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INCARA PHARMACEUTICALS CORP
Form 10-K405
December 21, 2001

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K
(MARK ONE)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended September 30, 2001

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 0-27410

INCARA PHARMACEUTICALS CORPORATION
(Exact name of registrant as specified in its charter)

DELAWARE	56-1924222
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

P.O. Box 14287
79 T.W. Alexander Drive
4401 Research Commons, Suite 200
Research Triangle Park, North Carolina
27709

(Address of principal executive offices)

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

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$.001 par value per share

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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.

The aggregate market value of the voting stock held by non-affiliates of the registrant based upon the closing price of the Common Stock on December 14, 2001, on the Nasdaq National Market System was approximately \$19,377,000 as of such date. Shares of Common Stock held by each executive officer and director

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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 14, 2001, the Registrant had outstanding 12,717,093 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the 2002 Annual Meeting of Stockholders are incorporated herein by reference into Part III.

INCARA PHARMACEUTICALS CORPORATION ANNUAL REPORT ON FORM 10-K

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that relate to future events or our future financial performance. You can identify forward-looking statements by terminology such as "may," "might," "will," "could," "should," "would," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential" or "continue" or the negative of these terms or other comparable terminology. Our actual results might differ materially from any forward-looking statement due to various risks,

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uncertainties and contingencies, including:

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

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Item 1. Business.

Overview

Incara Pharmaceuticals Corporation is developing therapies focused on tissue protection, repair and regeneration. In particular, we are focused on developing adult liver stem and progenitor cell therapy, referred to as liver progenitor cell therapy, for the treatment of liver failure. We are also conducting research on and development of a series of catalytic antioxidant molecules that we believe will provide strategic opportunities for collaboration with larger pharmaceutical companies in areas such as stroke and the prevention of side effects induced by radiation in cancer therapy. We are actively pursuing such collaborations. We are also developing catalytic antioxidants for applications in our liver cell therapy program and other uses of cell therapy. In collaboration with Elan Corporation, plc, we are conducting a Phase 2/3 clinical trial of an ultra-low molecular weight heparin for the treatment of ulcerative colitis. A summary of our current research and development programs is set forth below.

Liver progenitor cell transplant. Liver progenitor cells are young cells found in the human liver that can grow and divide many times. Our process produces a suspension of liver cells, designed to be enriched with human liver progenitor cells. These cells are obtained from the livers of organ donors which are not suitable for whole organ transplant. Based on animal models, we believe that following transplantation into patients our cells will be able to grow and mature to create new functioning liver tissue. Currently, chronic liver disease leads to approximately 330,000 hospitalizations and 30,000 deaths each year in the United States. There are, however, only approximately 4,900 donor livers available annually in the United States and over 18,500 people on the liver transplant waiting list. The number of patients with such severe cirrhosis that they could become candidates for a transplant exceeds 100,000. We are currently preparing an Investigational New Drug, or IND, application with the Food and Drug Administration, or FDA, in order to conduct clinical trials. Assuming allowance of our IND, we intend to initiate clinical trials that are designed to determine the safety and efficacy of our liver cell therapy for treatment of end-stage liver disease in adults and certain inherited liver diseases in infants and young children.

Small molecule catalytic antioxidants. We are investigating small molecule catalytic antioxidants as a treatment for stroke, as well as other neurological conditions, and prevention of radiation-induced side effects from cancer

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therapy. An estimated 600,000 individuals suffer strokes in the United States each year, with estimated direct costs of treating stroke exceeding \$28 billion annually. Our lead catalytic antioxidant molecule significantly reduced damaged brain tissue when administered as late as 7.5 hours after obstruction of blood flow in animal models of stroke.

Free radicals produced by radiation therapy 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. Incara's catalytic antioxidants have reduced the severity of damage to normal tissue induced by radiation in animal models and the compounds have been shown not to protect tumor cells from radiation in an animal model.

We believe compounds from our catalytic antioxidant program will also have application in the developing cell transplant industry. Antioxidants destroy free radicals, which damage cells within the human body. In cell culture experiments, our catalytic antioxidant compounds have been shown to improve the ability of liver cells to survive freezing and thawing. They have also been shown to protect neurons in culture from oxygen deprivation and pancreatic islet cells in culture from various toxins. In animals, one

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of our compounds has been shown to protect pancreatic islet cells against autoimmune attack in a model of juvenile onset diabetes. In addition, we are exploring the possibility that these compounds may enhance the viability of transplanted pancreatic islet cells and we intend to explore their effect on transplanted liver progenitor cells.

OP2000, an ultra-low molecular weight heparin. We are conducting clinical trials on behalf of Incara Development, Ltd. on the use of OP2000 as a treatment for inflammatory bowel disease. Heparin is a naturally occurring mixture of substances produced by the human body with anti-clotting and anti-inflammatory properties. OP2000 is derived from heparin by breaking it down into smaller molecules. Lower weight, or smaller molecules of heparin may prove to have advantages over heparin itself, including better safety, efficacy and convenience. OP2000 is being tested in a multicenter phase 2/3 clinical trial as a treatment for ulcerative colitis, a form of inflammatory bowel disease. Approximately 1,000,000 patients suffer from ulcerative colitis in the United States and Europe combined.

Our company was incorporated in Delaware as Intercardia, Inc. in 1994. In July 1999 our company changed its name to Incara Pharmaceuticals Corporation.

Human Liver Progenitor Cell Transplant

Liver progenitor cells are a population of immature cells in the liver with significant regenerative potential that can become mature liver cells and provide liver function. We obtain these cells from the livers of organ donors. Progenitor cells are the early cells in the maturation of the liver and include the liver stem cells and their early descendants. We are developing a treatment that contains human liver progenitor cells as a potential therapy for chronic liver diseases.

Incara established its liver stem and progenitor cell program with the acquisition of a majority ownership interest in Incara Cell Technologies, Inc., formerly Renaissance Cell Technologies, Inc., in September 1997. Renaissance was founded in 1995 to commercialize applications from research on human liver stem and progenitor cells from the laboratory of Dr. Lola Reid, previously at the Albert Einstein College of Medicine and now a Professor in the Department of

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Cell and Molecular Physiology, Program in Molecular Biology and Biotechnology, at the University of North Carolina at Chapel Hill School of Medicine. In March 2000, Incara Pharmaceuticals acquired the remaining minority interest of Incara Cell Technologies, which is now a wholly-owned subsidiary of Incara.

Liver Disease

The liver is one of the largest and most complex organs in the body, serving many critical metabolic functions. More than most other internal organs, the liver has the ability to regenerate itself by repairing or replacing injured tissue. Despite this protection, once a critical mass of liver cells has died through disease or damage, the liver can fail, leading to illness and death. Liver failure is a serious health problem. According to the National Center for Health Statistics, each year there are approximately 330,000 hospitalizations and 30,000 deaths in the United States due to chronic liver diseases, including viral hepatitis.

Currently, the only cure for many of these liver diseases is a liver transplant. However, only about 4,900 transplantable donor livers become available each year in the United States and the total cost of transplantation and first year follow-up is estimated to average over \$260,000. Over 18,500 patients are on the liver transplant waiting list, an increase of more than 100% over the last four years and up from 1,700 ten years ago. Furthermore, there are a total of approximately 100,000 adults with severe cirrhosis in the United States who could become candidates for a transplant. Not all of these people will get transplants, or even get onto the transplant waiting list. The incidence of chronic liver failure is expected to increase in the next ten years as a result of the "silent epidemic" of hepatitis C. Up to 4,000,000 people in the United States have been infected with the hepatitis C virus. Researchers estimate that 15% of these persons will develop cirrhosis, a disease that typically develops over a period of 10 to 20 years.

As a result of the shortage of donor organs, potential liver transplant patients must wait, often for years, for a donor liver to become available. The vast majority of patients with liver diseases therefore cannot rely on organ transplantation as a solution. We believe that transplanting cells that have the capacity to reproduce and function in an impaired liver could reduce the need for whole organ transplants and provide treatment for thousands of patients.

Liver Cell Transplantation

Positive results from liver cell transplants in rodents, both with mature liver cells and progenitor liver cells, have prompted physicians outside of Incara to transplant unfractionated human hepatocytes, which are liver cells not separated by their stage of maturity or other parameters, in a number of human patients. Unfractionated human hepatocytes, obtained from livers rejected for transplant use, have been introduced into approximately 40 patients, with improvement observed in some patients. In this procedure, a physician injects a suspension of donor liver cells, or hepatocytes, into blood vessels leading to the patient's liver or spleen. In patients who improved, the transplanted cells took up residence in the recipient's body and provided liver functions, including

detoxification and protein synthesis. These patients included individuals with cirrhosis and acute liver failure and patients with inherited metabolic disorders. Some patients whose liver failure resulted in coma, awoke after receiving liver cell transplant, coincident with other measures reflecting improved liver function such as decreased ammonia levels, improved cerebral

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blood flow and reduction of intracranial pressure. In one patient, a 10-year-old girl, the transplanted liver cells survived and partially corrected a metabolic disorder for over two years. These procedures were performed with a cell population different from that which we plan to use in our liver progenitor cell therapy and the studies were not blinded and were usually uncontrolled. These treatments included only a relatively small number of patients, primarily because of the lack of available organs from which viable liver cells can be obtained. The beneficial results observed in these treatments might not be seen in larger populations.

Human Liver Progenitor Cells

Incara proposes to use a more selective population of liver cells for transplantation. We intend to transplant a population of cells enriched for liver progenitor cells. Our cells are obtained from donor organs not suitable for whole organ transplant. Human liver progenitor cells potentially can divide many times, greatly expanding the utility of a single donor liver such that one liver might supply the needs of many patients. Moreover, progenitor cells might provide a much longer functional life, potentially surviving the lifetime of the recipient. These cells also can survive freezing and thawing better than mature cells, potentially permitting progenitors to be stored until the need for them arises. The progenitor cells might have the capability to differentiate into the entire lineage of liver cells, providing the functions of early cells that may be missing and unable to be regenerated by injection of unfractionated hepatocytes. The progenitor cells also might require a smaller injection volume than that of unfractionated cells. The human liver progenitors might also avoid some of the medical and scientific challenges associated with strategies involving pig livers, pig liver cells and human cells derived from tumors such as immune reactions and reduced function. However, because we have not tested these cells in human patients, these proposed advantages of liver progenitor cells might not be observed in human patients.

[GRAPHIC APPEARS HERE]

Selection of liver stem and progenitor cells may allow one donor liver to supply the needs of many recipients.

Use of Alternative Sources of Donor Livers

Currently, most whole organ liver transplantation procedures require a donor who has undergone brain death, but whose heart is still beating and supplying blood, oxygen and nutrients to the liver until the time it is removed. This occurs only in approximately one to two percent of hospital deaths, severely limiting the potential donor pool.

We believe a major advantage of liver progenitor cells is their ability to survive periods with limited oxygen. Incara and Dr. Reid have demonstrated that viable liver progenitor cells can be isolated after death from the livers of non-beating-heart donors, whose livers cannot be used for whole organ transplant. The window of time that viable liver progenitors can be isolated after the heart has stopped beating is now under investigation, along with the useful age range of donors. Because liver progenitor cells can be purified from livers inappropriate for transplant, our program will not compete for organs with existing liver transplant programs. We have established an arrangement with several traditional organ donor programs for procurement of livers and are actively pursuing relationships with others. Preliminary, preclinical experiments suggest that one donor liver might provide enough liver stem and progenitor cells for many recipients.

While we currently believe we have access to enough donor liver organs to conduct clinical trials, there is no assurance that this will continue. If we are not able to obtain a consistent supply of donor liver organs, or if one

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donor liver does not provide enough liver progenitor cells for multiple recipients, commercialization of our program will be adversely affected.

Development Strategy

We have demonstrated scale-up of the liver cell isolation and selection process. This step includes establishing processing procedures needed for a 1,500-gram to 3,000-gram whole human liver instead of the 100-gram portions of liver used in the basic research stage of the program. The scaled-up procedures are being adapted for a sterile good manufacturing practices, or cGMP, environment. We are working with a contract cell processor to develop the liver progenitor cell processing procedure in a facility

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compliant with cGMP. We might need to adjust our liver cell selection process to further enrich for the liver progenitor cells.

Clinical Trials

Incara is exploring two patient populations for the initial clinical trials of progenitor cell transplantation. One group consists of infants and young children who have life-threatening inherited genetic diseases but are unable to receive a liver transplant. This patient population represents a group with limited treatment alternatives where improvement in patient condition and production of the missing gene products would demonstrate the function of the transplanted cells. The other series of clinical trials being planned targets the approximately 100,000 adults in the United States with such severe cirrhosis and chronic liver failure that they could become candidates for a whole liver transplant. The goal of therapy would be to avoid or delay the need for whole liver transplant and to reduce hospitalization and treatments required for the complications of liver failure. Initially, these patients would receive the same immunosuppression as liver transplant patients to prevent rejection of the transplanted cells.

We are currently preparing an IND application to be filed with the FDA in order to conduct clinical trials. Clinical investigators from several leading research hospitals have expressed interest in participating in our clinical trials.

Gene Therapy

Progenitor cells, because of their extensive expansion potential, may be suitable to produce continued gene expression for gene therapy. We believe that logical target disorders for liver progenitor cell gene therapy are diseases resulting from the inability of the patient's liver cells to properly make an important protein, such as occurs in genetic disease including hemophilia and a hereditary form of severe high cholesterol. Many scientists believe gene therapy clinical trial results have often been disappointing because of the inability of the treatment to provide the patient with sustained expression of the inserted gene. Incara's gene therapy strategy will be to obtain progenitor liver cells from a patient and insert into the cells a correct copy of the gene deficient in that patient and transplant these cells back into the patient. We have not demonstrated the viability of this approach in the laboratory and in order to explore this approach, we must seek academic or corporate partners with expertise in this area, or develop additional expertise internally. We might not be able to develop this technology, either internally or through collaboration.

Genomics

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The liver progenitor cell technology developed by Incara has a potential application as a tool for identifying new drugs. Determining gene expression patterns at various stages of the liver lineage could provide genomic information for drug discovery. For example, this information could be used to identify new targets for drug discovery programs or to identify proteins performing biological functions that may have applications in therapy. To successfully commercialize this technology, we must seek academic or corporate partners with expertise in the area of genomics, or develop additional expertise internally. We might not be able to develop this technology, either internally or through collaboration.

Cells for Research Program

Currently, many pharmaceutical companies have difficulty obtaining a consistent supply of human liver cells for drug metabolism testing. We collect large numbers of non-progenitor liver cells as a byproduct of our stem and progenitor cell processing procedure. This allows us to supply human liver cells for a processing fee to pharmaceutical companies for use in drug metabolism testing of the drugs they are developing. In March 2001, we began shipping limited quantities of liver cells to several major pharmaceutical companies and expect to continue to do so for the foreseeable future.

The liver progenitor cells and their daughter cells could also be used to assess changes in gene expression patterns caused by drugs being developed by the pharmaceutical industry. The changes in gene expression pattern resulting from potential drugs could be compared with those caused by drugs known to damage the liver. This would allow a pharmaceutical company to screen compounds for their effect on the liver earlier in the development process, saving time and money. The full lineage of liver cells, from progenitors to mature cells, could also be used to test drugs for toxicity to the liver and to study how the drug is metabolized. We have not demonstrated, and might not demonstrate, the successful use of our liver progenitor cells for research applications for the pharmaceutical industry. Even if our research cells program is successfully commercialized, it might not provide us with significant revenue.

Liver Assist Device

Incara's liver progenitor cell technology has potential application in the development of a liver assist device, or LAD. LADs are external devices designed to provide liver function to a patient for a few days, providing time for a patient's own liver to recover from failure or function until a transplant liver is available. LADs developed by others have used pig hepatocytes or human liver cells derived from tumors in a wide variety of bioreactor types. These devices have shown promise, but all use cells with limitations. The

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pig hepatocytes, while easily obtained, have limitations such as potential immune reactions, limited lifetime and non-human viruses. The liver cells derived from tumor cells are easy to grow, but retain only a subset of the functions of normal liver cells and involve safety concerns. To date, functioning human liver cells from donor organs have not been a viable alternative due to the scarcity of donor livers.

We believe that if we can grow and differentiate progenitor cells outside the body to produce the quantity of cells required for a LAD, a LAD using our human liver progenitor cells could overcome some of these problems. Proteins secreted by these cells will be of human origin, so immune reactions should be reduced. The progenitor cells can divide extensively in culture, so

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that cells from one donor liver might be able to supply cells for many LADs. Most importantly, these cells should display the wide range of liver functions necessary for clinical use. We are currently developing a prototype cartridge for expansion of our liver progenitor cells to produce the volume of human liver cells needed for a LAD. Our design is still under development and has not been tested in patients. It might not prove to be superior to LADs using pig or other cell types, or even be feasible for human therapy at all. Developing the ability to grow and differentiate progenitor cells will require extensive research if it is successful at all.

Commercialization

There are approximately 120 liver transplant programs in hospitals in the United States. We believe that marketing the human liver progenitor cell therapy product to these hospitals could be accomplished by an internal sales force of approximately 15 to 20 trained specialists. If we establish the safety and efficacy of the program in clinical trials and receive required regulatory approval, we intend to maintain rights to market the liver progenitor cell therapy in the United States and develop a focused marketing effort. Outside of the United States, we plan to enter into an arrangement with another pharmaceutical or biotechnology company for commercialization of the liver progenitor cell therapy program. We also intend to seek collaborations with other companies for the development of our liver progenitor cells in gene therapy, drug research and genomic applications and for use in a liver assist device. We might not successfully commercialize any of these applications.

Catalytic Antioxidant Program

Antioxidants destroy free radicals, a class of reactive, oxygen-derived molecules that directly damage healthy cells and are believed to play a significant role in many conditions involving tissue injury and inflammation. We are developing a class of small molecule, catalytic antioxidants, that consume free radicals but are not themselves consumed in the reaction. Incara Pharmaceuticals established its catalytic antioxidant program with the acquisition of a majority interest in Aeolus Pharmaceuticals, Inc. in July 1995. In March 2000, Incara Pharmaceuticals acquired the remaining minority interest in Aeolus, which is now a wholly owned subsidiary of Incara Pharmaceuticals. The scientific founders of Aeolus, James D. Crapo, M.D., and Irwin Fridovich, Ph.D., in collaboration with colleagues at Duke University, the National Jewish Medical and Research Center and Incara, are working to develop small molecules as therapeutics that act in the same manner as naturally occurring antioxidant enzymes. Antioxidant enzymes such as superoxide dismutase normally help to protect the body from harmful free radicals.

Antioxidants 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 creates different forms of oxygen which can react harmfully with living organisms. In the body, a small amount of oxygen is converted to various free radicals, which can damage DNA, proteins and lipids. If too many free radicals are produced for the body's normal antioxidants to metabolize, the cumulative result is reduced cellular function and, ultimately, disease. Free radicals are thought to play a role in a large variety of conditions that result in damage, including stroke and damage to normal tissue from cancer radiation therapy. Free radicals are also believed to play a role in rejection of organ and cell transplant.

Incara has synthesized a group of small molecules that in laboratory experiments have multiple potent catalytic antioxidant activities, destroy free radicals and protect cells from damage initiated by free radicals. Because they

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are not consumed when they react with free radicals, each catalytic antioxidant molecule can destroy many free radicals. In laboratory experiments some of these compounds have shown antioxidant activities greater than the natural antioxidant enzymes on a weight basis. The lead compounds in this series, AEOL 10113 and AEOL 10150, have shown activity in preclinical models of organ or cell transplant, stroke and other neurological diseases, and protection of normal tissue from radiation damage in cancer therapy. We also have a number of related compounds which have not undergone as much laboratory testing.

Our catalytic antioxidant compounds have been tested in multiple animal models at multiple institutions but have not entered clinical trials in humans and are in an early stage of development. Animal models might not predict how a compound will act in human beings. Compounds from our catalytic antioxidant program might not demonstrate the efficacy and safety needed to gain product approval by the FDA or foreign authorities, and even if approval is given, such products might not become commercially

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successful.

Stroke

Stroke is an injury to the brain caused by the blockage of blood flow. The reestablishment of blood flow after a stroke can cause further damage, which is called reperfusion injury. An estimated 600,000 people in the United States annually suffer strokes. In the United States, strokes kill approximately 158,000 people each year and have left more than 1,000,000 people disabled to some extent, according to the American Heart Association. The estimated direct cost of stroke is over \$28 billion annually, much of which is attributable to the high expense of rehabilitating and caring for victims.

Many scientists believe that the damage from stroke and reperfusion injury is caused, at least in part, by free radicals. In a model of stroke, in which the middle cerebral artery of a rat is blocked for 90 minutes and then unblocked, our compounds significantly reduced damaged brain tissue when introduced as late as 7.5 hours after the start of the stroke. Our compounds 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.

We have chosen to develop AEOL 10150 as a potential treatment for stroke because it is easier to make and analyze and has an improved safety profile when compared to AEOL 10113. Assuming we can enter into a collaborative arrangement for development of AEOL 10150 and satisfactorily complete the preclinical studies, neither of which might occur, we intend to initiate Phase 1 clinical trials in 2002.

