$ 0.96
Exercised	(62,499)	$ 1.00
Cancelled	(18,930)	$ 6.77
Outstanding at September 30, 2005	2,394,091	$ 4.05

The details of stock options outstanding at September 30, 2005 were as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at September 30, 2005	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Number Exercisable at September 30, 2005	Weighted Average Exercise Price
$0.40 - $0.78	32,164	$ 0.67	9.2 years	32,164	$ 0.67
$0.85 - $0.97	238,744	$ 0.89	9.1 years	128,746	$ 0.88
$1.00	187,501	$ 1.00	9.8 years	187,501	$ 1.00
$1.12 - $1.45	52,950	$ 1.15	9.2 years	52,950	$ 1.15
$1.50	1,256,015	$ 1.50	7.8 years	1,256,015	$ 1.50
$1.52 - $1.85	222,500	$ 1.84	9.0 years	222,500	$ 1.84
$2.10 - $3.60	77,315	$ 2.97	7.2 years	74,396	$ 2.99
$5.00 - $10.00	111,232	$ 5.31	7.9 years	111,232	$ 5.31
$11.50 - $20.00	105,357	$ 14.47	6.0 years	105,357	$ 14.47
$22.50 - $205.00	110,313	$ 41.51	4.7 years	110,313	$ 41.51

$0.40 - $205.00	2,394,091	$	4.05	8.0 years	2,281,174	$ 4.21

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 supplemental information regarding options granted to employees. Stock options granted to consultants during fiscal 2005 and 2004 were fully vested when issued, and $85,000 and $138,000, respectively, were expensed upon issuance. For the fiscal years ended September 30, 2005, 2004 and 2003, 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 2005, 2004 and 2003 were approximately $0.96, $2.62 and $1.45 per share, respectively.

Restricted Stock

In September 1999, the Company s Board of Directors adopted the 1999 Equity Incentive Plan (the Equity Plan). 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 none, $104,000 and $113,000 of expenses related to Restricted Stock awards during the fiscal years ended September 30, 2005, 2004 and 2003, respectively. There were no unvested shares of Restricted Stock at September 30, 2004 or 2005. In October 2005, the Board of Directors terminated the Equity Plan.

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, 2005, Aeolus had sold 50,882 shares of common stock pursuant to the ESPP and 9,118 shares were reserved for future issuances. In October 2005, the Board of Directors terminated the ESPP.

M. Income Taxes

As of September 30, 2005 and 2004, the Company had federal net operating loss (NOL) carryforwards of $94,309,000 and $87,013,000, respectively, and North Carolina state operating loss carryforwards of $43,520,000 and $36,396,000, 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 begin to expire in fiscal year 2006. Additionally, the Company had federal research and development carryforwards as of September 30, 2005 and 2004 of $2,967,000 and $2,651,000, respectively.

Significant components of the Company s deferred tax assets at September 30, 2005 and 2004 consisted of the following (in thousands):

	2005	2004
Net operating loss carryforwards	$ 35,068	$ 33,500
AMT credit carryforwards	37	37
Research and development credit carryforwards	2,967	2,651
Accrued payroll related liabilities	2,464	1,779
Charitable contribution carryforwards	1,109	1,042
Total deferred tax assets	41,645	39,009
Deferred tax liabilities	(109)	(102)
Valuation allowance for deferred assets	(41,536)	(38,907)

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):

	2005	2004	2003
Effective tax rate	0 %	0 %	0 %
United States Federal tax at statutory rate	$ (2,348)	$ (5,837)	$ (996)
State taxes (net of federal benefit)	(296)	(773)	(132)
Change in valuation reserves	2,629	4,923	1,301
Loss in foreign subsidiary			26
Other	15	1,687	(199)
Provision for income taxes	$	$	$

N. Agreements

Duke Licenses

Aeolus has obtained exclusive worldwide licenses (the Duke Licenses) from Duke University (Duke) to develop, make, have made, use and sell products using certain technology in the field of free radical and antioxidant research, developed by certain scientists at Duke. Future discoveries in the field of antioxidant research from these scientists laboratories at Duke are also covered by the Duke Licenses. The Duke Licenses require Aeolus to use its best efforts to pursue development of products using the licensed technology and compounds. These efforts are to include the manufacture or production of products for testing, development and sale. Aeolus is also obligated to use its best efforts to have the licensed technology cleared for marketing in the United States by the U.S. Food and Drug Administration and in other countries in which Aeolus intends to sell products using the licensed technology. Aeolus will pay royalties to Duke on net product sales during the terms of the Duke Licenses, and milestone payments upon certain regulatory approvals and annual sales levels. In addition, Aeolus is obligated under the Duke Licenses to pay all or a portion of patent prosecution, maintenance and defense costs. Unless earlier terminated, the Duke Licenses continue until the expiration of the last to expire issued patent on the licensed technology.

