

INCARA PHARMACEUTICALS CORP  
Form S-1/A  
July 23, 2001

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON JULY 23, 2001  
REGISTRATION STATEMENT NO. 333-64868

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO.1  
TO

FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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

DELAWARE	8731	56-1924222
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

79 T.W. Alexander Drive  
4401 Research Commons, Suite 200  
P. O. Box 14287  
Research Triangle Park, North Carolina 27709  
(Address, including zip code, and telephone number, including area code, of  
registrant's principal executive offices)

CLAYTON I. DUNCAN  
CHAIRMAN AND CHIEF EXECUTIVE OFFICER  
INCARA PHARMACEUTICALS CORPORATION  
79 T.W. ALEXANDER DRIVE, 4401 RESEARCH COMMONS, SUITE 200  
P. O. Box 14287  
RESEARCH TRIANGLE PARK, NORTH CAROLINA 27709  
(919) 558-8688  
(Name, address, including zip code, and telephone number, including area code,  
of agent for service)

COPY TO:

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APPROXIMATE DATE OF PROPOSED SALE TO THE PUBLIC:

From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED JULY 23, 2001.

PROSPECTUS

\$10,000,000  
COMMON STOCK

[LOGO]

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## INCARA PHARMACEUTICALS CORPORATION

We are offering shares of our common stock continuously over time. This means:

- . we are offering our shares hereunder directly to anyone who wants to buy them;
- . we are also offering shares through the placement agent named below;
- . we may issue shares offered in this prospectus at any time;
- . we will provide a prospectus supplement or amendment, if necessary, to add, update or change the information contained in this prospectus;
- . you should read this prospectus and any prospectus supplement or amendment carefully before you invest.

Our common stock is traded on the Nasdaq National Market under the symbol "INCR." On July 20, 2001, the last sale price of our common stock on the Nasdaq National Market was \$1.75 per share.

While we are offering our shares directly to anyone who wants to buy them, we also have engaged Petkevich & Partners, LLC as placement agent to assist in this offering on a best efforts basis.

We are offering our common stock at a price per share equal to the closing sale price as reported by Nasdaq on the day before any sale.

Investing in our securities involves risks. See "Risk Factors" beginning on page 2.

Neither the SEC nor any state securities commission has approved or disapproved our securities or determined that this prospectus is truthful or complete. It is illegal for anyone to tell you otherwise.

Petkevich & Partners, LLC

The date of this prospectus is July \_\_, 2001.

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## PROSPECTUS SUMMARY

Because this is a summary, it does not contain all the information that may be important to you. You should read carefully the entire prospectus, including "Risk Factors" and the financial statements, before you decide whether to invest in our common stock.

### Incara Pharmaceuticals Corporation

#### Our Business

Incara Pharmaceuticals Corporation is developing therapies focused on tissue protection, repair and regeneration. In particular, we are focused on developing adult liver stem 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 and its subsidiaries, 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 purifies human liver progenitor cells from the livers of organ donors. Based on animal models, we believe that following transplantation into patients our cells will be able to grow and expand 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 17,500 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 plan to file in late 2001 an Investigational New Drug, or IND, application with the Food and Drug Administration, or FDA, in order to initiate clinical trials. We intend to conduct these clinical trials to determine the efficacy of our liver progenitor cell therapy for treatment of liver failure and some inherited liver diseases in infants and young children.

**Small molecule catalytic antioxidants.** We intend to investigate small molecule catalytic antioxidants as a treatment for stroke and prevention of

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radiation-induced side effects from cancer 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. An estimated 400,000 cancer patients in the U.S. each year develop mucositis caused by chemotherapy or radiation. Mucositis is characterized by painful oral ulcers which may limit or delay therapy. Incara's catalytic antioxidants have reduced the severity of mucositis and lung damage induced by radiation in animal models.

We believe compounds from our catalytic antioxidant program will also have application in the developing adult stem cell transplant industry. Antioxidants destroy free radicals, which damage cells within the human body. In cell culture experiments, these 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 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 exploring 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 History

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

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### ----- Corporate Information

We have two wholly owned subsidiaries, Aeolus Pharmaceuticals, Inc., a Delaware corporation, and Incara Cell Technologies, Inc., a Delaware corporation. We own 80.1% of Incara Development, Ltd., a Bermuda corporation, and 35% of CPEC, LLC, a Delaware limited liability company. Unless otherwise stated, "Incara" and "we" refer collectively to Incara Pharmaceuticals Corporation and its subsidiaries.