Catalytic Antioxidants and Cell Therapy

Laboratory experiments have shown that our catalytic antioxidants protect a number of cell types including islets, which are anatomical structures in the pancreas that contain beta cells, the cells that make and secrete insulin to regulate blood sugar levels. In these experiments, AEOL 10112 improved the ability of liver cells to survive freezing and thawing. Related compounds, AEOL 10113 and AEOL 10150, protected cultured neurons from toxicity due to oxygen and glucose deprivation. AEOL 10113 also protected cultured pancreatic beta cells from toxins.

Recently, an independent researcher has shown that AEOL 10113 exerts a protective effect in an animal model of human juvenile-onset diabetes. In this

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model, 100% of control mice became diabetic within 13 days after the injection of T lymphocytes directed against pancreatic beta cells. In contrast, AEOL 10113 prevented diabetes in 50% of the mice and significantly delayed the onset of diabetes in the others.

AEOL 10113 also protects pancreatic islets in culture, producing an approximate three-fold increase in the survival of human pancreatic islets for up to six days, with no loss of beta cell function. Islet transplantation, a potential cure for Type 1 diabetes, is limited by the ability to isolate functional human islets from donors. An agent that can significantly increase the number of functional human islets available for transplantation would represent an important advance in islet transplant treatment.

We are currently exploring the ability of our catalytic antioxidants to improve the survival of pancreatic beta cells after transplant in animals and intend to explore in the near term whether these compounds can improve the survival and growth of liver cells after transplant in animals. If the results of these experiments are positive, which might not happen, we intend to pursue the development of catalytic antioxidants as agents to improve the outcome of the transplantation of liver progenitor cells and pancreatic islets in humans.

Protection of Normal Tissue in Cancer 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.

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 lung caused by radiation. Lung damage leading to impaired lung function is one of the dose-limiting toxicities of chest radiation treatment, restricting the ability to deliver optimal doses of radiation to patients with lung cancer. Currently, radiation related pulmonary symptoms occur in up to 30% of patients irradiated for lung cancer, breast cancer, lymphoma or thymoma. In laboratory experiments, our catalytic antioxidant AEOL 10113 significantly protected the normal lung tissue of rats against damage caused by radiation.

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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. Incara is exploring the ability of its compounds to reduce the extent and duration of severe radiation-induced mucositis in a preclinical animal model.

Antitumor Effect of Catalytic Antioxidant. 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 also shown some degree of antitumor activity in the absence of radiation therapy in rat models of breast and skin cancers.

Commercialization

Because of the large numbers of patients suffering from stroke and cancer, effectively marketing a pharmaceutical for treatment of these indications requires the resources of a large sales organization. We intend to

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seek development, marketing or licensing arrangements for the stroke and adjunctive cancer therapy uses of our antioxidant compounds with pharmaceutical companies with an established marketing presence in the target indications. In the area of our catalytic antioxidants use in cell therapy, we may choose to commercialize a potential product internally. If our liver progenitor cell therapy program is successful in establishing a marketing effort to transplant centers, a catalytic antioxidant for use in cell therapy might make a complementary product.

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

OP2000

Our program for inflammatory bowel disease, or IBD, centers on OP2000, a polysaccharide, or carbohydrate, product derived from heparin. Heparin is a naturally occurring substance with anti-clotting and anti-inflammatory properties. Heparin, as a pharmaceutical product, is derived and purified from domestic mammals, primarily pigs. In July 1998 we obtained an exclusive 15-year license to develop OP2000 from its manufacturer, Opocrin S.p.A. of Modena, Italy. Clinical evidence of the successful treatment of IBD with heparin and the known anti-clotting effects of OP2000 provide the rationale for evaluating OP2000 in treating IBD. We have completed two Phase 1 clinical trials in normal volunteers to determine blood levels and anti-clotting effects following once daily injections of OP2000. In January 2001, we initiated a pivotal Phase 2/3 clinical trial in patients with ulcerative colitis. In January 2001, we also closed on a collaborative transaction for the joint development of OP2000 with Elan. As part of the transaction, we transferred the rights to our license for OP2000 to Incara Development. Incara Development is a company that we formed and jointly own with Elan to develop OP2000. For information on the three sequential phases of clinical trials, see "Government Regulation" below.

Inflammatory Bowel Disease

Inflammatory bowel disease describes a group of chronic inflammatory disorders of the intestine of unknown cause, often causing recurrent abdominal pain, cramps, diarrhea with or without bleeding, fever and fatigue. According to the Crohn's & Colitis Foundation of America, Inc., approximately 1,000,000 people in the United States have IBD. Two forms of IBD are Crohn's disease and ulcerative colitis. Crohn's disease typically affects the full thickness of the intestinal wall, most commonly in the lowest portion of the small intestine, but may involve any portion of the gastrointestinal tract. Ulcerative colitis results in the large intestine becoming inflamed with open sores and bleeding. Current treatments of IBD, such as steroids and other anti-inflammatory drugs, are designed to reduce inflammation and relieve symptoms. However patients frequently develop flare-ups of disease in spite of therapy, and side effects, particularly of steroids, can be severe. In serious cases, surgery is required. Ulcerative colitis can be so debilitating that up to 20% of patients opt for removal of their colon as a cure.

Heparins and IBD

A large number of case reports and a recent double blind placebo-controlled clinical trial of heparin in ulcerative colitis support the hypothesis that heparin can safely induce remission in IBD patients. A review (Korzenik, IBD 1997) of the clinical use of heparin in IBD (primarily ulcerative colitis) found benefit in 51 out of 60 reported cases, with increased bleeding in only three cases. In a recent U.S. double blind placebo-controlled trial of heparin in 68 patients with active ulcerative colitis receiving treatment with standard therapies, 42% of patients who were given additional heparin therapy

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had clinical remission or improvement, compared with 20% on placebo.

Clinical observations suggest that IBD may result from increased clotting activity. Investigators have observed evidence of increased clotting in the bowel and other organs during flares of IBD. Clotting is activated and the breakdown of clots is reduced

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during flares. Patients with inherited clotting deficiencies, such as von Willebrand's disease and hemophilia, have a much lower incidence of IBD than expected. The clinical results and other supporting studies discussed above provide a rationale for the use of an ultra-low molecular weight heparin such as OP2000 in the treatment of flares of IBD.

OP2000 is a product of the chemical cleavage of heparin, and has the comparatively low molecular weight of 2,500 daltons, compared with full-length heparin's molecular weight of about 14,000 daltons and other low molecular weight heparins' molecular weights of 4,000 to 6,000 daltons. Lower molecular weight, or smaller molecules of heparin, might prove to have advantages over heparin itself, including better safety, efficacy and convenience. OP2000 has been shown to be a potent anti-clotting agent. Like low molecular weight heparins, and unlike heparin, routine monitoring of clotting factors during treatment should not be necessary, providing an advantage over heparin. OP2000 has a longer lifetime in the body than heparin or low molecular weight heparins and initial results indicate that OP2000 can be given in once-daily injections under the skin. A key objective of Incara is to have OP2000 be the first heparin-related product to obtain regulatory approval to treat ulcerative colitis in the United States. We might not achieve this objective. The composition of OP2000 is covered by claims of patents issued to Opocrin in the United States and Europe. Incara Development has rights to a license for OP2000 from Opocrin for all uses worldwide, except in Japan and Korea.

Clinical Development Program

In late 1999 and early 2000, we completed two Phase 1 clinical trials for OP2000 with no significant unexpected side effects. These trials looked at single and multiple dose administrations of the drug, and preliminary results indicate that, should it be successfully commercialized, we will be able to give OP2000 on a once-a-day basis. OP2000 has been studied for another indication in over 150 healthy subjects and patients in Europe with no significant unexpected side effects.

In January 2001, Incara Development began a Phase 2/3 pivotal clinical study of OP2000 in patients with ulcerative colitis, a form of inflammatory bowel disease. The study will examine the effects of OP2000 in patients receiving standard treatment including aminosalicylates who have developed symptoms of active ulcerative colitis. The study is designed to enroll approximately 270 patients. Patients will be treated with aminosalicylates and other standard therapies plus either OP2000 or placebo once a day for six weeks. This initial study will utilize prefilled syringes to deliver OP2000 by subcutaneous injection. The objective of treatment will be to cause complete remission or significantly improve the signs and symptoms of ulcerative colitis.

If the results of the Phase 2/3 trial are positive, Incara Development plans to conduct a confirmatory Phase 3 safety and efficacy trial in ulcerative colitis. In addition, Incara Development would plan to conduct two or three small studies to assess the effect of disease states on OP2000 blood levels and anti-clotting effects. A pilot study in Crohn's disease would also be considered. Our clinical scientists will manage the trials, including all data

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collection and analysis activities.

Commercialization

If efficacy is demonstrated in clinical trials, Incara Development will determine the appropriate marketing arrangement for OP2000. Elan has a first option to negotiate an agreement for commercialization of OP2000. If Incara Development and Elan are not able to reach a mutually acceptable commercialization agreement, Incara Development will be free to negotiate with third parties for commercialization of OP2000 on terms no more favorable than those offered Elan.

Collaborative and Licensing Arrangements

Incara Development, Ltd.

In January 2001, we closed on a collaborative and financing transaction with Elan. As part of the transaction, Incara Pharmaceuticals and Elan formed Incara Development to develop OP2000. We own 80.1% of the outstanding shares of Incara Development and Elan owns 19.9%. As part of the transaction, Elan and we entered into license agreements under which we licensed to Incara Development the OP2000 compound and Elan licensed to Incara Development certain drug delivery technology.

Also as part of the transaction, Elan purchased shares of our common stock, shares of our Series B non-voting convertible preferred stock and a warrant for Series B preferred stock. Elan also purchased shares of our Series C convertible exchangeable non-voting preferred stock. The Series C preferred stock is exchangeable at the option of Elan at any time for the preferred stock of Incara Development held by us which, if exchanged, would give Elan ownership of 50% of the initial amount of stock of Incara Development. After December 20, 2002, the Series C preferred stock is convertible by Elan into shares of our Series B preferred stock. If the Series C preferred stock is outstanding as of December 21, 2006, we will exchange the Series C preferred stock and accrued dividends, at our option, for either cash or shares of our stock and warrants having a then fair market value of the amount due. The proceeds from the issuance of the Series C preferred stock were contributed by us to Incara Development in exchange for our ownership of Incara Development.

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Elan and we intend to fund Incara Development pro rata, based on our respective percentage ownership of the stock of Incara Development. Subject to mutual agreement, Elan will lend us up to \$4,806,000 to fund our pro rata share of development funding for Incara Development. In return, we issued a convertible promissory note that bears interest at 10% compounded semi-annually on the amount outstanding thereunder. For additional details on the Elan transaction see "Management's Discussion and Analysis of Financial Condition and Results of Operations--Overview."

Opocrin License

In July 1998, we signed a 15-year agreement with Opocrin to obtain the exclusive rights to OP2000 on a worldwide basis, except for Japan and Korea. We transferred the license rights to Incara Development in January 2001. We paid \$1,000,000 to Opocrin as a license fee upon execution of the agreement. Additional compensation will be payable to Opocrin by us or Incara Development upon initiation of specified clinical trials, upon filing for specified regulatory approval, upon obtaining specified regulatory approval, and upon achieving specified aggregate annual sales. Incara Development also is to pay

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Opocrin royalties on net sales and is responsible for the costs of conducting clinical trials for OP2000. Incara and Opocrin have agreed to diligently pursue the negotiation and execution of a manufacturing supply agreement, under which Opocrin would manufacture OP2000 for commercial purposes. We might not reach an agreement with Opocrin for the manufacture of OP2000.

University of North Carolina License

Through our subsidiary, Incara Cell Technologies, we have a sponsored research agreement which covers research at the University of North Carolina by scientists in the area of hepatic stem cells. This agreement grants us the first option to obtain an exclusive license to inventions resulting from the research during the term of the research agreement, or during the one-year period following termination of the agreement. We have obtained an exclusive worldwide license from UNC to make, use and sell products using proprietary information and technology developed under this sponsored research agreement. The UNC license includes rights to five U.S. patent applications filed during 1999, 2000 and 2001, including patent applications for isolating and purifying human liver progenitor cells. We are pursuing international patent protection, as we deem appropriate. We will make milestone payments to UNC 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 UNC license is terminable in the event of breach and expires when the last licensed patent expires.

Albert Einstein College of Medicine

Through Incara Cell Technologies, we have obtained exclusive worldwide rights from Albert Einstein College of Medicine for patents resulting from research conducted on liver stem and precursor cells by Dr. Reid and other scientists, while Dr. Reid was at Einstein. The U.S. component of this patent portfolio includes five issued patents and three pending patent applications. We also have six pending patent applications internationally. We must pay royalties to Einstein on net product sales during the term of the licenses and must pay minimum royalties beginning in 2004. We also must pay patent prosecution, maintenance and defense costs. The Einstein licenses are terminable in the event of breach, and otherwise expire when the last licensed patent expires.

Duke Licenses

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

National Jewish License

Through Aeolus, we have a Sponsored Research Agreement with National Jewish Medical and Research Center. The National Jewish Agreement grants Aeolus an option to negotiate a royalty-bearing exclusive license for technology, patents and inventions resulting from research at National Jewish within the field of antioxidant compounds and related discoveries. We have agreed to support National Jewish's costs incurred in performance of the research. In November 2000, we obtained an exclusive worldwide license from National Jewish to develop, make, use and sell products using proprietary information and

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technology developed under this sponsored research agreement. We will make milestone payments to National Jewish upon the occurrence of development milestones and pay royalties on net sales. We are also obligated to pay patent filing, prosecution, maintenance and defense costs. The National Jewish license is terminable in the event of breach and otherwise expires when the last licensed patent expires.

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Manufacturing

Our strategy is to contract with third parties for manufacturing capabilities.

The bulk drug substance for OP2000 is being provided for drug development activities by the licensor, Opocrin, on a cost-plus basis. Incara Pharmaceuticals and Opocrin have agreed to diligently pursue the negotiations and execution of a manufacturing supply agreement, under which Opocrin would manufacture OP2000 for commercial purposes. The formulated drug product is being manufactured for clinical trials in prefilled syringes by a contract manufacturer. The commercial supplier for the final drug product will be selected by Incara Development and Elan based on the final delivery system chosen for OP2000.

For our liver cell program, we have selected the Center for Cell and Gene Therapy at Baylor College of Medicine, Houston, Texas, as the cGMP facility to manufacture clinical trial material. Our scientists are currently working with Baylor on our process for the isolation and enrichment of liver progenitor cells. Once the process has been successfully performed and validated at Baylor, we will attempt to contract with Baylor to manufacture the clinical trial material for Phase 1 clinical trials. The source of livers for this process has historically been, and will continue to be, livers that are not suitable for transplantation (for reasons other than serology) from traditional organ transplant donor programs. Incara has successfully established a working relationship with a number of organ procurement organizations and expects to maintain and expand these relationships.

Pharm-Eco Laboratories is developing the chemical process for the commercial manufacture of the catalytic antioxidants. Pharm-Eco currently has the capability to manufacture clinical grade material in accordance with cGMPs for clinical as well as commercial purposes; however, we have not selected the manufacturer for the final clinical material, which will depend, in part, on the dosage form and the indication.

Marketing

We intend to establish our own marketing capabilities for the liver progenitor cell therapy program in the United States if we are successful in treating patients in clinical trials and are granted approval by the FDA. We believe a targeted marketing effort directed toward the 120 liver transplant centers in the country is an appropriate strategy for Incara in this area. Establishing our own marketing capabilities will require substantial funds and we might not successfully establish our own marketing capabilities on a cost-effective basis or at all. Outside the United States we plan to collaborate with an established pharmaceutical or biotechnology company for the liver progenitor cell therapy program.

Several of our potential catalytic antioxidant products are being developed for large therapeutic markets, such as stroke and cancer therapy adjunct. We believe these markets are best approached by collaborating with

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established biotechnology or pharmaceutical companies that have broad sales and marketing capabilities. We are pursuing collaborations of this type.

The rights to market OP2000 are licensed to Incara Development. At the time that Incara Development determines it intends to commercialize OP2000, Elan will have 45 days to exercise a first option to negotiate an agreement for commercialization of OP2000. If Incara Development and Elan are not able to reach a mutually acceptable commercialization agreement within 120 days from Elan's exercise of the option, Incara Development will be free to negotiate with third parties for commercialization of OP2000 on terms no more favorable than those offered Elan.

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

Competition

General

Competition in the pharmaceutical industry is intense and we expect it to increase. Technological developments in our fields of research and development occur at a rapid rate and we expect competition to intensify as advances in these fields 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 and marketing, and human resources than we have. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, competitors might develop technologies and products that are cheaper, safer or more effective than those being developed by us or that would render our technology obsolete.

We expect 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

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competitive product(s) 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 being targeted by us. In addition to the competitors and products discussed below, there might be other competitors of whom we are unaware with products which might be more effective or have fewer side effects than our products and those of our known competitors.

Inflammatory Bowel Disease

The two major forms of inflammatory bowel disease, ulcerative colitis and Crohn's disease, are treated by antidiarrheals, steroids, other anti-inflammatory drugs and immunosuppressants. Crohn's disease also is being treated by off-label use of metronidazole, an antibiotic that acts as an anti-inflammatory through an unknown mechanism. Some of the drugs used to treat these diseases are available in generic form and are being marketed at a price that could be less than the price of OP2000, if it were successfully developed and approved. Low molecular weight heparins are approved for non-IBD indications

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and marketed by others, who might try to develop their low molecular weight heparins for IBD. We believe there are planned or ongoing trials of low molecular weight heparins for the treatment of IBD in Europe and the Middle East.

Remicade(R) was approved by the FDA in 1998 for use in treating moderately to severely active Crohn's disease. It is not approved for ulcerative colitis. Remicade is an antibody to TNF alpha indicated for the reduction of the signs and symptoms of Crohn's disease in patients who have an inadequate response to conventional therapy. The drug is being marketed in the United States by Centocor, Inc. Its cost and the concern over possible allergic reaction to the protein, however, have limited its use in this indication. We are aware of other drugs that inhibit TNF alpha or intercellular adhesion molecule-1 that are being studied preclinically or in patients in IBD, which may have a better side effect profile.

Hepatic Diseases

We are aware of competitive efforts in academic, research and commercial institutions using human hepatic cells in treatment of liver disease. Tissue Transformation Technologies, Inc. and Diacrin, Inc. are conducting Phase 1 clinical trials for treatment of cirrhosis using human liver cell transplants. In addition, other companies and academic laboratories are investigating the use of pig livers in transplantation as a substitute for human liver and the use of hepatocytes prepared from pig livers as a form of cell therapy. Several other companies have conducted research and development on a bioartificial liver device to treat acute liver failure that could be competitive with our technology under development. In particular, VitaGen Incorporated is conducting a clinical trial with a bioartificial livers that utilize human liver cells derived from tumors. At least one company is pursuing the growth of mini-organs, including livers. StemCells, Inc. and other companies and academic institutions are conducting research in the area of liver and other organ stem and progenitor cells. Stem cell research in general is being conducted by a number of companies, including Geron Corporation, which has announced that it has isolated embryonic stem cells. In theory, embryonic stem cells, bone marrow and other cells could have the capacity to differentiate into all human systems, including the liver.

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 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, or SOD. Metaphore reported that this compound substantially reduced tissue damage due to inflammation and reperfusion in animal models. Eukarion, Inc. is also developing similar compounds, which are in preclinical development for conditions associated with damage caused by free radicals. AstraZeneca is developing a nitron compound with free radical trapping properties for stroke. The compound, licensed from Centaur Pharmaceuticals, Inc., is currently in Phase 2 development. Progenics Pharmaceuticals, Inc. is developing dehydroascorbic acid, a form of vitamin C for stroke. They have shown this compound reduces brain damage when given three hours after a stroke in an animal model.

Patents and Proprietary Rights

We currently license rights to all of our potential products from

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academic institutions and other third parties. We generally seek patent protection in the United States and other jurisdictions for the potential products and proprietary technology licensed from these third parties. The process for preparing and prosecuting patents is lengthy, uncertain and costly. Patents might not issue on any of the pending patent applications owned or licensed by us from third parties. Even if patents issue, the claims allowed might not be sufficiently broad to protect our technology or provide us protection against competitive products or otherwise be commercially

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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.

Incara Development has rights to an exclusive license from Opocrin, in all countries other than Japan and Korea, for an issued patent to develop and commercialize OP2000. Incara Development also has rights to a non-exclusive license from Opocrin to practice related patents, to the extent required for our activities related to OP2000. We are aware of a recently issued patent claiming the use of fractions of heparin for the treatment of inflammatory bowel disease. We do not believe the development of OP2000 will require the licensing of this patent. If OP2000 were to be determined to fall within the scope of this patent and if the patent's claims were found to be valid, Incara Development would have to license this patent in order to commercialize OP2000. Incara Development might not be able to license this patent at a reasonable cost which would result in Incara Development not being able to market OP2000. Uncertainty regarding the scope or validity of this patent might deter Elan from continuing development of OP2000 or deter other companies from collaborating with Incara Development for the development and commercialization of OP2000.