National Jewish Medical and Research Center Agreements

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

Elan Corporation, plc

In May 2002, the Company entered into a collaboration transaction with affiliates of Elan Corporation, plc for the development of our catalytic antioxidant compounds as a treatment for tissue damage from cancer radiation and chemotherapy. Although Elan and the Company terminated this collaboration in January 2003, the Company will pay Elan a royalty on net sales of our catalytic antioxidant products sold, if any, for the prevention and treatment of radiation-induced and chemotherapy-induced tissue damage.

O. Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in thousands, except per share amounts)				
Fiscal 2005					
Total revenue	$ 109	$ 6	$ 121	$ 16	$ 252
Net loss attributable to common stockholders	$ (1,957)	$ (1,659)	$ (1,636)	$ (1,653)	$ (6,905)
Net loss per common share (basic and diluted):					
Net loss attributable to common stockholders	$ (0.14)	$ (0.12)	$ (0.12)	$ (0.12)	$ (0.49)
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)

P. Subsequent Events

On November 21, 2005, we completed a private placement where we issued to certain investors an aggregate of 1,250,000 shares of Series A Convertible Preferred Stock and warrants to purchase 2,500,000 shares of common stock at an exercise price of $1.00 per share resulting in net proceeds of $2,400,000. Under the terms of the agreement, a dividend payment in the form of interest at the rate of 6% annually, based on funds used by us, may be paid in either cash or in our common stock at our option. Each convertible preferred share is convertible into two shares of our common stock.

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

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 principles, and did not contain an adverse opinion or disclaimer of opinion. 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, through August 23, 2004, there were no reportable events (as defined in Regulation S-K Item 304(a)(1)(v)). PwC issued a letter addressed to the SEC stating that it agreed with the above statements concerning PwC.

On October 13, 2004, we announced the appointment of Grant Thornton LLP (Grant Thornton) 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).

On September 9, 2005, Grant Thornton resigned as our independent registered public accounting firm. The resignation was the sole decision of Grant Thornton and was not sought, recommended or approved by our audit committee. Grant Thornton was engaged to audit our financial statements for the fiscal year ended September 30, 2004 and performed reviews of our financial statements for the quarters ended December 31, 2004, March 31, 2005

and June 30, 2005. Grant Thornton s report on our financial statements for the fiscal year ended September 30, 2004 did not contain an adverse opinion or disclaimer of opinion, nor was the report qualified or modified as to uncertainty, audit scope, or accounting principles. For the fiscal year ended September 30, 2004 and during the most recent three fiscal quarters ended June 30, 2005, and the subsequent interim period through September 9, 2005, there were no disagreements between us and Grant Thornton on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Grant Thornton s satisfaction, would have caused Grant Thornton to make reference to the subject matter of the disagreement in connection with its reports. None of the reportable events described under Item 304(a)(1)(v) of Regulation S-K have occurred for the fiscal year ended September 30, 2004, within the three most recent fiscal quarters ended June 30, 2005, or within the interim period through September 9, 2005. Grant Thornton issued a letter addressed to the SEC stating that it agreed with the above statements concerning Grant Thornton.

On September 9, 2005, we announced the appointment of Haskell & White LLP (Haskell & White) as our independent registered public accounting firm for our fiscal year ended September 30, 2005. Our Audit Committee approved this appointment. The engagement began on September 9, 2005. During the two most recent fiscal years ended September 30, 2004, and the subsequent interim period through September 9, 2005, we did not consult with Haskell & White regarding any of the matters or events set forth in Item 304(a)(2)(i) and (ii) of Regulation S-K.

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 Accounting Officer (the Company s Principal Accounting Officer), of the effectiveness of the Company s disclosure controls and procedures required by Exchange Act Rule 13a-15. Based upon that evaluation, the Company s Chief Executive Officer and Chief Accounting Officer have concluded that the Company s disclosure controls and procedures were effective as of September 30, 2005 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

(b)

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

Item 9B. Other Information.

None.

PART III

Certain information required by Part III is omitted from this report because the Registrant expects to file a definitive proxy statement for its 2006 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 this Item 10 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 this Item 10 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.

The information required herein is incorporated by reference to the information under the heading Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement.

Code of Ethics.

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. We have posted the text of Code of Ethics on our Internet website at www.aeoluspharma.com. A copy of the Code of Ethics can also be obtained free of charge by writing to Michael P. McManus, Corporate Secretary, Aeolus Pharmaceuticals, Inc., 23811 Inverness Place, Laguna Niguel, California 92677

Item 11. Executive Compensation.