Our offices are located at 79 T.W. Alexander Drive, 4401 Research Commons, Suite 200, P.O. Box 14287, Research Triangle Park, North Carolina 27709, and our telephone number is (919) 558-8688. Our Web site is located at [www.incara.com](http://www.incara.com).

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Information on our Web site is not part of this prospectus.  
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### RISK FACTORS

You should be aware that there are various risks to an investment in our common stock, including those described below. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to invest in shares of our common stock.

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, and you may lose all or part of your investment.

If we do not raise significant additional capital, we will be unable to fund all 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 March 31, 2001, we had cash and investments of \$4,954,000. While we believe our existing financial resources are adequate to fund operations through September 30, 2001, which is the end of our fiscal year, we will need the capital raised in this offering and from other sales of our stock, or through collaborations with third parties, to support operations after fiscal 2001.

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 are not required to sell all of the common stock we are offering, and we may not raise enough capital from the sale of our common stock to adequately fund our planned research and development activities.

There is no minimum amount of our common stock we must sell in this offering. Accordingly, investors will bear the risk that we will accept subscriptions for less than \$10,000,000 worth of common stock and then be unable to successfully complete all of the anticipated uses of the proceeds of this offering. If less than \$10,000,000 is raised, we might be unable to develop our programs as planned and our business, financial condition, and results of operations could be adversely affected.

The placement agent, Petkevich & Partners, LLC, is not obligated to purchase any number or dollar amount of our shares at any time. While Petkevich & Partners has agreed to use its best efforts to identify prospective purchasers of the common stock offered, there can be no assurance that any or all of the shares offered will be sold. Our inability to obtain adequate financing may impede our research and development activities and thus negatively affect the return on your investment in our common stock.

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

As of March 31, 2001, we had an accumulated deficit of \$93,685,000 from our

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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.

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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 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 cannot assure that we will be able to enter into or maintain these agreements on terms favorable to us. We currently license from third parties, and do not own, rights under patents and certain related intellectual property for our current development 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 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.

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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 a license agreement with Duke University. 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.

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Our licenses generally may be terminated by the licensor if we fail to perform our obligations, including obligations to develop the compounds and technologies under license. If terminated, we would lose the right to develop the products, which could adversely affect our business. The license agreements also generally require us to meet specified milestones or show reasonable diligence in development of the technology. If disputes arise over the definition of these requirements or whether we have satisfied the requirements in a timely manner, or if any other obligations in the license agreements are disputed by the other party, the other party could terminate the agreement and we could lose our rights to develop the licensed technology.

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 emerging 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.



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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 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.

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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,

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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.

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 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 collaborative partners to maintain the proprietary nature of this technology. However,

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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.

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

We face intense competition in all of our development programs. The markets for therapeutic products that address liver disease, stroke, cancer and inflammatory bowel disease is 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 the common stock issued in this offering and by future issuances of stock, including new offerings, conversion of currently outstanding preferred stock and exercises of currently outstanding options and warrants.

As of May 31, 2001, Incara had 8,387,531 shares of common stock outstanding. We are offering up to \$10,000,000 worth of shares of our common stock pursuant to this prospectus. This could result in up to 4,878,049 shares of our common stock being issued in this offering, based on the closing price of \$2.05 of our common stock on June 26, 2001, which represents 36.8% of the total number of our shares of common stock which would then be outstanding, based on shares outstanding as of May 31, 2001. In addition, under our compensation arrangement with Petkevich & Partners, we will issue a warrant for up to 80,000 shares of our common stock, depending on the amount of our common stock sold in this offering, which would further dilute our stockholders.

We may grant to our employees, directors and consultants options to purchase our common stock under the 1994 Stock Option Plan. As of May 31, 2001, options to purchase 2,066,564 shares at exercise prices ranging from \$0.04 to \$20.50, with a weighted average exercise price of \$3.04 were outstanding and 1,225,149 shares were reserved for issuance under the 1994 Stock Option Plan. In addition, warrants to purchase 17,783 shares of common stock at an exercise price of \$13.49 were outstanding, and we have reserved 36,208 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.