In the liver progenitor cell program, we have an exclusive license for five issued U.S. patents and three pending patent applications from Albert Einstein College of Medicine. Claims included in these issued patents include an isolated hepatocyte precursor capable of differentiating into a hepatocyte and a population of genetically engineered hepatocyte precursor cells. We also have six related pending patent applications internationally. Our UNC sponsored research agreement allows us to obtain an exclusive worldwide license to make, use and sell products using proprietary information and technology developed under the UNC sponsored research agreement. Rights to five U.S. patent applications filed during 1999, 2000 and 2001 are currently included in the UNC license, along with international applications as we deem appropriate. Pending claims on the UNC patents include those directed to human liver progenitor cell composition and process for their isolation, expansion and cryopreservation and the use of non-beating-heart donors as a source for progenitor cells.

Our catalytic antioxidant small molecule technology base is described in four issued U.S. patents and six patent applications that are pending. These patents and patent applications belong in whole or in part to Duke or National Jewish and are licensed to us. These patents and patent applications cover soluble manganic porphyrins as antioxidant molecules as well as targeted compounds obtained by coupling such antioxidant compounds to molecules that bind to specific extracellular elements. The pending U.S. applications include composition of matter claims for several series of compounds. Corresponding international patent applications have been filed as we deem appropriate, two of which have issued.

In addition to patent protection, we rely upon trade secrets, proprietary know-how and technological advances that we seek to protect in part through confidentiality agreements with our collaborative partners, employees

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and consultants. Our employees and consultants are required to enter into agreements providing for confidentiality and the assignment of rights to inventions made by them while in our service. We also enter into non-disclosure agreements to protect our confidential information furnished to third parties for research and other purposes. These types of agreements can be difficult to enforce and for some types of breach there is no satisfactory remedy for unauthorized disclosures. It is possible that our trade secrets and proprietary know-how will become known or will be independently discovered by others despite our efforts.

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

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

Government Regulation

Our research and development activities and the manufacturing and marketing of our proposed 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 may not successfully demonstrate the safety and efficacy of any products or result in marketable products.

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

- . preclinical studies;
- . the submission to the FDA of a request for authorization to conduct clinical trials on an investigational new drug or cell therapy, which must become effective before human clinical trials may commence;
- . adequate and well-controlled Phase 1, 2 and 3 human clinical trials to establish the safety and efficacy of the drug or cell therapy for its intended use;

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- . submission to the FDA of a New Drug Application, or NDA, for a drug, or submission to the FDA of a Biological License Application, or BLA, in the case of a cell therapy; and
- . review and approval of the NDA or BLA by the FDA before the product may be shipped or sold commercially.

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

Preclinical testing includes laboratory evaluation and characterization of the safety and efficacy of a drug or cell therapy and its formulation. Preclinical testing results are submitted to the FDA as a part of an Investigational New Drug Application, or IND, which must become effective prior to commencement of human clinical trials. Clinical trials are typically conducted in three sequential phases following submission of an IND. Phase 1 represents the initial administration of the drug or cell therapy to a small group of humans, either patients or healthy volunteers, typically to test for safety (adverse effects), dosage tolerance, absorption, distribution, metabolism, excretion and clinical pharmacology, and, if possible, to gain early evidence of effectiveness. Phase 2 involves studies in a small sample of the actual intended patient population to assess the efficacy of the drug or cell therapy 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 or cell therapy is found to have some efficacy and an acceptable safety profile in the targeted patient population, Phase 3 studies are initiated to further establish clinical safety and efficacy of the therapy in a broader sample of the general patient population, in order to determine the overall risk-benefit ratio of the drug or cell therapy and to provide an adequate basis for any physician labeling. During all clinical studies, we must take care to adhere to good clinical practice, or GCP, standards. The results of the research and product development, manufacturing, preclinical studies, clinical studies and related information are submitted in an NDA or BLA to the FDA.

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

The rate of completion of our clinical trials will be dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a

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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 may 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 FDA's evaluation of an NDA or BLA. 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.

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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 such countries. The requirements governing the conduct of clinical trials and product approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country at this time has its own procedures and requirements. There can be no assurance that any foreign approvals will 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.

Employees

We had 25 employees as of November 30, 2001. None of our employees is represented by a labor union. We consider our employee relations to be good. We are highly dependent on the principal members of our management and scientific staff. The loss of certain key employees could have a material adverse effect on us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific and managerial personnel. We face intense competition for such personnel from other companies, research and academic institutions, government entities and other organizations. We might not be successful in hiring or retaining the personnel we require.

Risks Associated with Our Business

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

If we do not raise significant additional capital, we will be unable to fund all

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of our research and development activities and will need to eliminate or curtail these programs.

One of the most significant issues we face is adequate funding of our existing projects. As of September 30, 2001, we had cash and investments of \$5,453,000. While we believe our existing financial resources are adequate to fund our current level of operations until mid-2002, we will need additional funds from the sale of our stock or from collaborations with third parties to support our current level of operations after mid-2002. Otherwise, we may be required to scale back, delay or discontinue one or more of our programs.

Our financial requirements will depend upon the success of our research and development programs. In addition, our ability to enter into new collaborations that provide fees and research and development funding depends on the successful results of our research programs. If some or all of our programs show scientific progress, we will need significant additional funds to move therapies through the preclinical stages and into clinical trials. If we are unable to raise the amount of capital necessary to complete development and reach commercialization of any of our therapeutic products, we will need to delay or cease development of one or more of our products.

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

As of September 30, 2001, we had an accumulated deficit of \$106,772,000 from our research, development and other activities. We have not generated any revenues from product sales and do not expect to do so for at least several more years. In the past, most of our revenues have come from collaborators who reimbursed us for research and development activities.

Our research and development programs are at an early stage and therefore might never result in viable products.

Our programs to develop products are in the early stages of development, involve unproven technology, require significant further research and development and regulatory approvals, and are subject to the risks of failure inherent in the development of

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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; that the proposed products or procedures are uneconomical to market or do not achieve broad market acceptance; that third parties hold proprietary rights that preclude us from marketing them; or that third parties market a superior or equivalent product. Further, the timeframes for commercialization of any products are long and uncertain, because of the extended testing and regulatory review process required before marketing approval can be obtained. As evidence of the difficulty in commercializing new products, in 1999, we terminated one product we were developing. We might have to terminate the development of current or future products and our results of operations could be adversely affected.

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

Our current business strategy is to enter into agreements with third parties both to license rights to our potential products and to develop and commercialize new products. We might not be able to enter into or maintain these

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agreements on terms favorable to us. We currently license from third parties, and do not own, rights under patents and certain related intellectual property for our current development programs. If any of these licenses were to expire, our business could be adversely affected.

The development of OP2000 depends on our collaboration with Elan Corporation, plc, which is outside of our control.

We are developing OP2000 through a collaboration with Elan. Incara Development, Ltd. is a company that we formed and jointly own with Elan to develop OP2000. We own 80.1% and Elan owns 19.9% of Incara Development. Despite our majority ownership of Incara Development, we have no control over the development activities regarding OP2000, because we control only 50% of the votes on the joint management committee of Incara Development. As a result, any revenue we earn on OP2000 will depend entirely on our ability to negotiate with Elan.

Elan has the right to exchange the Series C convertible exchangeable preferred stock of Incara Pharmaceuticals it owns for all of the preferred securities we own of Incara Development at any time until December 21, 2006, which would give Elan a 50% ownership interest in Incara Development. If Elan exercises this right, our ownership in Incara Development will be substantially diluted, which would reduce the return to which we would be entitled if OP2000 is successful.

Our liver progenitor cell program and product depends on a constant, available source of livers from organ donors.

We must maintain current or develop new sources of livers or liver tissues from which progenitor cells can be isolated. There are a limited number of suppliers and we face competition in obtaining livers from them. We have historically relied on several suppliers of liver tissues for research, but entering into the clinical trial stage of development will increase our needs. For clinical trials and ultimately for commercialization, we need to obtain, from traditional organ transplant donor programs, livers which are not suitable for full liver transplant. We might not be able to obtain these livers. If we are unable to maintain a supply of livers, our development of the liver progenitor cell program will be adversely affected.

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

We have exclusive worldwide rights to our antioxidant small molecule technology through license agreements with Duke University and National Jewish Medical Center. We also have the worldwide exclusive rights to patents licensed from Albert Einstein College of Medicine and patent applications and rights to license future technology arising out of research sponsored at the University of North Carolina at Chapel Hill (related to the liver progenitor cell program) and National Jewish Medical Center (related to antioxidant small molecules). Key financial and other terms, such as royalty payments, for the licensing of this future technology would still need to be negotiated with the research institutions, and it might not be possible to obtain any such license on terms that are satisfactory to us.

Our licenses generally may be terminated by the licensor if we fail to perform our obligations, including obligations to develop the compounds and technologies under license. If terminated, we would lose the right to develop the products, which could adversely affect our business. The license agreements also generally require us to meet specified milestones or show reasonable diligence in development of the technology. If disputes arise over the

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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.

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We need to obtain collaborative arrangements for manufacturing and marketing of our potential products, or we will have to develop the expertise, obtain the additional capital and spend the resources to perform those functions.

We do not have the staff or facilities to manufacture or market any products being developed in our programs. We need to enter into collaborative arrangements in the future to develop, commercialize, manufacture and market products expected to emerge from our catalytic antioxidant program. We also might rely on a third party to manufacture the liver progenitor cell therapy being developed by us. We intend to seek a company to work with us on development of a liver assist device, and we intend to seek a company or companies to work with us on development of gene therapy and genomics applications of the liver progenitor cell program. Incara Development also will need third parties to manufacture and market OP2000, if it reaches commercialization.

A large number of small biotechnology companies are seeking collaborators, some of whom compete in the same therapeutic areas as our programs, and obtaining and maintaining new collaborative arrangements will be difficult. We might not be successful in entering into third party arrangements on acceptable terms, if at all. If we are unable to obtain or retain third-party manufacturing or marketing on acceptable terms, we might be delayed in our ability to commercialize products. Substantial additional funds and personnel would be required if we needed to establish our own manufacturing or marketing operations. We might not be able to obtain adequate funding or establish such capabilities at all or in a cost-effective manner.

Even if we do succeed in obtaining a collaborator for any of our programs, the product might not be commercialized profitably, if at all. The compensation owed to our manufacturers and marketers will reduce our profit margins and might delay or limit our ability to develop, deliver and sell products on a timely and competitive basis. Furthermore, one of these companies could pursue alternative technologies or develop alternative compounds either on its own or in collaboration with others, targeted at the same diseases as those involved in our programs.

The manufacturers of any of our products, if they reach commercialization, must comply with applicable regulations.

A manufacturer must conform to FDA and any applicable foreign regulations for the production and packaging of products. If any of our manufacturers cannot meet our needs or applicable regulatory standards with respect to the timing, quantity or quality of products, our development programs would be delayed.

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

The success of our business depends, in part, on our ability to establish and maintain adequate protection for our intellectual property, whether owned by us or licensed from third parties. We rely primarily on patents in the United States and in other key markets to protect our intellectual

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property. If we do not have adequate patent protection, other companies could sell products that compete directly with ours, without incurring any liability to us. Patent prosecution, maintenance and enforcement on a global basis is expensive, and many of these costs must be incurred before we know whether a product covered by the claims can be successfully developed or marketed.

Even if we expend considerable time and money on prosecution, a patent application might never issue as a patent. We can never be certain that we were the first to invent the particular technology or that we were the first to file a patent application for the technology, because a majority of U.S. patent applications are maintained in secrecy until a patent issues. Publications in the scientific or patent literature generally do not identify the date of an invention, so it is possible that a competitor could be pursuing the patenting of the same invention in the United States and have an earlier invention date. Outside the United States, priority of invention is determined by the earliest effective filing date, not the date of invention. Consequently, if another person or company pursues the same invention and has an earlier filing date, patent protection outside the United States would be unavailable to us. Also, outside the United States, an earlier date of invention cannot overcome a date of publication that precedes the earliest effective filing date. Accordingly, the patenting of our proposed products would be precluded outside the United States if a prior publication anticipates the claims of a pending application, even if the date of publication is within a year of the filing of the pending application.

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

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

Our business also depends on our ability to develop and market products without infringing on the proprietary rights of others or being in breach of our license agreements. The pharmaceutical industry is subject to frequent and protracted litigation regarding patent and other intellectual property rights. Most companies have numerous patents that protect their intellectual property rights. These third parties might assert claims against us with respect to our product candidates and future products. If litigation were required to determine the validity of a third party's claims, we could spend significant resources and be distracted from our core business activities, regardless of the outcome. If we did not prevail in the litigation, we could be required to license a third party's technology, which might not be possible on satisfactory terms, or discontinue our own activities and develop non-infringing technology, any of which could prevent or delay pursuit of our development programs.

Incara Development has rights under an exclusive license from Opocrin S.p.A., until 2013 in all countries other than Japan and Korea, to develop and market OP2000. This license is based on an issued patent held by Opocrin

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claiming a heparin derivative with a specified range of molecular weight. Incara Development also has rights to a non-exclusive license from Opocrin to practice certain related patents, to the extent required for our activities related to OP2000. We are aware of a recently issued patent claiming the use of specified fractions of heparin for the treatment of inflammatory bowel disease. We do not believe the development of OP2000 will require the licensing of this patent. If OP2000 were to be determined to fall within the scope of this patent and if the patent's claims were found to be valid, Incara Development would have to license this patent in order to commercialize OP2000. Incara Development might not be able to license this patent at a reasonable cost which would result in Incara Development not being able to market OP2000. Uncertainty regarding the scope or validity of this patent might deter Elan from continuing development of OP2000 or deter other companies from collaborating with Incara Development for the development and commercialization of OP2000.

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

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

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

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

We face intense competition in all of our development programs. The markets for therapeutic products that address liver disease, stroke, cancer and inflammatory bowel disease are large and competition is increasing. Our most significant competitors are fully integrated pharmaceutical companies and more established biotechnology companies, which have substantially greater financial, technical, sales and marketing, and human resources than us. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, competitors might develop technologies and products that are cheaper, safer or more effective than those being developed by us or that would render our technology obsolete.

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

As of November 30, 2001, Incara had 12,717,093 shares of common stock outstanding.

We may grant to our employees, directors and consultants options to purchase our common stock under the 1994 Stock Option Plan. As of November 30, 2001, options to purchase 2,255,648 shares at exercise prices ranging from \$0.04 to \$20.50, with a weighted average exercise price of \$2.88 were outstanding and 1,027,065 shares were reserved for issuance under the 1994 Stock

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Option Plan. In addition, warrants to purchase 1,221,804 shares of common stock at exercise prices ranging from \$1.61 to \$13.49 were outstanding, with a weighted exercise price of \$2.19, and we have reserved 22,479 shares of common stock for issuance pursuant to our Employee Stock Purchase Plan.

In connection with a collaboration and financing transaction, we have issued preferred stock and warrants to purchase preferred stock to Elan. This preferred stock is convertible into common stock, as discussed below.

We will need to sell additional shares of our common stock, preferred stock or other securities, or enter into collaborations with third parties to meet our capital requirements, including the issuance of shares of our stock to Elan and Torneaux Fund Ltd., as discussed below. We might not be able to complete these transactions when needed. If these sales of stock occur, these issuances of stock will dilute the ownership interests of our stockholders. The possibility of dilution posed by shares available for future sale could reduce the market price of our common stock and could make it more difficult for us to raise funds through equity offerings in the future.

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

In January 2001, in connection with a collaboration and financing transaction, we sold to Elan 28,457 shares of our Series B convertible non-voting preferred stock, 12,015 shares of our Series C convertible exchangeable non-voting preferred stock and a warrant to purchase 22,191 shares of our Series B preferred stock. Each share of our Series B preferred stock is convertible into ten shares of our common stock. The Series C preferred stock has a face value of \$1,000 per share and bears a 7% dividend payable in Series C preferred stock, which compounds annually, and is convertible by Elan into shares of Series B preferred stock at the rate of \$64.90 per share. Accordingly, a total of 2,357,789 shares of our common stock could be issued to Elan, assuming the exercise of all warrants currently outstanding and the conversion into common stock of all shares of Series B and Series C preferred stock currently outstanding, but not including any dividends to be issued on the Series C preferred stock. This amount of shares represents 15.6% of the total shares of our common stock that would be outstanding after such conversion and exercise based on shares of common stock outstanding on November 30, 2001; however, pursuant to provisions in our Certificate of Incorporation, Elan may not own more than 9.9% of our common stock at any time.

In addition, upon the completion of enrollment of a Phase 2/3 clinical trial for OP2000, Elan will purchase an additional \$1,000,000 of our Series B preferred stock, at a per share price equal to ten times the greater of the average per share daily price of our common stock on the day before the purchase or a 25% premium to the average daily price per share of our common stock for the 60 trading day period immediately before the purchase. On that day, Elan also will receive a warrant to purchase an amount of Series B preferred stock equal to 20% of the shares of Series B preferred stock it purchases at that time. However, if the purchase price of the Series B preferred stock is less than \$8.00 per share, the purchase of this stock will be limited to 150,000 shares of Series B preferred stock and will be at Elan's option.

Further, we have issued to Elan a promissory note under which we can, subject to Elan's consent, borrow up to \$4,806,000 for the development of OP2000. The note bears interest at 10%, compounded semi-annually on the amount outstanding under the note, and the principal and interest is convertible at Elan's option into shares of our Series B preferred stock at \$43.27 per share.

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As of September 30, 2001, we had not borrowed any funds pursuant to this note. However, in October 2001, we borrowed \$857,000 from Elan under this note. Assuming the full amount is borrowed under the note and assuming the conversion of the principal, but not any interest on the note, at the conversion price, an additional 1,110,700 shares of our common stock could be issued to Elan.

If Elan does not exchange its Series C preferred stock for either increased ownership of Incara Development or for Series B preferred stock by December 21, 2006, Incara will exchange the Series C preferred stock and accrued dividends, at its option, for either cash or shares of Series B preferred stock and warrants of Incara having a then fair market value of the amount due. Any issuance of equity securities or warrants to purchase equity securities in this situation would be dilutive to our common stockholders.

If Elan does not exchange all or part of the note for either increased ownership of Incara Development or for Series B preferred stock by December 21, 2006, Incara will exchange the note and accrued interest, at its option, for either cash or shares of Series B preferred stock and warrants of Incara having a then fair market value of the amount due. Any issuance of equity securities or warrants to purchase equity securities in this situation would be dilutive to our common stockholders.

The perceived risk of dilution by the convertible securities held by Elan might cause our stockholders to sell their shares, which would decrease the market price of our common stock. Further, any subsequent sale of our common stock by Elan would increase the number of our publicly traded shares, which could also lower the market price of our common stock.

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Stockholders might experience dilution from our issuance to Torneaux Fund Ltd. of up to 550,055 shares of common stock, or 4.1% of the total number of shares of our common stock which would then be outstanding, based on shares outstanding as of November 30, 2001.

In August 2000, we entered into a financing arrangement with Torneaux Fund Ltd. under which we may sell our common stock to Torneaux and also issue to Torneaux warrants which are convertible into our common stock. As of November 30, 2001, we had not sold any shares or issued any warrants to Torneaux. The maximum number of shares that we could issue to Torneaux during the remaining term of the arrangement is 550,055 shares of our common stock (including shares covered by warrants). The issuance of shares to Torneaux under this financing arrangement will have a dilutive effect on our stockholders of as much as 4.1% of the total number of shares which would then be outstanding, based on the 12,717,093 shares of common stock outstanding on November 30, 2001. However, if the trading volume of our stock does not exceed an average of 200,000 shares per day during the purchase periods, the maximum number of shares that we could issue to Torneaux would be 386,704 shares and warrants, or 3.0% of the shares which would then be outstanding. The number of shares that we issue to Torneaux under the agreement is based upon a discount to the daily weighted average market price of our stock over a 20-day trading period. If we sell shares to Torneaux at a time when our stock price is low, our stockholders would be significantly diluted. In addition, the perceived risk of dilution might cause stockholders to sell their shares, which could further decrease the market price of our shares. Torneaux's resale of our common stock will increase the number of our publicly traded shares, which could also lower the market price of our common stock. Because we have not yet sold any shares to Torneaux, Torneaux has the right to receive, at its option, either \$60,000 or a warrant to purchase 60,000 shares of our common stock.

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A return on your investment in our common stock will be dependent on an increase in the price of our common stock.

There is no set yield on our common stock. In addition, we do not currently anticipate paying cash dividends on our common stock because we have had no earnings to date and intend to retain all future earnings, if any, for the foreseeable future to fund our business operations. As a result, anyone investing in our common stock must look to an increase in its price to derive any value on their investment.

Our common stock is not actively traded and the price of our common stock has fluctuated from \$0.50 to \$11.00 during the last two years.

Our common stock is listed on the Nasdaq National Market System under the symbol "INCR." The public market for our common stock has been characterized by low and/or erratic trading volume, often resulting in price volatility. An active public market for our common stock might be limited because of the small number of shares outstanding, the limited number of investors and the small market capitalization (which is less than that authorized for investment by many institutional investors).