The information required by this Item 11 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 and Related Stockholder Matters.

The information required by this Item 12 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 this Item 13 is incorporated by reference to the information under the heading Certain Related Transactions in the Proxy Statement.

Item 14. Principal Accounting Fees and Services.

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

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)

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

(1)

Financial Statement Schedules.

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

(2)

Exhibits.

		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	8-K	10/25/05	3.1	
3.3	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of the Company dated November 18, 2005	8-K	11/23/05	3.1	
4.1	Form of Common Stock Certificate	10-Q	06/30/04	4.1	
4.2	Warrant to Purchase Shares of Series B Preferred Stock issued to Elan International Services, Ltd.	10-Q	12/31/00	4.3	
4.3	Form of Warrant issued to investors in August 2001	S-1	08/02/01	4.4	
4.4	Warrant to Purchase Common Stock of Incara Pharmaceuticals Corporation	10-Q	06/30/03	4.5	

	dated July 11, 2003 issued to W. Ruffin Woody, Jr.			
4.5	Form of Series B Preferred Stock Certificate	S-4	09/19/03	4.8
4.6	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
4.7	Warrant to Purchase Common Stock of Incara Pharmaceuticals Corporation dated April 19, 2004 issued to SCO Securities LLC	8-K	04/21/04	4.10
4.8	Registration Rights Agreement dated November 21, 2005 by and among the Company and each of the Purchasers whose names appear on the Schedule attached thereto	8-K	11/23/05	4.1
4.9	Form of Warrant to Purchase Common Stock dated November 21, 2005	8-K	11/23/05	10.2
10.1*	License Agreement between Duke University and Aeolus Pharmaceuticals, Inc., dated July 21, 1995	S-1	12/08/95	10.4
10.2	Exchange Agreement dated July 15, 1999, between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc.	8-K	07/23/99	10.40
10.3	Registration Rights Agreement dated July 15, 1999, between Interneuron Pharmaceuticals, Inc. and Intercardia, Inc.	8-K	07/23/99	10.41
10.4	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

Exhibit Number	Description of Document	Incorporated by Reference To Registrant s Form	Dated	Exhibit Number	Filed Herewith
10.5	Assignment, Assumption and License Agreement dated July 15, 1999, between CPEC LLC and Intercardia, Inc.	8-K	07/23/99	10.43	
10.6*	License Agreement dated January 19, 2001 between Incara Pharmaceuticals Corporation and Incara Development, Ltd.	10-Q	12/31/00	10.59	
10.7*	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	
10.8	Convertible Promissory Note dated December 21, 2000 issued by Incara Pharmaceuticals Corporation to Elan Pharma International Ltd.	10-Q	12/31/00	10.61	
10.9	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	
10.10	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	
10.11	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	
10.12	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	
10.13	Commencement Agreement and Lease Amendment Number One, dated November 1, 2001, to Office Lease between Highwoods Realty Limited Partnership and	10-K	09/30/01	10.74	

	Incara Pharmaceuticals Corporation			
10.14	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
10.15	Employment Agreement between Richard W. Reichow and Incara Pharmaceuticals Corporation, dated April 2, 2002	10-Q	03/31/02	10.77
10.16*	License Agreement dated June 25, 1998 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	03/31/02	10.82
10.17*	License Agreement dated May 7, 2002 between Duke University and Aeolus Pharmaceuticals, Inc.	10-Q	03/31/02	10.83
10.18*	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
10.19*	Development and Option Agreement dated May 15, 2002, among Elan Pharma International Limited, Incara Pharmaceuticals Corporation and Aeolus Pharmaceuticals, Inc.	8-K	07/03/02	10.85
10.20	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

Exhibit Number	Description of Document	Incorporated by Reference To Registrant s Form	Dated	Exhibit Number	Filed Herewith
10.21	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	
10.22	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	
10.23	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	
10.24*	Asset Purchase Agreement dated October 21, 2002 between Incara Cell Technologies, Inc. and Vesta Therapeutics, Inc.	8-K	10/24/02	10.91	
10.25	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	
10.26	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	
10.27	Convertible Secured Promissory Note dated July 28, 2003 issued by Incara, Inc. to Goodnow Capital, Inc.	10-Q	06/30/03	10.97	
10.28	Guaranty dated July 28, 2003 issued by Incara Pharmaceuticals Incorporation to Goodnow Capital, Inc.	10-Q	06/30/03	10.98	
10.29	Security Agreement dated July 28, 2003 issued by Incara Pharmaceuticals Incorporation to Goodnow Capital, Inc.	10-Q	06/30/03	10.90	
10.30	Debenture and Warrant Purchase Agreement	S-4	09/19/03	10.100	