In the event that the capital raised in this offering is insufficient to fund operations, we will need to sell additional shares of our common stock,

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preferred stock or other securities, or enter into collaborations with third parties during our next fiscal year 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 21.9% 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 May 31, 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 later of the completion of enrollment of a Phase 2/3 clinical trial for OP2000 or December 21, 2001, 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

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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. Accordingly, assuming the purchase price for the later purchased Series B preferred stock is the same as ten times the greater of the average per share daily price of our common stock on June 26, 2001 or a 25% premium to the average daily for the 60 trading day period prior to June 27, 2001, an additional 512,821 shares of our common stock could be issued to Elan. 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 May 31, 2001, we had not borrowed any funds pursuant to this note. However, assuming the full amount is borrowed under the note, and assuming the conversion of the principal, but not any interest on the note, 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.

Stockholders might experience significant dilution from our issuance to Torneaux Fund Ltd. of up to 1,530,166 shares of common stock, or 15.4% of the total number of shares of our common stock which would then be outstanding, based on shares outstanding as of May 31, 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 May 31, 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 1,530,166 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 15.4% of the total number of shares which would then be outstanding, based on the 8,387,531 shares of common stock outstanding on May 31, 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 1,040,111 shares and warrants, or 11.0% 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.

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

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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.

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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).

All shares issued in this offering will be freely tradable. In addition, 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, as well as the shares underlying a warrant to be issued to Petkevich & Partners. The sale of a significant amount of shares sold to Torneaux or shares issued in this offering 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 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 February 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 proposed 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 March 31, 2001, our stockholders' equity was \$5,192,000, which was below the proposed requirement.

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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 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

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- . 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 May 31, 2001, we had only 22 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 the 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.

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

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Our research and development activities and the manufacturing and marketing of our 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 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 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 radioactive compounds. Although we believe that our procedures for handling



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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 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 the Incara 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 Incara's common stock in the future.

We remain contingently liable for IRL obligations.

In connection with the sale of Incara Research Laboratories, or 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 \$7,100,000 in May 2001 and should decline on an approximately straight-line basis to zero in May 2007.

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### FORWARD-LOOKING STATEMENTS

This prospectus 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

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comparable terminology. Our actual results might differ materially from any forward-looking statement due to various risks, uncertainties and contingencies, including:

- . the success or failure of our efforts to implement our business strategy;
- . the early stage of the products we are developing;
- . uncertainties relating to clinical trials and regulatory reviews;
- . the need for additional funds;
- . 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 discussed in the "Risk Factors" section and elsewhere in this prospectus.

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.

### USE OF PROCEEDS

Unless otherwise specified in a prospectus supplement or amendment accompanying this prospectus, we will add the net proceeds from the sale of the securities to which this prospectus and any prospectus supplement or amendment relate to our general funds which we will use for financing our operations.

### DIVIDEND POLICY

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.

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### CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2001. Our capitalization is presented on an actual basis and on a modified pro forma basis to reflect the issuance of \$5,000,000 and \$10,000,000 of our common stock in this offering at \$2.05 per share, which was the closing price of our stock on June 26, 2001, after deduction of an estimated \$530,000 and \$880,000, respectively, in commissions and expenses expected to be incurred in this offering. The pro forma figures are given as an example only, and there is no requirement in this offering that any minimum number of shares be sold. The

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outstanding share information shown in the table excludes 2,066,564 shares of common stock issuable upon exercise of stock options, 1,225,149 shares of common stock reserved for issuance under our 1994 Stock Option Plan, 17,783 shares issuable upon exercise of warrants for common stock, and 22,191 shares issuable upon exercise of warrants for Series B preferred stock as of March 31, 2001.

	Actual	
Capital lease obligations.....	\$	54
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 issued and outstanding (liquidation value of \$18,031,000).....		1
Series B convertible preferred stock, 600,000 shares authorized; 28,457 issued and outstanding.....		1
Common stock, \$.001 par value per share, 40,000,000 shares authorized; 8,385,171 shares issued and outstanding, actual; 10,824,195 and 13,263,220 shares issued and outstanding, as adjusted, respectively.....		8
Additional paid-in capital.....	99,046	
Restricted stock.....	(179)	
Accumulated deficit.....	(93,685)	
Total stockholders' equity.....		5,192
Total capitalization.....	\$	5,246

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### MARKET FOR SECURITIES

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, which prices do not reflect retail mark-up, markdown or commissions.