Shares of our common stock that we might issue to Torneaux have been registered for resale with the SEC and will be freely tradable and we have agreed to register shares of common stock that might be issued to Elan. In addition, the shares underlying substantially all of the warrants outstanding have been registered and will be freely tradable upon issuance. The sale of a significant amount of shares sold to Torneaux or to Elan at any given time could cause the trading price of our common stock to decline and to be highly volatile.

The market price of our common stock also 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 we fail to meet Nasdaq National Market listing requirements, our common stock will be delisted and become more illiquid.

Our common stock is currently listed on the Nasdaq National Market. Nasdaq has requirements that a company must meet in order to remain listed on the Nasdaq National Market. If we are unable to raise additional funds while we continue to experience losses from our operations, we might not be able to maintain the standards for continued quotation on the Nasdaq National Market, including a minimum bid price requirement of \$1.00 per share and a minimum net tangible assets value of \$4,000,000. In August

2001, Nasdaq notified us that our June 30, 2001 net tangible assets did not meet its listing requirements. The sale of \$6,978,000 of our common stock in August 2001 satisfied this requirement and Nasdaq closed the matter. Also, in February

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2001, Nasdaq notified us that our December 31, 2000 net tangible assets did not meet its listing requirements. Elan's investment in Incara in January 2001 satisfied this requirement and Nasdaq closed the matter. Nasdaq has adopted amendments to replace its minimum net tangible assets requirement with a stockholders' equity requirement that would require companies to have a minimum of \$10,000,000 of stockholders' equity in order to remain listed on the Nasdaq National Market after October 31, 2002. At September 30, 2001, our stockholders' equity was \$5,647,000, which was below the proposed requirement.

If as a result of the application of these current or proposed listing requirements, our common stock were delisted from the Nasdaq National Market, our stock would become harder to buy and sell. Further, our stock could be subject to what are known as the "penny stock" rules. The penny stock rules place additional requirements on broker-dealers who sell or make a market in such securities. Consequently, if we were removed from the Nasdaq National Market, the ability or willingness of broker-dealers to sell or make a market in our common stock might decline. As a result, your ability to resell your shares of our common stock could be adversely affected.

Our operating results are likely to fluctuate from quarter to quarter, which could cause the price of our common stock to decline.

Our revenues and expenses have fluctuated in the past. This fluctuation has in turn caused our operating results to vary from quarter to quarter and year to year. We expect the fluctuations in our revenues and expenses to continue and thus our operating results should also continue to vary, possibly significantly. These fluctuations might be due to a variety of factors, including:

- . the timing and amount of sales of our proposed products;
- . the timing and realization of milestone and other payments from any future collaborations with third parties;
- . the timing and amount of expenses relating to our research and development, product development, and collaborative activities; and
- . the extent and timing of costs related to our activities to obtain patents for our products and to extend, enforce and/or defend our rights to patents and other intellectual property.

Because of these fluctuations, it is possible that our operating results for a particular quarter or quarters will not meet the expectations of public market analysts and investors, causing the market price of our common stock to decline.

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

As of November 30, 2001, we had only 25 employees and we are highly dependent on the principal members of the management and scientific staff, including in particular Clayton I. Duncan, our Chairman, President and Chief Executive Officer. We also are highly dependent on the academic collaborators for each of our programs. The loss of key employees or academic collaborators could delay progress in our programs or result in termination of them in their entirety.

We believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific and managerial personnel. We face intense competition for these kinds of personnel from other companies, research and academic institutions, government entities and other organizations. We might not be successful in hiring or retaining the personnel needed for success.

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If we do not obtain and maintain government authorizations to manufacture and market proposed products, our business will be significantly harmed.

Our research and development activities and the manufacturing and marketing of our proposed products are subject to extensive regulation by governmental authorities in the United States and other countries. Clinical trials and the manufacturing and marketing of products are subject to the testing and approval processes of the FDA and foreign regulatory authorities. The process of obtaining required regulatory approvals for our products from the FDA and other regulatory authorities takes many years and is expensive. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, and if regulatory authorities do not agree with our analyses of data, our proposed product programs could be delayed or regulatory approval could be withheld. Additional government regulations might be promulgated which could delay or prevent regulatory approval of our products. Even if

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these approvals are obtained, post-marketing, adverse events or other monitoring of the products could result in suspension or limitation of the approvals.

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

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

Insurance covering product liability claims becomes increasingly expensive as a product moves through the development pipeline to commercialization. Incara Pharmaceuticals has limited product liability insurance coverage for the clinical trials for OP2000. However, the available insurance coverage might not be sufficient to cover us against all potential losses due to liability, if any, or to the expenses associated with defending liability claims. A product liability claim successfully asserted against us could exceed our coverage and require us to use our own cash resources, which would then not be available for our own products.

In addition, some of our licensing agreements with third parties require us to maintain product liability insurance. If we cannot maintain acceptable amounts of coverage on commercially reasonable terms, the corresponding agreements would be subject to termination.

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

Our business is subject to regulation under state and federal laws regarding occupational safety, laboratory practices, environmental protection and the use, generation, manufacture, storage and disposal of hazardous substances. We might be required to incur significant costs in the future to comply with existing or future environmental and health and safety regulations. Our research activities involve the use of hazardous materials, chemicals and

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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.

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

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

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

Further, some provisions of Delaware law could delay or make more difficult a merger, tender offer or proxy contest involving Incara. Incara is subject to the antitakeover provisions of Section 203 of the Delaware General Corporation Law. In general, the statute prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. While such provisions are intended to enable our Board of Directors to maximize stockholder value, they might have the effect of discouraging takeovers that could be in the best interest of some stockholders. Such provisions could reduce the market value of our common stock in the future.

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We remain contingently liable for IRL obligations.

In connection with the sale of Incara Research Laboratories, a former division of Incara Pharmaceuticals referred to as IRL, in December 1999 to a private pharmaceutical company, we agreed to remain contingently liable through May 2007 on debt and lease obligations assumed by the purchaser, including primarily the IRL facility lease in Cranbury, New Jersey. If the purchaser were to default, or the lender or landlord otherwise collect from us, our financial condition would be materially adversely affected. This contingent liability was approximately \$6,763,000 in September 2001 and should decline on an approximately straight-line basis to zero in May 2007.

Item 2. Properties

We currently lease 17,280 square feet of office and laboratory space in Research Triangle Park, North Carolina, which is leased through June 2006. We believe that these facilities are adequate to meet our needs for now and the foreseeable future.

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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, 2001.

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Executive Officers

The executive officers of Incara and their ages as of November 30, 2001 are as follows:

Name	Age	Position
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Clayton I. Duncan	52	President, Chief Executive Officer and Chairman of the Board
David P. Ward, M.D.	55	Executive Vice President, Research and Development
Richard W. Reichow	51	Executive Vice President, Chief Financial Officer
Mark E. Furth, Ph.D.	50	Senior Vice President, Research and Development
John P. Richert	51	Vice President, Market Development
W. Bennett Love	46	Vice President, Corporate Planning/Communications

Clayton I. Duncan has been President, Chief Executive Officer and a director of Incara since January 1995. Mr. Duncan has been Chairman of the Board of Directors since April 2000. From 1989 until December 1993, Mr. Duncan was President and Chief Executive Officer of Sphinx Pharmaceuticals Corporation, a biopharmaceutical company which was acquired by Eli Lilly and Company in September 1994. From December 1993 until September 1994, he served as an independent consultant to Sphinx with regard to the sale of Sphinx to Lilly. From 1987 to 1989, Mr. Duncan was a General Partner of Intersouth Partners, a venture capital firm. From 1979 to 1987, he was an executive with Carolina Securities Corporation, a regional investment banking firm, serving as Executive Vice President and a director from 1984 to 1987. Mr. Duncan was founder and Chairman of the Board of CRX Medical, Inc., a medical products company that conducted research and development in wound management, ophthalmic disorders and interventional radiology. Mr. Duncan is also a director of Aeolus Pharmaceuticals, Inc., Incara Development, Ltd., CPEC LLC, and Incara Cell Technologies, Inc., all of which are subsidiaries of Incara. Mr. Duncan received an M.B.A. from the University of North Carolina at Chapel Hill. In addition, Mr. Duncan is a director of The Forest at Duke, a continuing care retirement community, and Chairman of the Board of Directors of the Carolina Ballet, a professional ballet company.

David P. Ward, M.D. has been Executive Vice President, Research and Development of Incara since July 1998, and was Senior Vice President, Research and Development from March 1995 to July 1998. Dr. Ward was Group Vice President, Medical, Regulatory Affairs and Clinical Operations of Quintiles Transnational Corporation, a contract research organization, from October 1994 to March 1995. Dr. Ward was Vice President of Clinical Development and Regulatory Affairs of Sphinx from January 1992 to September 1994. Prior to that time, Dr. Ward was employed by SmithKline Beecham, a multinational pharmaceutical company, for more than six years, serving as a Vice President in various clinical areas. Dr. Ward

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received his M.D. degree from Case Western Reserve University Medical School.

Richard W. Reichow has been Executive Vice President since July 1998, Secretary since October 1995, and Senior Vice President, Chief Financial Officer and Treasurer since March 1995. Mr. Reichow was employed by Sphinx as President and Chief Executive Officer from December 1993 to September 1994, as Vice President, Finance & Administration from August 1991 to September 1994, and as Chief Financial Officer and Treasurer from March 1990 to September 1994. Between September 1994 and March 1995, he was an independent financial consultant. Mr. Reichow was Vice President, Chief Financial Officer and Treasurer of CRX Medical from 1987 to 1990. Mr. Reichow is a Certified Public Accountant.

Mark E. Furth, Ph.D. joined Incara in September 2001 as Senior Vice President, Research. Dr. Furth is a molecular biologist with 15 years of executive experience in the industry. From 1997 through 2000 he was Chief Scientific Officer of PPD Discovery, a company focused on drug discovery platforms including functional genomics and combinatorial chemistry, and then served the same role at PPGx, a company initially formed as a joint venture between PPD and Axys Pharmaceuticals Inc. From 1995 through 1997 he was President and Chief Executive Officer of Ingenex, a company focused on functional genomics and gene therapy. Prior to 1995, Dr. Furth was Vice President, Molecular Sciences of GlaxoSmithKline and prior to that was Vice President for Technology of Regeneron Pharmaceuticals, Inc. Dr. Furth obtained his B.A. from Harvard University, his Ph.D. in Molecular Biology from the University of Wisconsin-Madison and spent four years as head of the Laboratory of Molecular Oncogenesis at the Memorial Sloan-Kettering Cancer Center.

John P. Richert has been employed by Incara since 1995, and has been Vice President, Market Development since December 1996. Mr. Richert served as Director, Market Development with Sphinx from 1991 to 1994. Mr. Richert was employed by Schering-Plough Corporation, a major pharmaceutical manufacturer, from 1981 to 1990 where he held positions of increasing responsibility in marketing. Mr. Richert received an M.B.A. in Pharmaceutical Marketing from Fairleigh-Dickinson University.

W. Bennett Love has been employed by Incara since 1995, and has been Vice President, Corporate Planning/Communications since June 1997. From 1990 to 1994, Mr. Love was employed at Sphinx as Director, Corporate Planning/Communications. From 1983 through 1989, he was an investment banker with a regional securities firm. Mr. Love received an M.B.A. from the University of North Carolina at Chapel Hill.

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PART II

Item 5. Market for Company's Common Equity and Related Stockholder Matters.

(a) Price Range of Common Stock

Our common stock trades on the Nasdaq National Market under the symbol "INCR". The following sets forth the quarterly high and low sales prices as reported by Nasdaq 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

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Fiscal Year Ended September 30, 2000	
October 1, 1999 through December 31, 1999	\$1.8125
January 1, 2000 through March 31, 2000.	\$ 11.00
April 1, 2000 through June 30, 2000	\$ 6.125
July 1, 2000 through September 30, 2000	\$ 4.75
Fiscal Year Ended September 30, 2001	
October 1, 2000 through December 31, 2000	\$ 3.75
January 1, 2001 through March 31, 2001	\$ 3.25
April 1, 2001 through June 30, 2001	\$ 2.25
July 1, 2001 through September 30, 2001	\$ 1.95

(b) Approximate Number of Equity Security Holders

As of November 30, 2001, the number of record holders of our common stock was 161 and we estimate that the number of beneficial owners was approximately 5,000.

(c) Dividends

We have never paid a cash dividend on our common stock and we do not anticipate paying cash dividends in the foreseeable future. In addition, we cannot pay any cash dividends on our common stock unless we are current on the mandatory dividend payable on our Series C preferred stock. Further, if we pay a cash dividend on our common stock we also must pay the same dividend on an as converted basis on the Series B preferred stock and the Series C 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.

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 fiscal years ended September 30, 1997, 1998, 1999, 2000 and 2001 and the consolidated balance sheet data at September 30, 1997, 1998, 1999, 2000 and 2001 from our consolidated financial statements which have been audited by PricewaterhouseCoopers LLP, independent accountants, and, except for the consolidated statements of operations for the fiscal years ended September 30, 1997 and 1998 and the consolidated balance sheet data at September 30, 1997, 1998 and 1999, are included elsewhere in this Form 10-K.

Statement of Operations Data:
(in thousands, except per share data)

	Year Ended Sep		
	2001	2000	1999
	----	----	----

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Revenue:

Cell processing revenue	\$ 44	\$ --	\$ 2,0
Contract and license fee revenue	--	100	2,0
	-----	-----	-----
Total revenues	44	100	2,0
	-----	-----	-----

Costs and expenses:

Research and development	7,520	7,645	18,9
Purchase of in-process research and development	--	6,664	3,0
General and administrative	3,077	2,613	3,0
	-----	-----	-----
Total costs and expenses	10,597	16,922	22,0
	-----	-----	-----

Loss from operations	(10,553)	(16,822)	(19,9
Gain on sale of division	--	9,751	3,0
Gain on settlement of accrued liability	767	--	3,0
Equity in loss of Incara Development	(12,650)	--	3,0
Investment income, net	223	406	3,0
Minority interest	--	--	3,0
	-----	-----	-----

Net loss	(22,213)	(6,665)	(19,5
Preferred stock dividend accreted	(652)	--	3,0
	-----	-----	-----

Net loss attributable to common stockholders	\$ (22,865)	\$ (6,665)	\$ (19,5
	=====	=====	=====

Net loss per weighted share attributable to common stockholders:			
Basic and diluted	(\$ 2.78)	(\$ 1.21)	(\$ 2.78)
	=====	=====	=====

Weighted average common shares outstanding:

Basic and diluted	8,233	5,522	6,522
	=====	=====	=====

Balance Sheet Data:

(in thousands)

	2001	2002	2003
	-----	-----	-----
Cash and cash equivalents and marketable securities	\$ 5,453	\$ 6,453	\$ 6,453
Working capital	\$ 3,967	\$ 4,967	\$ 4,967
Total assets	\$ 8,618	\$ 7,618	\$ 7,618
Long-term portion of capital lease obligations and notes payable	\$ 17	\$ 17	\$ 17
Total liabilities	\$ 2,971	\$ 2,971	\$ 2,971
Total stockholders' equity	\$ 5,647	\$ 4,647	\$ 4,647

Unaudited Pro Forma Consolidated Financial Information:

The audited consolidated financial statements of Incara are included elsewhere in this Form 10-K. You should read the unaudited pro forma

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consolidated financial information presented herein in conjunction with those financial statements and related notes.

The unaudited pro forma consolidated financial information of Incara for the year ended September 30, 2000 include adjustments to give effect in the unaudited pro forma condensed consolidated statement of operations for the disposition of IRL as if it had occurred on October 1, 1999.

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The unaudited pro forma condensed consolidated statements of operations are provided for informational purposes and are not necessarily indicative of the results of operations that would have been achieved had the transactions been in effect as of the beginning of the period presented and are not necessarily indicative of future results of operations.

Pro Forma Consolidated Statement of Operations:
(In thousands, except per share data)

	Fiscal Year Ended September 30, 2000	
	Consolidated Actual	Pro Forma Adjustments - IRL
Revenue:		
Contract and license fee revenue	\$ 100	\$ 100
Costs and expenses:		
Research and development	7,645	1,339
Purchased in-process research and development	6,664	--
General and administrative	2,613	--
Total costs and expenses	16,922	1,339
Loss from operations	(16,822)	(1,239)
Gain on sale of division	9,751	9,751
Interest income, net	406	(37)
Net income (loss)	\$ (6,665)	\$ 8,475
Net loss per common share:		
Basic and diluted	\$ (1.21)	
Weighted average common shares outstanding	5,522	

The pro forma adjustments reflect the elimination of revenue and expenses related to IRL for the fiscal year ended September 30, 2000 as if the IRL sale had occurred at the beginning of the fiscal year. The pro forma adjustments also reflect the elimination of the gain recognized on the sale of IRL.

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

Introduction

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

Overview

We are focused on the development of potential therapies for protection and regeneration of tissue damaged by injury and disease. We currently have programs in three areas: liver stem and progenitor cell therapy as a treatment for liver failure; catalytic antioxidants as treatment for stroke and other tissue damage; and OP2000, an ultra-low molecular weight heparin being developed with Elan Corporation, for treatment of ulcerative colitis.

We had net losses attributable to common stockholders of \$22,865,000 and \$6,665,000 for the fiscal years ended September 30, 2001 and 2000, respectively. We had an accumulated deficit of \$106,772,000 at September 30, 2001. 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.

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Until July 15, 1999, Incara Pharmaceuticals was a majority-owned subsidiary of Interneuron Pharmaceuticals, Inc. On July 15, 1999, Incara Pharmaceuticals restructured its corporate relationship with Interneuron to reduce Interneuron's majority ownership of Incara Pharmaceuticals in exchange for an increased ownership by Interneuron of CPEC. Prior to the restructuring, CPEC was a subsidiary owned 80.1% by Incara Pharmaceuticals and 19.9% by Interneuron. As a preliminary step in the restructuring, Incara Pharmaceuticals acquired Interneuron's 19.9% interest in CPEC. Incara Pharmaceuticals redeemed 4,229,381 of the 4,511,084 shares of Incara Pharmaceuticals common stock owned by Interneuron, in exchange for a 65.0% ownership of CPEC and cancellation of liabilities owed to Interneuron by Incara Pharmaceuticals and CPEC that totalled \$2,421,000. This cancellation was treated as a contribution to capital by Interneuron to Incara Pharmaceuticals.

Until July 1999, our most advanced product was bucindolol HCl, a beta-blocker that was being evaluated in a Phase 3 clinical trial conducted by the National Institutes of Health and the U.S. Department of Veterans Affairs for use in treating congestive heart failure patients. The agencies terminated the study in July 1999, prior to its scheduled termination date, because an interim data analysis indicated there was no significant survival advantage of treatment with bucindolol for the patient population as a whole. In August 1999, the Company agreed to end the collaboration with BASF Pharma/Knoll AG for bucindolol for countries outside the United States and Japan, and terminated the European trial of bucindolol. On December 20, 2000, we entered into a Settlement Agreement and Release with Knoll AG to resolve a dispute regarding a payable owed by us to Knoll for the discontinued program. As of the settlement date, the accrued liability, net of related receivables, was \$1,250,000. We paid Knoll \$70,000 and issued to Knoll 175,000 shares of Incara Pharmaceuticals common stock (with a fair value of approximately \$416,000) in exchange for a full

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release of all amounts owed to Knoll. This settlement eliminated the accrued liability owed to Knoll and reduced our net loss by \$767,000 in fiscal 2001.

On December 29, 1999, we sold our anti-infectives division, known as Incara Research Laboratories, or IRL, to a private pharmaceutical company for \$11,000,000. The transaction involved the sale of assets associated with IRL, including rights under the collaboration with Merck & Co., Inc. and the assumption of related liabilities by the purchaser. We remain contingently liable through May 2007 on debt and lease obligations of approximately \$6,763,000 assumed by the purchaser, including primarily the IRL facility lease in Cranbury, New Jersey. We recognized a gain of \$9,751,000 on the sale of IRL in the first quarter of fiscal 2000. The effect of the IRL transaction on Incara's financial statements for the fiscal year ended September 30, 2000 is shown in "Unaudited Pro Forma Consolidated Financial Information."

On March 31, 2000, Incara Pharmaceuticals acquired all of the minority interests of Aeolus Pharmaceuticals, Inc. and Renaissance Cell Technologies, Inc., which has since changed its name to Incara Cell Technologies, Inc. Prior to this acquisition, Incara owned 78.0% of Incara Cell Technologies and 65.8% of Aeolus. Incara Pharmaceuticals issued 1,220,041 shares of its common stock for the subsidiaries' minority ownership. We accounted for the acquisition using the purchase method of accounting with a total purchase price of \$6,664,000. We allocated the total purchase price to purchase of in-process research and development and immediately charged it to operations because at the date of the acquisition the in-process research purchased was in preclinical stages, feasibility had not been established and we deemed it to have no alternative future use. We estimated at the acquisition date that Incara Cell Technologies and Aeolus would need to spend in excess of an additional \$50,000,000 to complete the research and development and that it would be at least 2006 before the research and development is completed. We might share the cost to complete research and development for these programs with collaborative partners in the future. The acquisition of these minority interests should not have a significant impact on future operating results because we previously recognized all losses of Incara Cell Technologies and Aeolus due to our majority interest in the subsidiaries.