	dated September 16, 2003 among Incara Pharmaceuticals Corporation, Incara, Inc. and Goodnow Capital, L.L.C.			
10.31	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
10.32	Purchase Agreement dated April 19, 2004 among Incara Pharmaceuticals Corporation and certain investors	8-K	04/21/04	10.102
10.33	Registration Rights Agreement dated April 19, 2004 among Incara Pharmaceuticals Corporation, certain investors and SCO Securities LLC	8-K	04/21/04	10.103
10.34	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
10.35	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
10.36	Aeolus Pharmaceuticals, Inc. 1994 Stock Option Plan, as amended	10-Q	06/30/04	10.109
10.37	Aeolus Pharmaceuticals, Inc. 2004 Stock Option Plan, as amended on December 13, 2004	8-K	12/15/04	10.110
10.38	Letter Agreement dated January 5, 2005 by and between Aeolus Pharmaceuticals, Inc. and Richard P. Burgoon, Jr.	8-K	1/5/05	10.115

Exhibit Number	Description of Document	Incorporated by Reference To Registrant s Form	Dated	Exhibit Number	Filed Herewith
10.39	Consulting Agreement dated February 21, 2005 by and between Aeolus Pharmaceuticals, Inc. and Elaine Alexander, M.D., Ph.D.	8-K	2/18/05	10.117	
10.40	Consulting Agreement dated June 20, 2005 by and between Aeolus Pharmaceuticals, Inc. and John L. McManus	8-K	6/16/05	10.119	
10.41	Consulting Agreement dated June 20, 2005 by and between Aeolus Pharmaceuticals, Inc. & McManus & Company, Inc.	8-K	6/16/05	10.120	
10.42	Separation Agreement and General Release dated June 20, 2005 by and between Aeolus Pharmaceuticals, Inc. and Richard Reichow	8-K	6/16/05	10.121	
10.43	Form of Indemnification Agreement	8-K	2/18/05	10.118	
10.44	Terms of Outside Director Compensation	10-K	12/17/04	10.114	
10.45	Form of Incentive Stock Option Agreement	10-Q	2/8/05	10.115	
10.46	Form of Nonqualified Stock Option Agreement	10-Q	2/8/05	10.116	
10.47	Consulting Agreement dated December 14, 2004 by and between Aeolus Pharmaceuticals, Inc. and Dr. Shayne C. Gad	8-K	12/14/04	10.112	
10.48	Purchase Agreement dated November 21, 2005 by and among the Company and the investors whose names appear on the signature pages thereof	8-K	11/23/05	10.1	
14.1	Aeolus Pharmaceuticals, Inc. Code of Ethics for Chief Executive Officer and Senior Financial Officers, as amended on December 13, 2004	8-K	12/14/04	10.113	
16.1	Letter of Grant Thornton LLP Regarding Change in Independent Public Accountants	8-K	9/15/05	16.1	
21.1	List of Subsidiaries				X
23.1	Consent of Haskell & White, LLP, Independent Registered Public Accounting Firm				X

23.2	Consent of Grant Thornton, LLP, Independent Registered Public Accounting Firm	X
23.3	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm	X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a)	X
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a)	X
32.1	Certification by the Chief Executive Officer and Chief Accounting Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X

*

Portions of this exhibit have been omitted based on a request for confidential treatment submitted to the U.S. Securities and Exchange Commission. The omitted portions have been filed separately with the Commission.

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/ Richard P. Burgoon, Jr.
Richard P. Burgoon, Jr.
Chief Executive Officer

Date: December 27, 2005

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

Signatures	Title	Date
/s/ Richard P. Burgoon, Jr. Richard P. Burgoon, Jr.	Chief Executive Officer (Principal Executive Officer)	December 27, 2005
/s/ Michael P. McManus Michael P. McManus	Chief Accounting Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	December 27, 2005
/s/ David C. Cavalier David C. Cavalier	Chairman of the Board of Directors	December 27, 2005
/s/ John M. Farah, Jr. John M. Farah, Jr., Ph.D.	Director	December 27, 2005
/s/ Joseph J. Krivulka Joseph J. Krivulka	Director	December 27, 2005
/s/ Amit Kumar Amit Kumar, Ph.D.	Director	December 27, 2005
/s/ Michael E. Lewis Michael E. Lewis, Ph.D.	Director	December 27, 2005

/s/ Chris A. Rallis Chris A. Rallis	Director	December 27, 2005
/s/ Peter D. Suzdak Peter D. Suzdak, Ph.D.	Director	December 27, 2005