In January 2001, we closed on a collaborative and financing transaction with Elan. As part of the transaction, Elan and Incara Pharmaceuticals formed a Bermuda corporation, Incara Development, Ltd., to develop OP2000. We own all of the common stock and 60.2% of the non-voting preferred shares of Incara Development and Elan owns 39.8% of the non-voting preferred shares of Incara Development. Of the outstanding combined common and non-voting preferred shares of Incara Development, we own 80.1% and Elan owns 19.9%. As part of the transaction, Elan and Incara Pharmaceuticals entered into license agreements under which we licensed to Incara Development the OP2000 compound and Elan licensed to Incara Development a proprietary drug delivery technology.

As part of the transaction, Elan purchased 825,000 shares of Incara Pharmaceuticals' common stock, 28,457 shares of Incara Series B non-voting convertible preferred stock and a five-year warrant to purchase 22,191 shares of Series B preferred stock at an exercise price of \$72.12 per share for an aggregate purchase price of \$4,000,000. Each share of Series B preferred stock is convertible into ten shares of our common stock.

Elan also purchased 12,015 shares of Incara Series C convertible exchangeable non-voting preferred stock with a face value of \$1,000 per share, or a total of \$12,015,000. Incara Pharmaceuticals contributed to Incara Development the proceeds from the issuance of the Series C preferred stock to Elan in exchange for its securities of Incara Development. Elan also contributed \$2,985,000 to Incara Development for its shares of preferred stock of Incara Development. In addition, Elan granted Incara Development a license to Elan's proprietary drug delivery technology for a license fee of \$15,000,000.

The Series C preferred stock bears a mandatory stock dividend of 7%, compounded annually. The Series C preferred stock is exchangeable at the option of Elan at any time for all of the preferred stock of Incara Development held by Incara Pharmaceuticals which, if exchanged, would give Elan ownership of 50% of the initial amount of combined common and preferred stock of Incara Development. After December 20, 2002, the Series C preferred stock is convertible by Elan into shares of our Series B preferred stock at the rate of \$64.90 per share. If the Series C preferred stock is outstanding as of December 21, 2006, we will exchange the Series C preferred stock and accrued dividends, at our option, for either cash or shares of our stock and warrants having a then fair market value of the amount due.

Upon the completion of enrollment of a Phase 2/3 clinical trial for OP2000, Elan will purchase \$1,000,000 of our Series B preferred stock at a per share price that will be ten times the greater of (1) the average per share price of Incara Pharmaceuticals common stock for the day prior to the purchase, or (2) a 25% premium to the average daily price per share of Incara Pharmaceuticals common stock for the 60 trading day period immediately prior to the purchase. In addition, as part of the payment, we will issue to Elan a five-year warrant for 20% of the shares of Series B preferred stock purchased by Elan at that time. The exercise price of the Series B preferred stock under this warrant will be equal to twice the per share purchase price of the Series B preferred stock purchased on the same date. However, if the purchase price of the Series B preferred stock is less than \$8.00 per share, the purchase of this stock will be limited to 150,000 shares of Series B preferred stock and will be at Elan's option.

Elan and Incara Pharmaceuticals intend to fund Incara Development pro rata, based on their respective percentage ownership of the combined outstanding common and preferred stock of Incara Development. Subject to mutual agreement, Elan will lend us up to \$4,806,000 to fund our pro rata share of development funding for Incara Development. In return, we issued a convertible promissory note that bears interest at 10% compounded semi-annually on the amount outstanding thereunder. After December 20, 2002, the note is convertible at the option of Elan into shares of Series B preferred stock at \$43.27 per share. The note will mature on December 21, 2006, when the outstanding principal plus accrued interest will be due and payable. We have the option to repay the note either in cash or in shares of Series B preferred stock and warrants having a then fair market value of the amount due. As of September 30, 2001, we had not borrowed any funds pursuant to this note. However, we borrowed \$857,000 under the note in October 2001.

For financial reporting purposes, the value recorded as Incara's investment in Incara Development is the same as the fair value of the Series C preferred stock issued, which was \$12,015,000. The technology obtained by Incara Development from Elan was expensed at inception because the feasibility of using the contributed technology in conjunction with OP2000 had not been established and Incara Development had no alternative future use for the contributed technology. We immediately expensed as "Equity in loss of Incara Development" our investment in Incara Development, reflective of our pro rata interest in Incara Development. During the second quarter of fiscal 2001, the Company initially recorded the value of the Series C Stock as \$5,496,000. Pursuant to an independent valuation of the Series C Stock completed subsequent to the end of the fiscal year, the Company revised the value of the Series C Stock to \$12,015,000 and increased the related charge to "Equity in loss of Incara Development". From the date of issue up to December 21, 2006, we will accrete the Series C preferred stock for its 7% dividend from its recorded value up to

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its redemption value.

While we own 80.1% of the outstanding stock of Incara Development, Elan has retained significant minority investor rights, including 50% control of the management committee which oversees the OP2000 program, that are considered "participating rights" as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Incara Pharmaceuticals does not consolidate the financial statements of Incara Development, but instead accounts for its investment in Incara Development under the equity method of accounting. Net losses of Incara Development will be recognized by Incara at its 80.1% interest to the extent of Incara Pharmaceuticals' investments, advances and commitments to make future investments in or advances to Incara Development. Further, because Elan can exchange its investment in our Series C preferred stock for Incara Pharmaceuticals' 30.1% preferred interest in Incara Development, we will only recognize 50% of any accumulated net earnings of Incara Development. During the fiscal year ended September 30, 2001, Incara Pharmaceuticals' equity in loss of Incara Development was \$12,650,000, which included \$12,015,000 for Incara Pharmaceuticals' interest in the immediate write-off at inception of the technology contributed by Elan to Incara Development.

In August 2001, we sold 4,323,044 shares of common stock and warrants to purchase 1,037,531 shares of common stock with an average warrant exercise price of approximately \$2.02 per share for net proceeds of approximately \$6,423,000, net of approximately \$556,000 of issuance costs.

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Results of Operations

Fiscal Year Ended September 30, 2001 Compared to Fiscal Year Ended September 30, 2000

We incurred net losses attributable to common stockholders of \$22,865,000 and \$6,665,000 for the fiscal years ended September 30, 2001 and 2000, respectively. The net loss for the fiscal year ended September 30, 2001 was reduced by a \$767,000 gain recognized on the settlement of a disputed accrued liability for a discontinued program and increased by the \$12,650,000 equity in loss of Incara Development. The net loss for the fiscal year ended September 30, 2000 was reduced by the \$9,751,000 gain on the sale of IRL.

We had cell processing revenue of \$44,000 for the fiscal year ended September 30, 2001. This revenue resulted from fees we earned for processing liver cells that are used for research purposes by other pharmaceutical companies. Contract revenue of \$100,000 for the fiscal year ended September 30, 2000 resulted from a collaboration that we sold with our IRL division in December 1999.

Our research and development, or R&D, expenses decreased \$125,000, or 2%, to \$7,520,000 for fiscal 2001 from \$7,645,000 for fiscal 2000. R&D expenses for fiscal 2000 included \$1,339,000 of expenses for IRL, which was sold in December 1999.

R&D expenses for our liver cell program increased \$1,806,000, or 150%, to \$3,007,000 for fiscal 2001 from \$1,201,000 for fiscal 2000. Expenses were higher in fiscal 2001 due to increased activity in the program and the establishment of our own laboratory facility for the program. We incurred increases in personnel, sponsored research, consultants and laboratory supplies.

R&D expenses for our antioxidant program increased \$1,249,000, or 74%, to \$2,943,000 for fiscal 2001 from \$1,694,000 for fiscal 2000. R&D expenses were

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higher in fiscal 2001 due to increased activity in the program, including the costs of process improvement, scale-up and preclinical testing.

In January 2001, Incara Pharmaceuticals transferred the rights to its OP2000 compound being developed for inflammatory bowel disease to Incara Development. In January 2001, we also initiated a Phase 2/3 clinical trial in patients with ulcerative colitis, a form of inflammatory bowel disease. R&D expenses for OP2000 incurred prior to December 21, 2000 were on behalf of Incara Pharmaceuticals, while costs for OP2000 incurred thereafter were on behalf of Incara Development. Expenses for OP2000 during fiscal 2000 were \$1,712,000. Amounts billable to Incara Development for OP2000 for expenses incurred and work performed by Incara Pharmaceuticals are netted against R&D expenses. Subsequent to our investment in Incara Development, our expenses associated with OP2000 development flow through "Equity in loss of Incara Development." While Incara Pharmaceuticals owns 80.1% of the outstanding stock of Incara Development, Elan has retained significant minority investor rights, including 50% control of the management committee that oversees the OP2000 program, which are considered "participating rights" as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Incara Pharmaceuticals does not consolidate the financial statements of Incara Development, but instead accounts for its investment in Incara Development under the equity method of accounting. Incara Pharmaceuticals will recognize 80.1% of Incara Development's net losses to the extent of Incara Pharmaceuticals' investments, advances and commitments to make future investments in or advances to Incara Development. Further, since Elan can exchange its investment in Incara Pharmaceuticals' Series C Stock for Incara Pharmaceuticals' 30.1% preferred interest in Incara Development, Incara Pharmaceuticals will only recognize 50% of any accumulated net earnings of Incara Development. During fiscal 2001, our equity in loss of Incara Development was \$12,650,000, which included \$12,015,000 for Incara Pharmaceuticals' interest in the immediate write-off at inception of the technology contributed by Elan to Incara Development.

Purchased in-process research and development expenses for fiscal 2000 resulted from the acquisition of the minority interests of Aeolus and Incara Cell Technologies in March 2000. The acquisition was accounted for using the purchase method of accounting. The total purchase price of \$6,664,000 was allocated to purchase of in-process research and development and immediately charged to operations because the in-process research purchased was in preclinical stages and feasibility had not been established at the date of the acquisition. At that time, we deemed the in-process research to have no alternative future use.

General and administrative, or G&A, expenses increased \$464,000, or 18%, to \$3,077,000 for fiscal 2001 from \$2,613,000 for fiscal 2000. These increases resulted primarily from expenses related to personnel and financing activities, including higher investor relations, legal and accounting expenses.

We accreted \$652,000 of dividends on our Series C preferred stock during fiscal 2001. From the date of issue until the earlier of December 21, 2006 or the date the Series C preferred stock is exchanged or converted, we will accrete the Series C preferred stock for the 7% dividend, compounded annually from its recorded value up to its redemption value.

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Fiscal Year Ended September 30, 2000 Compared to Fiscal Year Ended September 30, 1999

Our net loss of \$6,665,000 for fiscal 2000 was \$12,933,000 less than the \$19,598,000 net loss for fiscal 1999. The net loss for fiscal 2000 resulted

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from the net effect of recognizing a \$9,751,000 gain on the sale of IRL, offset by fiscal 2000 operating expenses and the write-off of \$6,664,000 for purchased in-process research and development in connection with the acquisition of the minority interests of Aeolus and Incara Cell Technologies.

Contract and license fee revenue for fiscal 2000 was \$100,000, as compared to \$2,088,000 for fiscal 1999. The revenue in both fiscal years resulted from an IRL collaboration with Merck. We will not receive any additional revenue from this collaboration, because it was sold with the other IRL assets in December 1999.

Our research and development expenses decreased \$11,351,000, or 60%, to \$7,645,000 in fiscal 2000 from \$18,996,000 in fiscal 1999. The lower expenses were primarily due to the result of discontinuing our bucindolol development program in the fourth quarter of fiscal 1999 and to the sale of our IRL operation in December 1999.

During the last quarter of fiscal 1999, we discontinued our bucindolol development program and, therefore, we did not incur any bucindolol-related expenses for fiscal 2000. During fiscal 1999, we incurred \$6,469,000 of bucindolol-related R&D expenses.

Because we sold IRL at the end of December 1999, we did not incur any significant R&D expenses for IRL after December 1999. R&D expenses for IRL were \$1,339,000 for fiscal 2000 and \$8,245,000 for fiscal 1999.

We incurred \$1,712,000 of R&D expenses for OP2000 during fiscal 2000, versus \$228,000 during fiscal 1999. The higher expenses in fiscal 2000 were primarily due to costs incurred in connection with our Phase 1 clinical trials that began in October 1999 and were completed in April 2000, as well as preparation for a Phase 2/3 clinical trial.

R&D expenses for our liver cell program increased \$369,000, or 44%, to \$1,201,000 for fiscal 2000 from \$832,000 for fiscal 1999. The higher expenses in fiscal 2000 resulted primarily from more R&D staff time being devoted to the program.

R&D expenses for our antioxidant program decreased \$418,000, or 20%, to \$1,694,000 for fiscal 2000 from \$2,112,000 for fiscal 1999. The decrease in expenses from fiscal 1999 to fiscal 2000 was primarily due to the reduction of outside contract services and sponsored research costs.

General and administrative expenses decreased \$432,000, or 14%, to \$2,613,000 for fiscal 2000 from \$3,045,000 for fiscal 1999. The higher G&A expenses in fiscal 1999 were primarily for expenses related to the bucindolol program, which we terminated in the last quarter of fiscal 1999, and the IRL operation, which we sold in December 1999.

In January 2000, our Board of Directors authorized the repurchase of up to \$2,000,000 of our common stock during the following two months through purchases on the stock market. During fiscal 2000, we repurchased a total of 140,100 shares of our common stock at a total cost of \$412,000.

Liquidity and Capital Resources

At September 30, 2001, we had cash and cash equivalents of \$5,453,000, a decrease of \$1,102,000 from September 30, 2000. Cash decreased primarily due to operating losses of \$10,553,000 for fiscal 2001, offset by net proceeds of \$6,423,000 from the sale of common stock and warrants to purchase common stock in August 2001 and \$4,000,000 received from the net effect of investment transactions with Elan in January 2001.

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During the past 21 months, which is the period in which we have operated without ongoing expenses for the development of bucindolol and IRL operations, we have incurred average operational expenses of approximately \$10,000,000 per year, on an annualized basis, including expenses of our R&D programs, but excluding non-cash charges for the purchase of in-process research and development. We anticipate our annual net operational costs to remain at approximately this level, or slightly higher, during fiscal 2002 and for the foreseeable future, although our ongoing cash requirements will depend on numerous factors, particularly the progress of our R&D programs and our ability to negotiate and complete collaborative agreements. In order to fund on-going operating cash requirements, we intend to raise significant additional funds during 2002 and beyond. We intend to:

- . establish new collaborations for our current research programs that include initial cash payments and on-going research support;
- . sell additional shares of our stock;

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- . borrow additional cash from Elan under the terms of an existing note arrangement that we have with Elan to meet our obligations for Incara Development; and
- . to the extent possible, sell shares of our common stock under an equity financing line we currently have with Torneaux Fund Ltd.;

There are uncertainties as to all of these potential sources of capital. Due to market conditions and other limitations on the stock offerings, we might not be able to sell securities under these arrangements, or raise other funds on terms acceptable or favorable to us. At times it is difficult for biotechnology companies to raise funds in the equity markets. Any additional equity financing, if available, would likely result in substantial dilution to Incara Pharmaceuticals' stockholders.

Similarly, our access to capital might be restricted because we might not be able to enter into collaborations for any of our programs or to enter into any collaborations on terms acceptable or favorable to us due to conditions in the pharmaceutical industry or in the economy in general or based on the prospects of any of our programs. Even if we are successful in obtaining collaborations for any of our programs, we might have to relinquish rights to technologies, product candidates or markets that we might otherwise develop ourselves.

We may borrow up to \$4,806,000 through December 21, 2003 under the note arrangement with Elan to fund our 80.1% pro rata interest in the operating costs of Incara Development. We had not borrowed any funds under this note at September 30, 2001. We borrowed \$857,000 under the note in October 2001. Advances under the note are subject to the mutual consent of Elan and Incara Pharmaceuticals. The note matures on December 21, 2006.

The Torneaux equity line is available to us until February 28, 2002. Under the equity line, we can require Torneaux to purchase our common stock approximately once per month, provided our common stock price is \$2.00 or more. Assuming the price of our stock does not increase to \$3.00 or higher, we are limited to selling a maximum of approximately \$250,000 of our stock to Torneaux each month. Since July 1, 2001, the price of our stock has traded from \$1.05 to \$1.95 and on December 14, 2001 closed at \$1.75.

If we are unable to enter into new collaborations or raise additional

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capital to continue to support our operations, we might be required to scale back, delay or discontinue one or more of our programs, which could have a material adverse affect on our business. Reduction or discontinuation of programs could result in additional charges, which would be reflected in the period of the reduction or discontinuation.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

See Index to Financial Statements on page F-1.

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

Not applicable.

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PART III

Certain information required by Part III is omitted from this report because the Registrant will file a definitive proxy statement for its 2002 Annual Meeting of Stockholders (the "Proxy Statement") within 120 days after the end of its fiscal year pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended, and the information included therein is incorporated herein by reference to the extent provided below.

Item 10. Directors and Executive Officers of the Registrant.

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

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

To the Company's knowledge, there were no reports required under Section 16(a) of the Securities Exchange Act of 1934 that were not timely filed during the fiscal year ended September 30, 2001.

Item 11. Executive Compensation.

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

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

The information required by Item 12 of Form 10-K is incorporated by reference to the information under the heading "Other Information - Principal

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Stockholders" in the Proxy Statement.

Item 13. Certain Relationships and Related Transactions.

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

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PART IV

Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a) The following Financial Statements, Financial Statement Schedules and Exhibits are filed as part of this report or incorporated herein by reference:

(1) Financial Statements.

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

(2) Financial Statement Schedules.

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

(3) Exhibits.

Exhibit Number	Description of Document	Incorporated Registrant's Form
3.1	Certificate of Incorporation, as amended.....	8-K
3.2	Bylaws.....	S-1
3.3	Amendment to Bylaws dated September 23, 1999.....	10-K
4.1	Form of Common Stock Certificate.....	10-K
4.2	Form of Warrant to be issued to Torneaux Fund Ltd.....	S-1
4.3	Warrant to Purchase Shares of Series B Preferred Stock issued to Elan International Services, Ltd.....	10-Q
4.4	Form of Warrant issued to investors in August 2001.....	S-1
10.4*	License Agreement between Duke University and Aeolus Pharmaceuticals, Inc., dated July 21, 1995.....	S-1
10.9	Office Lease between Highwoods/Forsyth Limited Partnership and Intercardia, Inc., dated April 24, 1995.....	S-1
10.12	Incara Pharmaceuticals Corporation 1995 Employee Stock Purchase Plan, as amended.....	S-8
10.19	Lease Amendment Number One, dated March 6, 1996, to Office Lease between Highwoods/Forsyth Limited Partnership and Intercardia Inc.....	10-Q
10.22	Lease Amendment Number Two, dated March 14, 1997, to Office Lease between Highwoods/Forsyth Limited Partnership and Intercardia, Inc.....	10-Q
10.23	Sponsored Research Agreement between The University of North Carolina at Chapel Hill and Renaissance Cell Technologies, Inc.	

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10.24	dated September 4, 1997.....	10-K
	Sponsored Research Agreement between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc., dated September 11, 1997	10-K
10.31	Lease Agreement dated September 19, 1996, as amended, between Cedar Brook Corporate Center, L.P. and Transcell Technologies, Inc., as assigned to Intercardia, Inc. effective May 8, 1998.....	10-Q
10.34*	License, Development, Marketing and Clinical Trials Supply Agreement between Opocrin S.p.A. and Intercardia, Inc., dated July 20, 1998.....	10-K
10.35	Employment Agreement between Richard W. Reichow and Intercardia, Inc., dated November 16, 1998.....	10-K
10.36	Employment Agreement between David P. Ward and Intercardia, Inc., dated November 16, 1998.....	10-K
10.37	Employment Agreement between John P. Richert and Intercardia, Inc., dated November 16, 1998.....	10-K
10.38	Employment Agreement between W. Bennett Love and Intercardia, Inc., dated November 16, 1998.....	10-K
10.39*	Development, Manufacturing, Marketing and License Agreement, effective as of December 19, 1996, among Knoll AG, CPEC, Inc. and Intercardia, Inc.....	10-Q

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Exhibit Number	Description of Document	Incorpora ----- Registrant's Form	
10.40	Exchange Agreement dated July 15, 1999, between Intercardia, Inc. and Interneuron Pharmaceuticals, Inc.....	8-K	0
10.41	Registration Rights Agreement dated July 15, 1999, between Interneuron Pharmaceuticals, Inc. and Intercardia, Inc.....	8-K	0
10.42	Amended and Restated Limited Liability Company Agreement of CPEC LLC dated July 15, 1999, among CPEC LLC, Intercardia, Inc. and Interneuron Pharmaceuticals, Inc.....	8-K	0
10.43	Assignment, Assumption and License Agreement dated July 15, 1999, between CPEC LLC and Intercardia, Inc.....	8-K	0
10.44	Incara Pharmaceuticals Corporation 1997 Equity Incentive Plan, Form of Restricted Stock Award Agreement (7-month vesting) and Form of Restricted Stock Award Agreement (3-year vesting).....	8-K	1
10.47	Form of Severance Agreement dated September 23, 1999 with Clayton I. Duncan, Richard W. Reichow, David P. Ward, John P. Richert and W. Bennett Love.....	10-K	0
10.48*	Asset Purchase Agreement dated December 17, 1999.....	10-K	0
10.49*	License Agreement dated August 23, 1999 between The University of North Carolina at Chapel Hill and Renaissance Cell Technologies, Inc.....	10-Q	0
10.50*	License Agreement, effective July 1996, between Albert Einstein College of Medicine of Yeshiva University and Renaissance Cell Technologies, Inc.....	10-Q	0
10.51	Registration Rights Agreement dated August 17, 2000 between Incara Pharmaceuticals Corporation and Torneaux Fund Ltd.....	Proxy	0
10.52	Common Stock Purchase Agreement dated August 17, 2000 between Incara Pharmaceuticals Corporation and Torneaux Fund Ltd.....	Proxy	0

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10.53	Employment Agreement between Clayton I. Duncan and Incara Pharmaceuticals Corporation, dated December 11, 2000.....	10-K	0
10.55	Securities Purchase Agreement among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited dated as of December 21, 2000.....	8-K	0
10.56*	License Agreement dated November 17, 2000 between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc.....	10-Q	1
10.57	Office Lease between Highwoods Realty Limited Partnership and Incara Pharmaceuticals Corporation, dated January 25, 2001.....	10-Q	1
10.58*	Subscription, Joint Development and Operating Agreement dated January 19, 2001 among Elan Corporation, plc, Elan Pharma International Ltd., Elan International Services, Ltd., Incara Pharmaceuticals Corporation and Incara Development, Ltd.....	10-Q	1
10.59*	License Agreement dated January 19, 2001 between Incara Pharmaceuticals Corporation and Incara Development, Ltd.....	10-Q	1
10.60*	License Agreement dated January 19, 2001 between Elan Corporation, plc, Elan Pharma International Ltd. and Incara Development, Ltd.....	10-Q	1
10.61	Convertible Promissory Note dated December 21, 2000 issued by Incara Pharmaceuticals Corporation to Elan Pharma International Ltd.....	10-Q	1
10.62	Registration Rights Agreement dated December 21, 2000 among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Ltd.....	10-Q	1
10.63	Incara Pharmaceuticals Corporation 1994 Stock Option Plan, as amended on March 27, 2001.....	S-8	0
10.64	Agreement and Amendment, effective as of January 22, 2001, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited.....	10-Q	0
10.65	Second Agreement and Amendment, effective as of January 22, 2001, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited.....	10-Q	0
10.66	Third Agreement and Amendment, effective as of January 22, 2001, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Limited.....	8-K	0
10.67	Amendment dated May 1, 2001 to Employment Agreement between Richard W. Reichow and Intercardia, Inc., dated November 16, 1998..	S-1	0

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Exhibit Number	Description of Document	Incorpora ----- Registrant's Form
10.68	Amendment dated May 1, 2001 to Employment Agreement between David P. Ward and Intercardia, Inc., dated November 16, 1998.....	S-1
10.69	Amendment dated May 1, 2001 to Employment Agreement between John P. Richert and Intercardia, Inc., dated November 16, 1998.....	S-1
10.70	Amendment dated May 1, 2001 to Employment Agreement between W. Bennett Love and Intercardia, Inc., dated November 16, 1998.....	S-1
10.71	Amendment No. 5, effective June 30, 2001, to Sponsored Research	

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	Agreement between the University of North Carolina at Chapel Hill and Incara Cell Technologies, Inc.....	10-Q
10.72	Amendment 5, effective as of July 1, 2001, to Sponsored Research Agreement between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc.....	10-Q
10.73	Master Loan and Security Agreement between Transamerica Technology Finance Corporation, Incara Pharmaceuticals Corporation, Aeolus Pharmaceuticals, Inc. and Incara Cell Technologies, Inc., dated October 31, 2001.....	
10.74	Commencement Agreement and Lease Amendment Number One, dated November 1, 2001, to Office Lease between Highwoods Realty Limited Partnership and Incara Pharmaceuticals Corporation.....	
21.1	List of Subsidiaries.....	
23.1	Consent of PricewaterhouseCoopers LLP, Independent Accountants.....	

*confidential treatment granted

(b) Reports on Form 8-K.

(1) Filed August 30, 2001 to provide a pro forma balance sheet for June 30, 2001.

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INDEX TO FINANCIAL STATEMENTS

Incara Pharmaceuticals Corporation

Fiscal Years Ended September 30, 2001, 2000 and 1999

Report of Independent Accountants.	
Consolidated Balance Sheets - As of September 30, 2001 and 2000.	
Consolidated Statements of Operations - For the fiscal years ended September 30, 2001, 2000 and 1999.	
Consolidated Statements of Stockholders' Equity - For the fiscal years ended September 30, 2001, 2000 and 1999.	
Consolidated Statements of Cash Flows - For the fiscal years ended September 30, 2001, 2000 and 1999.	
Notes to Consolidated Financial Statements	

Incara Development, Ltd.

Report of Independent Accountants.	
Balance Sheet.	
Statement of Operations.	
Statement of Stockholders' Deficit.	
Statement of Cash Flows	

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Notes to Financial Statements

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REPORT OF INDEPENDENT ACCOUNTANTS

TO THE BOARD OF DIRECTORS AND STOCKHOLDERS OF
INCARA PHARMACEUTICALS CORPORATION

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Incara Pharmaceuticals Corporation and its subsidiaries (the "Company") at September 30, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2001, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Raleigh, North Carolina
December 20, 2001

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INCARA PHARMACEUTICALS CORPORATION

CONSOLIDATED BALANCE SHEETS

(Dollars in thousands, except per share data)

2

ASSETS

Current assets:

Cash and cash equivalents	\$	5,
Marketable securities		
Accounts receivable from Incara Development		1,
Other accounts receivable		
Prepays and other current assets		

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Total current assets	6,
Property and equipment, net	1,
Other assets	\$ 8,
	=====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	\$ 1,
Accrued expenses	
Accumulated losses of Incara Development in excess of investment	
Current portion of capital lease obligations	
Current portion of note payable	

Total current liabilities	2,
Long-term portion of capital lease obligations	
Stockholders' equity:	
Preferred stock, \$.01 par value per share, 3,000,000 shares authorized:	
Series C convertible exchangeable preferred stock, 20,000 shares authorized; 12,015 and no shares issued and outstanding as of September 30, 2001 and 2000, respectively (liquidation value of \$12,667)	
Series B convertible preferred stock, 600,000 shares authorized; 28,457 and no shares issued and outstanding as of September 30, 2001 and 2000, respectively	
Common stock, \$.001 par value per share, 40,000,000 shares authorized; 12,717,093 and 7,365,849 shares issued and outstanding at September 30, 2001 and 2000, respectively	112,
Additional paid-in capital	(
Restricted stock	
Accumulated deficit	(106,

Total stockholders' equity	5,

	\$ 8,
	=====

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

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INCARA PHARMACEUTICALS CORPORATION

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

Fiscal Year Ended S	
2001	2000
-----	-----

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Revenue:		
Cell processing revenue	\$ 44	\$ -
Contract revenue	-	100
	-----	-----
Total revenue	44	100
	-----	-----
Costs and expenses:		
Research and development	7,520	7,645
Purchase of in-process research and development	-	6,664
General and administrative	3,077	2,613
	-----	-----
Total costs and expenses	10,597	16,922
	-----	-----
Loss from operations	(10,553)	(16,822)
Gain on sale of division	-	9,751
Gain on settlement of accrued liability	767	-
Equity in loss of Incara Development	(12,650)	-
Investment income, net	223	406
	-----	-----
Net loss	(22,213)	(6,665)
Preferred stock dividend and accretion	(652)	-
	-----	-----
Net loss attributable to common stockholders	\$ (22,865)	\$ (6,665)
	=====	=====
Net loss per weighted share attributable to common stockholders:		
Basic and diluted	\$ (2.78)	\$ (1.21)
	=====	=====
Weighted average common shares outstanding	8,233	5,522
	=====	=====

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

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INCARA PHARMACEUTICALS CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Dollars in thousands)

	Common Stock	Series A Preferred Stock
	Number of Shares	Par Value
	-----	-----
Balance at September 30, 1998.....	7,289,153	\$ 7
Exercise of common stock options.....	21,851	-
Amortization of deferred compensation.....	-	-

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Proceeds from offerings of Employee Stock Purchase Plan.....	67,851	-
Contribution of payables to capital by Interneuron.....	-	-
Cancellation of common stock returned by Interneuron.....	(4,229,381)	(4)
Common stock issued to unrelated parties in conjunction with Transcell Merger.....	867,583	1
Write-off of deferred compensation related to common stock options cancelled.....	-	-
Restricted common stock sold to employees and consultants.....	1,209,912	1
Stock-based compensation and amortization of Restricted Stock....	-	-
Net loss for the fiscal year ended September 30, 1999.....	-	-
	-----	-----
Balance at September 30, 1999.....	5,226,969	5
Exercise of common stock options.....	140,000	-
Proceeds from offerings of Employee Stock Purchase Plan.....	208,744	-
Common stock issued in conjunction with Transcell Merger.....	856,861	1
Common stock issued in conjunction with Aeolus and Cell Technologies mergers.....	1,220,041	1
Stock-based compensation and amortization of Restricted Stock....	-	-
Restricted Stock forfeited.....	(146,666)	-
Common stock repurchased.....	(140,100)	-
Net loss for the fiscal year ended September 30, 2000.....	-	-
	-----	-----
Balance at September 30, 2000.....	7,365,849	7
Sale of common stock and Series B preferred stock and warrants to Elan, net of issuance costs of \$25.....	825,000	1
Sale of common stock pursuant to stock offering, net of issuance costs of \$556	4,323,044	5
Series C preferred stock issued to Elan for investment in Incara Development	-	-
Series C preferred stock dividends and accretion.....	-	-
Exercise of common stock options.....	27,360	-
Proceeds from offerings of Employee Stock Purchase Plan.....	58,449	-
Stock-based compensation and amortization of Restricted Stock....	-	-
Restricted Stock forfeited.....	(22,784)	-
Net shares of common stock issued for settlement of accrued liability	140,175	-
Net loss for the fiscal year ended September 30, 2001.....	-	-
	-----	-----
Balance at September 30, 2001.....	12,717,093	\$ 13
	=====	=====

	Additional Paid-in Capital	Restricted Stock	Co
	-----	-----	-----
Balance at September 30, 1998.....	\$ 78,399	\$ -	
Exercise of common stock options.....	53	-	
Amortization of deferred compensation.....	-	-	
Proceeds from offerings of Employee Stock Purchase Plan.....	134	-	
Contribution of payables to capital by Interneuron.....	2,421	-	
Cancellation of common stock returned by Interneuron.....	4	-	
Common stock issued to unrelated parties in conjunction with Transcell Merger.....	(1)	-	
Write-off of deferred compensation related to common stock options cancelled.....	(259)	-	
Restricted common stock sold to employees and consultants.....	755	(755)	
Stock-based compensation and amortization of Restricted Stock....	266	11	

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Net loss for the fiscal year ended September 30, 1999.....	-	-
Balance at September 30, 1999.....	81,772	(744)
Exercise of common stock options.....	50	-
Proceeds from offerings of Employee Stock Purchase Plan.....	122	-
Common stock issued in conjunction with Transcell Merger.....	(1)	-
Common stock issued in conjunction with Aeolus and Cell Technologies mergers.....	6,663	-
Stock-based compensation and amortization of Restricted Stock.....	838	424
Restricted Stock forfeited.....	(81)	81
Common stock repurchased.....	(412)	-
Net loss for the fiscal year ended September 30, 2000.....	-	-
Balance at September 30, 2000.....	88,951	(239)
Sale of common stock and Series B preferred stock and warrants to Elan, net of issuance costs of \$25.....	3,973	-
Sale of common stock pursuant to stock offering, net of issuance costs of \$556	6,418	-
Series C preferred stock issued to Elan for investment in Incara Development	12,014	-
Series C preferred stock dividends and accretion.....	652	-
Exercise of common stock options.....	13	-
Proceeds from offerings of Employee Stock Purchase Plan.....	89	-
Stock-based compensation and amortization of Restricted Stock.....	83	117
Restricted Stock forfeited.....	(10)	10
Net shares of common stock issued for settlement of accrued liability.....	333	-
Net loss for the fiscal year ended September 30, 2001.....	-	-
Balance at September 30, 2001.....	\$ 112,516	\$ (112)

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

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INCARA PHARMACEUTICALS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Fiscal Year	
	----- 2001 -----	
Cash flows from operating activities:		
Net loss	\$ (22,213)	\$
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	164	
Noncash compensation	200	

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Purchase of in-process research and development	-	
Gain on sale of division	-	
Equity in loss of Incara Development	12,984	
Loss on disposal of property and equipment	-	
Gain on settlement of accrued liability	(767)	
Change in assets and liabilities:		
Accounts receivable from Incara Development	(1,147)	
Other accounts receivable	(54)	
Prepays and other assets	(246)	
Accounts payable and accrued expenses	839	
	<hr/>	
Net cash used in operating activities	(10,240)	
	<hr/>	
Cash flows from investing activities:		
Proceeds from sale of division	-	
Proceeds from sales and maturities of marketable securities	4,678	
Purchases of marketable securities	-	
Purchases of property and equipment	(1,312)	
	<hr/>	
Net cash provided by investing activities	3,366	
	<hr/>	
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants	9,070	
Proceeds from issuance of Series B preferred stock and warrants	1,430	
Proceeds from capital leases	-	
Repurchase of Incara Pharmaceuticals common stock	-	
Proceeds from notes payable	-	
Principal payments on notes payable	(27)	
Principal payments on capital lease obligations	(23)	
Advances from Interneuron, net	-	
	<hr/>	
Net cash provided by (used by) financing activities	10,450	
	<hr/>	
Net increase (decrease) in cash and cash equivalents	3,576	
Cash and cash equivalents at beginning of period	1,877	
	<hr/>	
Cash and cash equivalents at end of period	\$ 5,453	\$
	<hr/> <hr/>	
Supplemental disclosure of cash flow information:		
Cash payments of interest	\$ 15	\$
Supplemental disclosure of non-cash investing and financing activities:		
Common stock issued in settlement of accrued liability	\$ 416	\$
Retirement of common stock in connection with settlement of accrued liability	\$ 83	\$
Series C preferred stock issued for investment in Incara Development..	\$ 12,015	\$
Series C preferred stock dividend accreted	\$ 652	\$
Restricted Stock forfeited	\$ 10	\$
Contribution of payables to capital by Interneuron	\$ -	\$
Property and equipment acquired through financing arrangements	\$ -	\$

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

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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A. NATURE OF THE BUSINESS

The Company is developing therapies focused on tissue protection, repair and regeneration. In particular, the Company is focused on developing adult liver stem cell therapy for the treatment of liver failure. The Company is also conducting research and development of a series of catalytic antioxidant molecules and, in collaboration with Elan Corporation, plc, an Irish company, and its subsidiaries ("Elan"), is conducting a Phase 2/3 clinical trial of an ultra-low molecular weight heparin for the treatment of ulcerative colitis.

The "Company" refers collectively to Incara Pharmaceuticals Corporation, a Delaware corporation ("Incara Pharmaceuticals"), its two wholly owned subsidiaries, Aeolus Pharmaceuticals, Inc., a Delaware corporation ("Aeolus"), and Incara Cell Technologies, Inc., a Delaware corporation ("Cell Technologies"), formerly Renaissance Cell Technologies, Inc., as well as its equity investee, Incara Development, Ltd., a Bermuda corporation ("Incara Development"). As of September 30, 2001, Incara Pharmaceuticals owned 80.1% of Incara Development and 35.0% of CPEC LLC ("CPEC").

Until July 15, 1999, Incara Pharmaceuticals was a majority-owned subsidiary of Interneuron Pharmaceuticals, Inc. ("Interneuron"). On July 15, 1999, Incara Pharmaceuticals restructured its corporate relationship with Interneuron to reduce Interneuron's majority ownership of Incara Pharmaceuticals in exchange for an increased ownership by Interneuron of CPEC (the "Restructuring"). Prior to the Restructuring, CPEC was a subsidiary owned 80.1% by Incara Pharmaceuticals and 19.9% by Interneuron. As a preliminary step in the Restructuring, Incara Pharmaceuticals acquired Interneuron's 19.9% interest in CPEC. Incara Pharmaceuticals redeemed 4,229,381 of the 4,511,084 shares of Incara Pharmaceuticals common stock owned by Interneuron, in exchange for a 65.0% ownership of CPEC and cancellation of liabilities owed to Interneuron by Incara Pharmaceuticals and CPEC that totalled \$2,421,000. This cancellation was treated as a contribution to capital by Interneuron to Incara Pharmaceuticals.

Until July 1999, the Company's most advanced product was bucindolol HCl, a beta-blocker that was being evaluated in a Phase 3 clinical trial conducted by the National Institutes of Health and the U.S. Department of Veterans Affairs for use in treating congestive heart failure patients. The agencies terminated the study in July 1999, prior to its scheduled termination date, because an interim data analysis indicated there was no significant survival advantage of treatment with bucindolol for the patient population as a whole. In August 1999, the Company agreed to end the collaboration with BASF Pharma/Knoll AG ("Knoll") for bucindolol for countries outside the United States and Japan (the "Knoll Territory"), and terminated the European trial of bucindolol. On December 20, 2000, Incara Pharmaceuticals entered into a Settlement Agreement and Release with Knoll AG to resolve a dispute regarding a payable owed by Incara Pharmaceuticals to Knoll for the discontinued program. As of the settlement date, the accrued liability, net of related receivables, was \$1,250,000. Incara Pharmaceuticals paid Knoll \$70,000 and issued to Knoll 175,000 shares of common stock (with a fair value of approximately \$416,000) in exchange for a full release of all amounts owed to Knoll. This settlement eliminated the accrued liability owed to Knoll and reduced the Company's net loss by \$767,000 in fiscal 2001.

B. LIQUIDITY

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company had an accumulated deficit of \$106,772,000 at September 30, 2001, incurred a net loss of \$22,213,000 for the year then ended, and expects to incur additional losses in

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fiscal 2002 and for several more years.

The development of OP2000 depends on the Company's collaboration with Elan Corporation, plc, which is outside of its control. As described in note J to these financial statements, the collaboration involves various arrangements that involve additional funding of this program. Should the interim results not be as expected, such funding may not be forthcoming. If that occurred, the Company could reduce its expenditures for this program significantly.

The Cell Technologies and Aeolus programs involve significant expenditures during the 2002 fiscal year and later years. The Company has the intent and ability to quickly and sharply reduce such expenditures during 2002 or later years if sufficient resources are not available to fund these programs.

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company intends to enter into additional collaborative arrangements for research and development, and will need to obtain additional arrangements for the manufacturing and marketing of its potential products. Otherwise, the Company will have to develop the expertise, obtain the additional capital and spend the resources to perform those functions.

The continued funding of the Company's operations is affected by its ability to sell additional equity in the form of common or preferred stock. The Company's common stock is not actively traded and the price of its common stock has fluctuated from \$0.50 to \$11.00 during the last two years. Further, the Company must meet certain minimum capital requirements set by the Nasdaq National Market. If the Company fails to meet such listing requirements, its common stock may be delisted and become more illiquid.

The ability of the Company to continue in its present form is largely dependent on its ability to obtain additional debt or equity financing, generate additional revenues primarily through collaborations, and control overall expenses. Management has raised an aggregate of approximately \$10,000,000 during the past year and believes that it has the ability to continue to raise funds. Management plans to fund fiscal 2002 operations through the raising of capital and establishing collaborations.

Although management continues to pursue these plans, there is no assurance that the Company will be successful in raising capital or establishing the collaboration agreements on terms acceptable to the Company. If management is not successful raising sufficient cash for anticipated fiscal 2002 operations, then management intends to modify its spending, primarily in the research and development and general and administrative areas, to continue operating as a going concern.

C. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation: The consolidated financial statements include the accounts of Incara Pharmaceuticals and its wholly owned subsidiaries. The Company uses the equity method to account for its 35.0% ownership interest in CPEC. While Incara Pharmaceuticals owns 80.1% of the outstanding stock of Incara Development and Elan owns 19.9%, Elan has retained significant minority investor rights, including 50% control of the management committee which oversees the research program, that are considered "participating rights" as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Incara

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Pharmaceuticals does not consolidate the financial statements of Incara Development, but instead accounts for its investment in Incara Development under the equity method of accounting. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates: The preparation of financial statements in conformity with generally accepted accounting principles 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, 2001 and 2000 due to their short-term nature.

Marketable Securities: The Company considers its investment portfolio available-for-sale. Debt and equity securities are reported at fair value, with unrealized gains and losses excluded from earnings and reported as a separate component of stockholders' equity, net of related income taxes. Premiums are amortized and discounts accreted using the interest method over the remaining terms of the related securities. Gains and losses on the sale of securities are determined using the specific identification method. The amortized cost of marketable securities approximates their market value, yielding no unrealized holding gains or losses at September 30, 2001 and 2000. The Company owned \$4,678,000 of bank certificates of deposit due within one year at September 30, 2000.

Accounts Receivable: The accounts receivable from Incara Development balance at September 30, 2001 was comprised of amounts due for management services and expenses incurred by Incara Pharmaceuticals for Incara Development. The accounts

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

receivable balance at September 30, 2000 was primarily comprised of amounts due from Interneuron for a portion of the amount payable by the Company to Knoll for bucindolol-related liabilities.

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, 2001 and 2000.

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: In September 2001, the Company adopted Staff

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Accounting Bulletin No. 101, as amended, "Revenue Recognition in Financial Statements" ("SAB 101") issued by the Securities and Exchange Commission ("SEC"). SAB 101 provides guidance on the recognition, presentation and disclosure of revenue in financial statements filed with the SEC. The Company has adopted the milestone payment method to account for milestone payments received pursuant to development agreements. The adoption of SAB 101 did not have any impact on the Company's financial position or results of operations.

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 either capitalized or expensed based upon the stage of development of the acquired compound or technology at the date of acquisition. Research and development expenses which are incurred on behalf of Incara Development and billed to Incara Development are 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, warrants and convertible preferred stock using the treasury stock method and are excluded if their effect is antidilutive. At September 30, 2001 diluted weighted average common shares excluded incremental shares of approximately 5,986,000 related to stock options, unvested shares of restricted common stock, 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 Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25"), as amended by the Financial Accounting Standards Board ("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.

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

Recent Accounting Pronouncements: In October 2000, the Company adopted Statement of Financial Accounting Standards No. 133, as amended, "Accounting for Derivative Instruments and Hedging Activities." SFAS 133 establishes accounting and reporting standards for derivative instruments, including derivative instruments embedded in other contracts, and for hedging activities. The Company does not currently use nor does it intend to use derivative instruments, and, therefore, the adoption of SFAS 133 did not have any impact on the Company's financial position or results of operations.

INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In July 2001, the FASB issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS 141 supersedes Accounting Principles Board ("APB") Opinion No. 16, "Business Combinations" and is applicable for all business combinations initiated after June 30, 2001. The most significant provisions of SFAS 141 require (a) the application of the purchase method of accounting for all business combinations; (b) the establishment of specific criteria for the recognition of intangible assets separately from goodwill; and (c) unallocated negative goodwill to be written off immediately as an extraordinary gain. SFAS 142 supersedes APB No. 17, "Intangible Assets" and will be effective for the Company's first quarter ending December 31, 2001. The most significant provisions of SFAS 142 provide (a) goodwill and indefinite lived intangible assets will no longer be amortized; (b) goodwill and intangible assets deemed to have an indefinite life will be tested at least annually for impairment; and (c) the amortization period of intangible assets with finite lives will no longer be limited to forty years. The Company believes that the effects of adopting SFAS 142 will not have a material effect on the Company's financial position or results of operations as the Company currently has no goodwill and no intangible assets.

D. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30, 2001 and 2000 (in thousands):

	2001	2000
	-----	-----
Office equipment	\$ 441	\$ 428
Laboratory equipment	1,079	341
Leasehold improvements	561	58
	-----	-----
	2,081	827
Less: accumulated depreciation and amortization ..	(740)	(634)
	-----	-----
	\$ 1,341	\$ 193
	=====	=====

The above amounts included equipment under capital lease obligations with a cost of \$92,000 and \$268,000 at September 30, 2001 and 2000, respectively, and a net book value of \$33,000 and \$57,000 at September 30, 2001 and 2000, respectively. Depreciation and amortization expense was \$164,000, \$260,000 and \$771,000 for the fiscal years ended September 30, 2001, 2000 and 1999, respectively.

E. ACCRUED EXPENSES

At September 30, 2001 and 2000, accrued expenses consisted of the following (in thousands):

	2001	2000
	----	----
Payroll-related liabilities	\$474	\$ 446
Bucindolol development costs	-	1,350
Other	49	11
	----	-----

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\$523 \$1,807
 =====

F. 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 \$292,000, \$423,000 and \$1,147,000 for the fiscal years ended September 30, 2001, 2000 and 1999, respectively. The Company also leases equipment under capital leases.

At September 30, 2001, the Company's non-cancelable future minimum payments under lease arrangements were as follows (in thousands):

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INCARA PHARMACEUTICALS CORPORATION
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Operating Leases -----	Capital Leases -----
2002	\$ 357	\$ 28
2003	368	18
2004	379	-
2005	391	-
2006	300	-
	-----	-----
Total minimum lease payments	\$ 1,795 =====	46
Less: amount representing interest ..		(4) -----
Present value of future minimum lease payments		\$ 42 =====

The Company remains contingently liable through May 2007 on debt and lease obligations of approximately \$6,763,000 assumed by the purchaser of Incara Research Laboratories, a division of the Company referred to as IRL, including the IRL facility lease in Cranbury, New Jersey (See Note K).

G. NOTES PAYABLE

The Company had a \$27,000 note payable to the North Carolina Biotechnology Center at September 30, 2000. Principal and accrued interest at 8.75% was due and paid in December 2000. The Company had no notes payable outstanding at September 30, 2001.

H. STOCKHOLDERS' EQUITY

Preferred Stock: The Certificate of Incorporation of Incara Pharmaceuticals 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. No shares of Preferred Stock were outstanding at September 30, 2000 and 1999. In January 2001, Incara Pharmaceuticals issued to Elan 28,457 shares of Series B non-voting convertible preferred stock ("Series B Stock") and 12,015 shares of Series C

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convertible exchangeable non-voting preferred stock ("Series C Stock"), which shares were outstanding at September 30, 2001 (see Note J). Series C Stock has liquidation preferences in advance of common stock and Series B Stock, which is on par with common stock upon a liquidation.

Common Stock: In August 2001, Incara Pharmaceuticals sold 4,323,044 shares of its common stock and warrants to purchase 1,037,531 shares of common stock resulting in net proceeds to the Company of approximately \$6,423,000, net of \$556,000 of issuance costs. The warrants have an average exercise price of approximately \$2.02 per share and expire in August 2006. Incara Pharmaceuticals has the option, upon 30 days notice, to redeem unexercised warrants at a price of \$0.01 per warrant share if, and only if, at the time notice of such redemption is given, the closing price for the stock for each of the 30 consecutive trading days immediately preceding the date that the redemption notice is given exceeded approximately \$6.075. Incara Pharmaceuticals also issued a warrant to purchase 48,902 shares of common stock to the placement agent that assisted the Company in this stock sale.

In January 2001, Incara Pharmaceuticals issued to Elan 825,000 shares of common stock (see Note K).

On December 20, 2000, Incara Pharmaceuticals entered into a Settlement Agreement and Release with Knoll AG ("Knoll") to resolve a dispute regarding a payable owed by Incara Pharmaceuticals to Knoll for the discontinued program. As of the settlement date, the accrued liability, net of related receivables, was \$1,250,000. Incara Pharmaceuticals paid Knoll \$70,000 and issued to Knoll 175,000 shares of common stock (with a fair value of approximately \$416,000) in exchange for a full release of all amounts owed to Knoll. In conjunction with the settlement, Interneuron returned 34,825 shares of Incara Pharmaceuticals common stock to the Company as partial payment of a related receivable owed to Incara Pharmaceuticals by Interneuron. This settlement eliminated the accrued liability owed to Knoll and reduced the Company's net loss by \$767,000 in fiscal 2001.

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INCARA PHARMACEUTICALS CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In August 2000, the Company entered into a definitive agreement with Torneaux Fund Ltd. ("Torneaux"), an institutional investor, for an equity financing facility covering the purchase of Incara Pharmaceuticals' common stock over 15 months. Under this facility, the Company controls the amount and timing of stock sold to Torneaux, with the amount of the investment being dependent, in part, on Incara Pharmaceuticals' stock price. The agreement includes the issuance of warrants to purchase an amount of common stock equal to 15% of the common stock shares purchased by Torneaux and is subject to a number of conditions. Incara Pharmaceuticals' stockholders approved this financing transaction in October 2000. As of September 30, 2001, Incara Pharmaceuticals had not sold any shares or issued any warrants to Torneaux and, therefore, Torneaux has the right to receive, at its option, either \$60,000 or a warrant to purchase 60,000 shares of common stock.

In January and February 2000, Incara Pharmaceuticals repurchased 104,100 shares of its common stock at a cost of \$331,000 through purchases on the stock market. In July 2000, Incara Pharmaceuticals purchased from each of Lola M. Reid, Ph.D. and James D. Crapo, M.D., both of whom are consultants to Incara Pharmaceuticals, 18,000 shares of Incara Pharmaceuticals' common stock at a per share price of \$2.25, the closing price as listed on Nasdaq on July 26, 2000. The shares repurchased had been issued to Drs. Reid and Crapo in the

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acquisitions of Cell Technologies and Aeolus on March 31, 2000 (see Note K).

In May 1998, Incara Pharmaceuticals issued 494,823 shares of common stock as the first installment of a merger (the "Transcell Merger") with Transcell Technologies, Inc. ("Transcell"). Interneuron was the majority stockholder of Transcell. In lieu of the second installment payment due to Interneuron, Interneuron retained 281,703 shares of Incara Pharmaceuticals common stock as part of the Restructuring. In August 1999, Incara Pharmaceuticals issued 867,583 shares of Incara Pharmaceuticals common stock, valued at approximately \$1.38 per share, to the other former Transcell stockholders as payment for their second installment of the Transcell Merger in the principal amount of \$1,202,000. Incara Pharmaceuticals issued the third and final installment of the purchase price of 856,861 shares of Incara Pharmaceuticals common stock, valued at approximately \$3.36 per share, to the former stockholders of Transcell in February 2000. The issuance of these additional shares did not impact the Company's operating results, because the value of these shares was included in the determination of the purchase price of Transcell in fiscal 1998.

Restricted Stock: As an integral component of a management and employee retention program designed to motivate, retain and provide incentive to the Company's management, employees and key consultants, the Company's Board of Directors adopted the 1999 Equity Incentive Plan (the "1999 Plan") in September 1999. The 1999 Plan provides for the grant of restricted stock ("Restricted Stock") awards which entitle employees and consultants to receive up to an aggregate of 1,400,000 shares of common stock upon satisfaction of specified vesting periods. During September 1999, an aggregate of 1,209,912 shares of Restricted Stock were granted to employees and key consultants of the Company (the "Participants") 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. A total of 270,707 shares of Restricted Stock were unvested at September 30, 2001. These remaining shares of Restricted Stock vest in equal quarterly installments through October 1, 2002.

The Company has incurred and will continue to incur compensation expense through the vesting period of the Restricted Stock. The value of the Restricted Stock awards of 1,209,912 shares at the date of the grant totaled \$755,000, based on the trading price of the Company's common stock of \$0.625 per share. The value of the Restricted Stock is amortized on a straight-line basis over the vesting period. The Company recognized \$117,000, \$424,000 and \$11,000 of expenses related to these awards during the fiscal years ended September 30, 2001, 2000 and 1999, respectively.

Employee Stock Purchase Plan: In October 1995, Incara Pharmaceuticals adopted the Employee Stock Purchase Plan (the "ESPP"). In April 2000, the stockholders approved an amendment to increase the common stock reserved for issuance under the ESPP to 400,000 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 Incara Pharmaceuticals' common stock on the first day of an Offering or the last day of the related Purchase Period. As of September 30, 2001, Incara Pharmaceuticals had sold 377,521 shares of common stock pursuant to the ESPP and 22,479 shares were reserved for future issuances.

Stock Option Plan: Under Incara Pharmaceuticals' 1994 Stock Option Plan (the "1994 Plan"), incentive stock options ("ISOs") or non-qualified stock options to purchase 3,500,000 shares of Incara Pharmaceuticals' common stock may be granted to employees, directors and consultants of the Company. The exercise price of the ISOs granted under the 1994 Plan must not be

INCARA PHARMACEUTICALS CORPORATION
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 to four years following the date of the grant.

Stock option activity under the 1994 Plan was as follows:

	Shares	Weighted Average Exercise Price
Outstanding at September 30, 1998	2,270,132	\$ 5.47
Granted	95,500	\$ 5.66
Exercised	(21,851)	\$ 2.45
Cancelled	(1,359,220)	\$ 7.53

Outstanding at September 30, 1999	984,561	\$ 2.70
Granted	781,540	\$ 3.93
Exercised	(140,000)	\$ 0.36
Cancelled	(288,941)	\$ 5.57

Outstanding at September 30, 2000	1,337,160	\$ 3.05
Granted	1,004,516	\$ 2.62
Exercised	(27,360)	\$ 0.48
Cancelled	(61,168)	\$ 3.31

Outstanding at September 30, 2001	2,253,148	\$ 2.88
	=====	

The details of stock options outstanding at September 30, 2001 were as follows:

Range of Exercise Prices	Options Outstanding			Options
	Number Outstanding at September 30, 2001	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Number Exercisable at September 30, 2001
-----	----	-----	-----	----

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\$0.04	17,029	\$ 0.04	5.1 years	17,029
\$0.36	267,048	\$ 0.36	3.4 years	267,048
\$0.60 - \$ 1.00	239,309	\$ 0.88	4.1 years	237,642
\$1.45 - \$ 1.75	253,855	\$ 1.59	9.5 years	169,105
\$1.87 - \$ 2.00	228,516	\$ 1.95	9.3 years	103,932
\$2.25 - \$ 2.69	100,000	\$ 2.54	8.8 years	17,500
\$3.19	593,026	\$ 3.19	9.0 years	186,318
\$5.09 - \$ 5.13	487,989	\$ 5.12	8.5 years	457,374
\$7.12 - \$20.50	66,376	\$10.38	6.1 years	65,376
	-----			-----
	2,253,148	\$ 2.88	7.7 years	1,521,324
	=====			=====

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 after September 30, 1995. Stock options were granted to consultants under the 1994 Plan for fiscal years ended September 30, 2001, 2000 and 1999. Such options were issued fully vested and \$83,000, \$838,000 and \$266,000 was charged to expense upon issuance for fiscal years ended September 30, 2001, 2000 and 1999, respectively.

The Company's pro forma information utilizing the Black-Scholes option valuation model for the fiscal years ended September 30, 2001, 2000 and 1999 is as follows:

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INCARA PHARMACEUTICALS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2001	2000
	----	----
Net loss attributable to common stockholders (in thousands):		
As reported	\$22,865	\$6,665
Pro forma	\$24,215	\$6,965
Basic and diluted net loss per weighted share attributable to common stockholders:		
As reported	\$ 2.78	\$ 1.21
Pro forma	\$ 2.94	\$ 1.26

Pro forma information regarding net loss was determined as if the Company had accounted for its employee stock options and shares sold under the ESPP under the fair value method of SFAS 123. 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:

	2001	2000
	----	----
Dividend yield	0%	0%

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Expected volatility	131%	133%
Risk-free interest rate	5.1% - 5.7%	6.0% - 6.3%
Expected option life after shares are vested	2 years	2 years

For the fiscal years ended September 30, 2001, 2000 and 1999, all stock options were issued at the fair market value of a share of common stock or above. The weighted average fair value of the options granted during fiscal 2001 was approximately \$2.10 per share.

Warrants: As of September 30, 2001, warrants to purchase 1,104,216 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. The details of the warrants for common stock outstanding at September 30, 2001 were as follows:

Number of Shares -----	Exercise Price -----	Expiration Date -----
17,783	\$ 13.49	May 2003
1,067,828	\$ 2.025	August 2006
18,605	\$ 1.6125	August 2006

1,104,216		
=====		

The Company has the option, upon 30 days notice, to redeem warrants to purchase 1,037,531 shares of common stock that expire in August 2006 at a price of \$0.01 per warrant share, if, and only if, at the time notice of such redemption is given, the closing price for the stock for each of the 30 consecutive trading days immediately preceding the date that the redemption notice is given exceeded approximately \$6.075.

I. INCOME TAXES

As of September 30, 2001 and 2000, the Company had federal net operating loss carryforwards of \$66,798,000 and \$57,359,000, respectively, and state operating loss carryforwards of \$27,931,000 and \$18,493,000, respectively. The use of these federal net operating loss carryforwards might be subject to limitation under the rules regarding a change in stock ownership as determined by the Internal Revenue Code. The federal net operating losses will begin to expire in 2010. The state net operating losses began to expire in 2001. Additionally, the Company had federal research and development carryforwards as of September 30, 2001 and 2000 of \$1,740,000 and \$1,195,000, respectively.

Significant components of the Company's deferred tax assets at September 30, 2001 and 2000 consisted of the following (in thousands):

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2001 ----	2000 ----
Net operating loss carryforwards	\$ 24,002	\$ 20,448
AMT credit carryforwards	37	37
Research and development credit carryforwards	1,740	1,195

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Accrued payroll related liabilities	1,159	1,204
Charitable contribution carryforwards	874	637
Other	653	495
	-----	-----
Total deferred tax assets	28,465	24,016
Valuation allowance for deferred assets	(28,465)	(24,016)
	-----	-----
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):

United States Federal statutory rate	\$ (7,552)	\$ (2,266)	\$ (6,663)
State taxes (net of federal benefit)	(356)	1	(273)
Change in valuation reserves	4,449	226	4,909
Gain on sale of subsidiary	--	--	2,371
Pipeline research and development	--	2,273	--
Equity in loss of investee	4,187	--	--
Other	(728)	(234)	(344)
	-----	-----	-----
Provision for income taxes	\$ -	\$ --	\$ --
	=====	=====	=====

J. ELAN CORPORATION TRANSACTIONS

On January 22, 2001, Incara Pharmaceuticals closed on a collaborative transaction with Elan. As part of the transaction, Elan and Incara Pharmaceuticals formed a Bermuda corporation, Incara Development, Ltd., to develop a compound being investigated as a drug treatment for inflammatory bowel disease ("OP2000"). Incara Pharmaceuticals owns all of the common stock and 60.2% of the non-voting preferred shares of Incara Development and Elan owns 39.8% of the non-voting preferred shares of Incara Development. Of the outstanding combined common and non-voting preferred shares of Incara Development, Incara Pharmaceuticals owns 80.1% and Elan owns 19.9%. As part of the transaction, Elan and Incara Pharmaceuticals entered into license agreements under which Incara Pharmaceuticals licensed to Incara Development rights to the OP2000 compound and Elan licensed to Incara Development proprietary drug delivery technology.

As part of the transaction, Elan also purchased 825,000 shares of Incara Pharmaceuticals' common stock, 28,457 shares of Incara Pharmaceuticals Series B

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non-voting convertible preferred stock and a five-year warrant to purchase 22,191 shares of Series B Stock at an exercise price of \$72.12 per share for an aggregate purchase price of \$4,000,000. Each share of Series B Stock is convertible into ten shares of common stock.

Elan also purchased 12,015 shares of Incara Pharmaceuticals Series C convertible exchangeable non-voting preferred stock with a face value of \$1,000 per share, or a total of \$12,015,000. Incara Pharmaceuticals contributed to Incara Development the proceeds from the issuance of the Series C Stock to Elan in exchange for its securities of Incara Development. Elan also contributed \$2,985,000 to Incara Development for its shares of preferred stock of Incara Development. In addition, Elan granted Incara Development a license to Elan's proprietary drug delivery technology for a license fee of \$15,000,000.

The Series C Stock bears a mandatory stock dividend of 7%, compounded annually. The Series C Stock is exchangeable at the option of Elan at any time for all of the preferred stock of Incara Development held by Incara Pharmaceuticals which, if exchanged, would give Elan ownership of 50% of the initial amount of combined common and preferred stock of Incara

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Development. After December 20, 2002, the Series C Stock is convertible by Elan into shares of Incara Pharmaceuticals' Series B Stock at the rate of \$64.90 per share. If the Series C Stock is outstanding as of December 21, 2006, Incara Pharmaceuticals will exchange the Series C Stock and accrued dividends, at its option, for either cash or shares of stock and warrants of Incara Pharmaceuticals having a then fair market value of the amount due.

Upon the completion of enrollment of a Phase 2/3 clinical trial for OP2000, Elan will purchase \$1,000,000 of Incara Pharmaceuticals' Series B Stock at a per share price that will be ten times the greater of (1) the average per share price of Incara Pharmaceuticals common stock for the day prior to the purchase, or (2) a 25% premium to the average daily price per share of Incara Pharmaceuticals common stock for the 60 trading day period immediately prior to the purchase. In addition, as part of the \$1,000,000 payment, Incara Pharmaceuticals will issue to Elan a five-year warrant for 20% of the shares of Series B Stock purchased by Elan. The exercise price of the Series B Stock under this warrant will be equal to twice the per share purchase price of the Series B Stock purchased on the same date. However, if the purchase price of the Series B Stock is less than \$8.00 per share, the purchase of this stock will be limited to 150,000 shares of Series B Stock and will be at Elan's option.

Elan and Incara Pharmaceuticals intend to fund Incara Development pro rata, based on their respective percentage ownership of the combined outstanding common and preferred stock of Incara Development. Subject to mutual agreement, Elan will lend Incara Pharmaceuticals up to \$4,806,000 to fund Incara Pharmaceuticals' pro rata share of development funding for Incara Development. In return, Incara Pharmaceuticals issued a convertible promissory note that bears interest at 10% compounded semi-annually on the amount outstanding thereunder. After December 20, 2002, the note is convertible at the option of Elan into shares of Series B Stock at \$43.27 per share. The note will mature on December 21, 2006, when the outstanding principal plus accrued interest will be due and payable. Incara Pharmaceuticals 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. As of September 30, 2001, Incara Pharmaceuticals had

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not borrowed any funds pursuant to this note.

For financial reporting purposes, the value recorded as Incara Pharmaceuticals' investment in Incara Development is the same as the fair value of the Series C Stock issued, which was \$12,015,000. The technology obtained by Incara Development from Elan was expensed at inception because the feasibility of using the contributed technology in conjunction with OP2000 had not been established and Incara Development had no alternative future use for the contributed technology. Incara Pharmaceuticals immediately expensed as "Equity in loss of Incara Development" its investment in Incara Development, reflective of Incara Pharmaceuticals' pro rata interest in Incara Development. During the second quarter of fiscal 2001, the Company initially recorded the value of the Series C Stock as \$5,496,000. Pursuant to an independent valuation of the Series C Stock completed subsequent to the end of the fiscal year, the Company revised the value of the Series C Stock to \$12,015,000 and increased the related charge to "Equity in loss of Incara Development". From the date of issue up to December 21, 2006, Incara Pharmaceuticals will accrete the Series C Stock for the 7% dividend from its recorded value up to its redemption value. Upon a liquidation of the Company, holders of Series C Stock will be entitled to liquidation payments equal to the face value per share at issuance plus accrued dividends.

While Incara Pharmaceuticals owns 80.1% of the outstanding stock of Incara Development, Elan has retained significant minority investor rights, including 50% control of the management committee which oversees the OP2000 program, that are considered "participating rights" as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Incara Pharmaceuticals does not consolidate the financial statements of Incara Development, but instead accounts for its investment in Incara Development under the equity method of accounting. Net losses of Incara Development will be recognized by Incara Pharmaceuticals at its 80.1% interest to the extent of Incara Pharmaceuticals' investments, advances and commitments to make future investments in or advances to Incara Development. Further, because Elan can exchange its investment in Incara Pharmaceuticals' Series C Stock for Incara Pharmaceuticals' 30.1% preferred interest in Incara Development, Incara Pharmaceuticals will only recognize 50% of any accumulated net earnings of Incara Development. During the fiscal year ended September 30, 2001, Incara Pharmaceuticals' equity in loss of Incara Development was \$12,650,000, including \$12,015,000 for Incara Pharmaceuticals' interest in the immediate write-off at inception of the contributed technology by Elan to Incara Development. Incara Development is a development stage company with no revenue. Excluding the initial license fee for the contributed technology by Elan, Incara Development had operating expenses of approximately \$1,235,000 for the fiscal year ended September 30, 2001, which included \$1,147,000 for expenses and management services invoiced to Incara Development by Incara Pharmaceuticals. Separate financial statements for Incara Development are included elsewhere in the Form 10-K.

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

K. ACQUISITIONS AND DISPOSITION

Incara Cell Technologies, Inc. and Aeolus Pharmaceuticals, Inc.

On March 31, 2000, Incara Pharmaceuticals purchased all of the minority interests of Cell Technologies and Aeolus. Prior to the acquisitions, Incara Pharmaceuticals owned 78.0% of Cell Technologies and 65.8% of Aeolus. Incara Pharmaceuticals issued 1,220,041 shares of its common stock in exchange for the

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subsidiaries' minority ownership. The acquisitions have been accounted for using the purchase method of accounting. The total purchase price of \$6,664,000 consisted of 1,220,041 shares of Incara Pharmaceuticals' common stock with a fair value of \$5.46 per share, based on the price of Incara Pharmaceuticals' common stock at the date of acquisition. The total purchase price was allocated to purchased in-process research and development and immediately charged to operations because at the date of the acquisition the in-process research purchased was in preclinical stages, feasibility had not been established and it was deemed to have no alternative future use.

Additionally, Cell Technologies and Aeolus had no workforce or other tangible fixed assets. Cell Technologies and Aeolus had incurred approximately \$10,000,000 in research and development costs prior to the acquisition of the minority interests by Incara Pharmaceuticals. Incara Pharmaceuticals expects that it will take until at least 2006 to complete development of all aspects of the research and that Cell Technologies and Aeolus will need to spend in excess of an additional \$50,000,000 to do so.

Incara Research Laboratories

On December 29, 1999, the Company sold IRL, its anti-infectives drug discovery division, to a private pharmaceutical company for \$11,000,000 in cash. The transaction involved the sale of assets associated with IRL, including rights under a research collaboration (the "Merck Collaboration") with Merck & Co., Inc. ("Merck") and the assumption of related liabilities by the purchaser. The Company recognized a gain of \$9,751,000 on the sale of IRL. The Company remains contingently liable through May 2007 on debt and lease obligations of approximately \$6,763,000 assumed by the purchaser, including the IRL facility lease in Cranbury, New Jersey.

L. AGREEMENTS

UNC License

Cell Technologies has a sponsored research agreement (the "UNC Agreement") with the University of North Carolina at Chapel Hill ("UNC") which covers research at UNC by scientists in the area of hepatic stem cells and which grants Cell Technologies a first option to obtain an exclusive license to inventions resulting from the agreement with UNC. Cell Technologies has agreed to reimburse UNC for certain costs incurred in connection with the research, of which \$488,000 remained to be paid as of September 30, 2001. In August 1999, Cell Technologies obtained an exclusive worldwide license (the "UNC License") from UNC to make, use and sell products using proprietary information and technology developed under the UNC Agreement. Cell Technologies paid license fees of \$75,000 to UNC and will also pay milestones on certain development events and royalties on net sales. Cell Technologies is also obligated to pay patent filing, prosecution, maintenance and defense costs. Unless terminated earlier, the UNC License continues until the last underlying patent expires.

Albert Einstein College of Medicine Agreements

Cell Technologies has exclusive worldwide license rights from Albert Einstein College of Medicine ("AECM") for patents resulting from research conducted on liver and precursor cells by Dr. Lola M. Reid, a consultant, and other scientists, while Dr. Reid was at AECM. Cell Technologies must pay royalties to AECM on net product sales during the term of the licenses and must pay minimum royalties beginning in 2004. Cell Technologies must also pay patent prosecution, maintenance and defense costs. Unless terminated earlier, the license continues until the last underlying patent expires. Cell Technologies has agreed to support certain of AECM's costs incurred in liver cell research, of which \$163,000 remained to be paid as of September 30, 2001. Cell Technologies has a first option to obtain an exclusive license to inventions

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resulting from this sponsored research.

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INCARA PHARMACEUTICALS CORPORATION

NOTES CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Opocrin License

In July 1998, Incara Pharmaceuticals licensed a development compound ("OP2000") from Opocrin S.p.A., of Modena, Italy ("Opocrin"). The license rights were transferred to Incara Development in January 2001. Incara Development is investigating the use of OP2000 as a drug for the treatment of inflammatory bowel disease. The license is worldwide except for Japan and Korea. Incara Development is responsible for conducting clinical trials for OP2000 and Incara Pharmaceuticals or Incara Development is required to make additional milestone payments to Opocrin upon initiation of Phase 3 clinical trials, upon filing for regulatory approval, upon obtaining regulatory approval and upon achieving specified annual sales.

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 world-wide license ("NJC License") from National Jewish Medical and Research Center ("NJC") to develop, make, have made, use and sell products using certain technology developed by certain scientists at NJC. The NJC License requires Aeolus to use commercially reasonable efforts to diligently pursue the development and government approval of products using the licensed technology. Aeolus will pay royalties to NJC on net product sales during the term of the NJC License and a milestone payment upon regulatory approval. In addition, Aeolus is obligated under the NJC License to pay all or a portion of patent prosecution, maintenance and defense costs. Unless earlier terminated, the NJC License continues until the expiration of the last to expire issued patent on the licensed technology. Aeolus also has a sponsored research agreement with NJC that grants Aeolus an option to negotiate a royalty-bearing exclusive license for certain technology, patents and inventions resulting from research by certain individuals at NJC within the field of antioxidant, nitrosylating and related areas. Aeolus has agreed to support certain of NJC's costs incurred in performance of the research, of which \$75,000 remained to be

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paid as of September 30, 2001.

Merck Collaboration

In July 1997, IRL entered into the Merck Collaboration to discover and commercialize certain novel antibacterial agents. The Company recognized contract revenue in conjunction with this agreement of \$100,000 and \$2,063,000 for the fiscal years ended September 30, 2000 and 1999, respectively, including a \$1,500,000 milestone payment received from Merck in August 1999. In conjunction with the sale of IRL, the Company transferred its rights and obligations under the Merck Collaboration and its related licenses to the purchaser.

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Consolidated)

M. QUARTERLY FINANCIAL DATA

(Unaudited)

(in thousands, except per share amounts)

	Fiscal 2001 -----	First Quarter -----	Second Quarter -----	T Qu ---
Total revenue	\$ --	\$ 3	\$ 3	\$ 3
Net loss	\$ (1,639)	\$ (14,444)	\$ (14,444)	\$ (14,444)
Net loss attributable to common stockholders	\$ (1,639)	\$ (14,623)	\$ (14,623)	\$ (14,623)
Net loss per weighted share attributable to common stockholders				
Basic	\$ (0.24)	\$ (1.89)	\$ (1.89)	\$ (1.89)
Diluted	\$ (0.24)	\$ (1.89)	\$ (1.89)	\$ (1.89)
Fiscal 2000 -----				
Total revenue	\$ 100	\$ --	\$ --	\$ --
Net income (loss)	\$ 6,923	\$ (8,460)	\$ (8,460)	\$ (8,460)
Net income (loss) per common share				
Basic	\$ 1.72	\$ (1.80)	\$ (1.80)	\$ (1.80)
Diluted	\$ 1.39	\$ (1.80)	\$ (1.80)	\$ (1.80)

In December 2001, the Company revised net loss information for the second and third quarters of fiscal 2001 due to a revision in the recorded value of the Series C Stock issued in January 2001 (see Note J). The above table reflects the net loss information as revised. For the second quarter of fiscal 2001, the Company initially reported a net loss of \$7,925,000, net loss attributable to common stockholders of \$8,139,000 and basic and diluted net loss per weighted share attributable to common stockholders of \$1.05. For the third quarter of fiscal 2001, the Company initially reported net loss attributable to common stockholders of \$3,295,000 and basic and diluted net loss per weighted share attributable to common stockholders of \$0.41.

N. SUBSEQUENT EVENTS (unaudited)

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In October 2001, the Company executed a Master Loan and Security Agreement (the "Note") with Transamerica Technology Finance Corporation ("Transamerica"), which provides that the Company may borrow up to \$700,000 from Transamerica prior to January 1, 2002 to finance equipment purchases. In October 2001, the Company borrowed \$565,000 pursuant to the Note and pledged equipment with a cost of \$686,000 as collateral on the Note. Incara Pharmaceuticals issued a seven-year warrant to Transamerica to purchase 17,588 shares of common stock at an exercise price of \$1.99 per share in connection with the Note.

Also in October 2001, Incara Pharmaceuticals borrowed \$857,000 from Elan under its note arrangement with Elan (see Note J).

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Incara Development, Ltd.
(A Development Stage Company)

Financial Statements
For the Period from Inception (January 5, 2001)
through September 30, 2001
(expressed in U.S. dollars)

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[LETTERHEAD OF PRICEWATERHOUSECOOPERS]

December 20, 2001

Report of Independent Accountants

To the Board of Directors of
Incara Development, Ltd.

In our opinion, the accompanying balance sheet and the related statements of operations, of changes in stockholders' deficit and of cash flows present fairly, in all material respects, the financial position of Incara Development, Ltd. (a development stage company) (the "Company") as of September 30, 2001, and the results of its operations and its cash flows for the period from inception on January 5, 2001 through September 30, 2001, 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 auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about

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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.

PricewaterhouseCoopers LLP

Chartered Accountants

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Incara Development, Ltd.
 (A Development Stage Company)
 Balance Sheet
 As at September 30, 2001

 (expressed in U.S. dollars)

	\$
Assets	-----
Current assets	
Cash and cash equivalents	-----
Total current assets	-----
Intangible assets (note 5)	-----
Total assets	-----
Liabilities	
Current liabilities	
Accrued liabilities	10,000
Due to related parties	1,225,388
Total current liabilities	-----
Stockholders' deficit	
Common stock, \$1 par value; 6,000 shares authorized; 6,000 shares issued and outstanding at September 30, 2001	6,000
Preferred stock, \$1 par value; 6,000 shares authorized; 6,000 shares issued and outstanding at September 30, 2001	6,000
Additional paid-in capital	12,003,000
Accumulated deficit	(13,250,388)
Total stockholders' deficit	-----

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Total liabilities and stockholders' deficit	-
	=====

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

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Incara Development, Ltd.
 (A Development Stage Company)
 Statement of Operations
 For the period from Inception (January 5, 2001) through September 30, 2001

 (expressed in U.S. dollars)

	\$

Operating expenses	
Purchased in-process research and development (note 5)	12,015,000
Research and development (note 4)	1,210,447
General and administrative	24,941

Total operating expenses	13,250,388

Net loss	(13,250,388)
	=====

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

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Incara Development, Ltd.
 (A Development Stage Company)
 Statement of Changes in Stockholders' Deficit
 For the period from Inception (January 5, 2001) through September 30, 2001

 (expressed in U.S. dollars)

	Preferred stock	Common stock	Additi pai
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	Shares	Amount \$	Shares	Amount \$	cap
Contributed at Inception (January 5, 2001)	6,000	6,000	6,000	6,000	12,003
Net loss	-	-	-	-	
Balance at September 30, 2001	6,000	6,000	6,000	6,000	12,003

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

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Incara Development, Ltd.
(A Development Stage Company)
Statement of Changes in Stockholders' Deficit
For the period from Inception (January 5, 2001) through September 30, 2001

(expressed in U.S. dollars)

	\$
Cash flows from operating activities	
Net loss	(13,250,388)
Adjustments to reconcile net loss to net cash used in operating activities	
Purchased in-process research and development	12,015,000
Changes in operating assets and liabilities	
Accrued liabilities	10,000
Due to related parties	1,225,388
Net cash used in operating activities	-
Cash flow from investing activity	
Purchase of license agreements	(15,000,000)
Net cash used by investing activity	(15,000,000)
Cash flow from financing activity	
Proceeds from sale of shares	15,000,000
Net cash provided by financing activity	15,000,000
Cash and cash equivalents - Beginning of period	-

Cash and cash equivalents - End of period

-
=====

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

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Incara Development, Ltd.
(A Development Stage Company)
Notes to Financial Statements
September 30, 2001

(expressed in U.S. dollars)

1. Organization and basis of presentation

Incara Development, Ltd. (the "Company or IDL") was incorporated on January 5, 2001 in Bermuda. The Company is owned jointly by Incara Pharmaceuticals Corporation ("Incara"), and Elan International Services, Ltd. ("EIS"), a wholly-owned subsidiary of Elan Corporation plc ("Elan"). The primary objective of the Company is to carry on the business of the development, testing, registration, manufacturing, commercialization, and licensing of "Products" (as defined in the Subscription, Joint Development and Operating Agreement ("JDOA") dated January 19, 2001 between IDL, EIS, Incara and others). The focus of the collaborative venture is to develop "Products" using the intellectual property of Elan and Incara pursuant to the JDOA.

Incara owns all of the common stock and 60.2% of the non-voting convertible preferred shares of IDL and Elan owns 39.8% of the non-voting convertible preferred shares of IDL. Of the outstanding combined common and non-voting preferred shares of the Company, Incara owns 80.1% and Elan owns 19.9%. As part of the transaction, Elan and Incara entered into license agreements under which Incara licensed to IDL rights to a compound being investigated as a drug treatment for inflammatory bowel disease ("OP2000") and Elan licensed to IDL proprietary drug delivery technology. EIS and Incara may provide to the Company, by way of contributed surplus or a loan, as agreed by both parties, up to an aggregate maximum amount of \$6,000,000 in development funding, and any additional funding to develop the Company's "Products" pursuant to the JDOA. This funding is to be provided by EIS and Incara on a pro-rata basis, based on their fully diluted equity interests in the Company at the time of each funding.

Elan purchased 12,015 shares of Incara Series C convertible exchangeable non-voting preferred stock with a face value of \$1,000 per share, or a total of \$12,015,000. Incara contributed to IDL the proceeds from the issuance of the Series C Stock to Elan in exchange for its securities of IDL. Elan also contributed \$2,985,000 to IDL for its shares of preferred stock of IDL. In addition, Elan granted IDL a license to Elan's proprietary drug delivery technology for a license fee of \$15,000,000. The Incara Series C Stock is exchangeable at the option of Elan at any time for all of the preferred stock of IDL held by Incara which, if exchanged, would give Elan ownership of 50% of the initial amount of combined common and

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preferred stock of IDL.

For financial reporting purposes, the values recorded for the shares issued by IDL were based on the estimated fair value of the Incara Series C Stock issued to Elan, as this was the most objectively determinable indicator of fair value. Incara issued the Series C stock valued at \$12,015,000 for their 80.1% ownership interest in the Company, and accordingly this was the value assigned to the total equity in the Company.

2. Significant accounting policies

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. These principles require that the financial statements be prepared on a going concern basis. The Company's ability to continue as a going concern is entirely dependent upon the funds it receives from its shareholders in connection with the shareholders' respective obligations to fund the Company's operations (see note 1). The Company believes Incara and Elan will continue to provide funding to IDL, if needed, through at least September 30, 2002.

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Incara Development, Ltd.
(A Development Stage Company)
Notes to Financial Statements
September 30, 2001

(expressed in U.S. dollars)

Significant accounting policies are as follows:

- (a) Research and development costs
Research and development costs are charged as an expense of the period in which they are incurred.
- (b) Use of estimates
The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates.

3. Comprehensive income

Comprehensive income (loss) approximates net loss for the period ended September 30, 2001.

4. Research and Development

At the end of the period, the amount due to shareholders and companies related through common ownership represents costs for research and development that are subcontracted to Incara and Elan. Research and development expenses of \$1,146,817 charged by Incara and \$63,630 charged by Elan, represent costs under such agreements. These transactions are in the

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normal course of operations and are measured at the exchange amount, which is the amount of consideration established at contractual rates agreed to by the related parties. Further, the amount due to shareholders is unsecured, and interest free with no set terms of repayment.

5. In-process research and development

During the period from inception to September 30, 2001, the Company entered into license arrangements with Elan and Incara to acquire rights to certain intellectual property (as described in note 1). The license acquired from Incara related to early stage technology that, in the opinion of management, had not reached technological feasibility. In addition, management concluded that the license from Elan was only to be used in conjunction with Incara's OP2000 compound and had no alternative future uses. Therefore, all the license fees were deemed to be in-process research and development and were charged to expense for the period.

6. Stockholders' equity

In January 2001, the Company issued 6,000 voting common shares to Incara with a par value of \$1.00 each.

In January 2001, the Company issued 6,000 non-voting convertible preference shares (Preferred Shares) with a par value of \$1.00 each. 3,612 Preferred Shares were issued to Incara and 2,388 Preferred Shares were issued to EIS. At any time after January 19, 2003, the holders of the Preferred Shares have the right to convert all, or a portion, of such Preferred Shares into common shares on a one-to-one basis. Upon liquidation of the Company, the holders of the Preferred Shares will be entitled to be paid out of the assets of the Company available for distribution to shareholders before any distribution or payment is made to the holders of any other classes of stock.

While each joint venture partner contributed \$1,250 per share to IDL at inception, the Company determined that the fair value assignable to the initial equity was \$12,015,000. The fair value assigned to the initial equity reflects the structure and the overall financing of the joint venture. As a

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Incara Development, Ltd.
(A Development Stage Company)
Notes to Financial Statements
September 30, 2001

(expressed in U.S. dollars)

result, the Company recorded the issuance of the common and preferred shares at their \$12,000 par value with \$12,003,000 recorded as additional paid-in capital.

7. Taxes

Under current Bermuda law the Company is not required to pay any taxes in Bermuda on either income or capital gains. The Company has received an undertaking from the Minister of Finance in Bermuda that in the event of such taxes being imposed, the Company will be exempted from taxation until

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the year 2016.

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SIGNATURES

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

INCARA PHARMACEUTICALS CORPORATION

By: /s/ Clayton I. Duncan

President and Chief Executive Officer

Date: December 21, 2001

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

Signature -----	Capacity -----
/s/ Clayton I. Duncan ----- Clayton I. Duncan	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)
/s/ Richard W. Reichow ----- Richard W. Reichow	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)
/s/ Eugene J. McDonald ----- Eugene J. McDonald	Director
/s/ J. Misha Petkevich ----- J. Misha Petkevich	Director
/s/ Stephen M. Prescott ----- Stephen M. Prescott	Director
/s/ Edgar H. Schollmaier ----- Edgar H. Schollmaier	Director
/s/ David B. Sharrock -----	Director

David B. Sharrock