	High	Low
	-----	-----
Fiscal Year Ended September 30, 1999		
October 1, 1998 through December 31, 1998..	\$ 10 1/8	\$ 3 3/8
January 1, 1999 through March 31, 1999.....	15 1/2	5
April 1, 1999 through June 30, 1999.....	8 1/4	4 1/16
July 1, 1999 through September 30, 1999.....	5 5/8	1/2

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### Fiscal Year Ended September 30, 2000

October 1, 1999 through December 31, 1999..	1 13/16	1/2
January 1, 2000 through March 31, 2000.....	11	1 17/32
April 1, 2000 through June 30, 2000.....	6 1/8	1 1/2
July 1, 2000 through September 30, 2000....	4 3/4	1 11/16

### Fiscal Year Ending September 30, 2001

October 1, 2000 through December 31, 2000..	3 3/4	1 13/16
January 1, 2001 through March 31, 2001.....	3 1/4	1 1/2
April 1, 2001 through June 30, 2001.....	2 1/4	1
July 1, 2001 through July 20, 2001.....	1.95	1.75

On July 20, 2001, the high and low sales prices of our common stock, as reported by Nasdaq, were \$1.95 and \$1.70, respectively. As of May 31, 2001, the number of record holders of our common stock was 152 and we estimate that the number of beneficial owners was approximately 5,000.

### 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 prospectus. We derived the consolidated statements of operations data for the fiscal years ended September 30, 1996, 1997, 1998, 1999 and 2000 and the consolidated balance sheet data at September 30, 1996, 1997, 1998, 1999 and 2000 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, 1996 and 1997 and the consolidated balance sheet data at September 30, 1996, 1997 and 1998, are included elsewhere in this prospectus.

The unaudited six-month financial information is derived from our financial records and includes all adjustments (consisting only of normal recurring adjustments) necessary to present our consolidated financial position for the respective periods.

Please be advised that historical results are not necessarily indicative of the results to be expected in the future, particularly given our acquisition and disposition history. Our historical cash expenditures prior to December 31, 1999 were significantly higher than our current cash spending rate. This lower level of expenditures has resulted from the discontinuance of the IRL and BEXTRA programs. For more information on our discontinued programs see "Business - Discontinued Programs".

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STATEMENT OF OPERATIONS DATA:  
(in thousands, except per share data)

Six Months Ended March 31,			Year En
2001	2000	2000	1999
----	----	----	----
(Unaudited)			

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Revenue:					
Contract and license fee revenue.....	\$	-	\$ 100	\$ 100	\$ 2,088
Cell processing revenue.....		3	-	-	-
Total revenue.....		3	100	100	2,088
Costs and expenses:					
Research and development.....		3,375	3,625	7,645	18,996
Purchase of in-process research and development.....		-	6,664	6,664	-
General and administrative.....		1,446	1,252	2,613	3,045
Total costs and expenses.....		4,821	11,541	16,922	22,041
Loss from operations.....		(4,818)	(11,441)	(16,822)	(19,953)
Gain on sale of division.....		-	9,751	9,751	-
Gain on settlement of accrued liability....		767	-	-	-
Equity in loss of Incara Development.....		(5,669)	-	-	-
Investment income, net.....		156	153	406	355
Income taxes.....		-	-	-	-
Minority interest.....		-	-	-	-
Net loss.....		(9,564)	(1,537)	(6,665)	(19,598)
Preferred stock dividend accreted.....		(214)	-	-	-
Net loss attributable to common stockholders	\$	(9,778)	\$ (1,537)	(6,665)	\$ (19,598)
Net loss per weighted share attributable to common stockholders:					
Basic and diluted.....	\$	(1.26)	\$ (0.29)	\$ (1.06)	\$ (2.98)
Weighted average common shares outstanding:					
Basic and diluted.....		7,772	5,379	6,312	6,583

BALANCE SHEET DATA:  
(in thousands)

	March 31,				Se
	2001	2000	2000	1999	
	(Unaudited)				
Cash and cash equivalents and marketable securities.....	\$ 4,954	\$ 10,522	\$ 6,555	\$ 4,960	
Working capital.....	\$ 4,529	\$ 8,867	\$ 4,662	\$ 2,207	
Total assets.....	\$ 6,615	\$ 11,151	\$ 7,348	\$ 8,044	
Long-term portion of capital lease obligations and notes payable.....	\$ 31	\$ 27	\$ 43	\$ 981	
Total liabilities.....	\$ 1,423	\$ 2,150	\$ 2,536	\$ 4,253	
Total stockholders' equity.....	\$ 5,192	\$ 9,001	\$ 4,812	\$ 3,791	

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### QUARTERLY FINANCIAL DATA:

(Unaudited)

(in thousands, except per share amounts)

Fiscal 2001 -----	First Quarter -----	Second Quarter -----	Third Quarter -----
Total revenue.....	\$ -	\$ 3	
Net loss.....	\$ (1,639)	\$ (7,925)	
Net loss attributable to common stockholders.....	\$ (1,639)	\$ (8,139)	
Net loss per weighted share attributable to common stockholders			
Basic.....	\$ (0.22)	\$ (1.00)	
Diluted.....	\$ (0.22)	\$ (1.00)	
Fiscal 2000 -----			
Total revenue.....	\$ 100	\$ -	\$ -
Net income (loss).....	\$ 6,923	\$ (8,460)	\$ (2,944)
Net income (loss) per common share			
Basic.....	\$ 1.33	\$ (1.53)	\$ (0.41)
Diluted.....	\$ 1.26	\$ (1.53)	\$ (0.41)
Fiscal 1999 -----			
Total revenue.....	\$ 191	\$ 209	\$ 188
Net loss.....	\$ (6,121)	\$ (6,176)	\$ (4,119)
Net loss per common share			
Basic.....	\$ (0.84)	\$ (0.85)	\$ (0.56)
Diluted.....	\$ (0.84)	\$ (0.85)	\$ (0.56)

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### UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL INFORMATION

The consolidated financial statements of Incara are included elsewhere in this prospectus. You should read the unaudited pro forma 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.

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)  
(Unaudited)

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Fiscal Year Ended September 30, 2000

	Consolidated Actual	Pro Forma Adjustments - IRL	Pro Forma As Adjusted
Revenue:			
Contract and license fee revenue.....	\$ 100	\$ 100	\$
Costs and expenses:			
Research and development.....	7,645	1,339	6,306
Purchase of in-process research and development.....	6,664	-	6,664
General and administrative.....	2,613	-	2,613
Total costs and expenses.....	16,922	1,339	(15,583)
Loss from operations.....	(16,822)	(1,239)	(15,583)
Gain on sale of division.....	9,751	9,751	
Interest income, net.....	406	(37)	44
Net income (loss).....	\$ (6,665)	\$ 8,475	\$ (15,149)
Net loss per common share:			
Basic.....	\$ (1.06)		\$ (2.4)
Diluted.....	\$ (1.06)		\$ (2.4)
Weighted average common shares outstanding.....	6,312		6,312

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.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion in conjunction with our consolidated financial statements and the notes appearing elsewhere in this prospectus. 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 "Risk Factors" and elsewhere in this prospectus.

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### OVERVIEW

Incara is 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 and its subsidiaries, for treatment of ulcerative colitis.

On January 22, 2001, we closed on a collaborative and financing transaction with Elan. As part of the transaction, Elan and Incara 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 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's 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 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 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 later of the completion of enrollment of a Phase 2/3 clinical trial for OP2000 or December 21, 2001, 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 common stock for the day prior to the purchase, or (2) a 25% premium to the average daily price per share of Incara 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.



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Elan and Incara 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 May 31, 2001, we had not borrowed any funds pursuant to this note.

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For financial reporting purposes, the value initially recorded as Incara's investment in Incara Development is the same as the fair value of the Series C preferred stock issued, which was approximately \$5,496,000. This value is the estimated fair market value of Incara's common stock into which the Series C preferred stock could have converted, calculated as of the closing date. 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. From the date of issue up to December 21, 2006, we will accrete the Series C preferred stock from its recorded value up to its face value plus the 7% dividend.

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 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's investments, advances and commitments to make future investments in or advances to Incara Development. Further, because Elan can exchange its investment in Incara's Series C preferred stock for Incara's 30.1% preferred interest in Incara Development, Incara will only recognize 50% of any accumulated net earnings of Incara Development. During the six months ended March 31, 2001, Incara's equity in loss of Incara Development was \$5,669,000, which included \$5,496,000 for Incara's interest in the immediate write-off at inception of the contributed technology by Elan to Incara Development and \$173,000 for net losses.

On March 31, 2000, Incara 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 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

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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.

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 \$7,100,000 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 "Pro Forma Consolidated Financial Information."

In May 1998, Incara acquired all of the outstanding stock of Transcell Technologies, Inc., a majority-owned subsidiary of Interneuron Pharmaceuticals, Inc., through a merger with Transcell in exchange for Incara common stock, stock options and stock warrants. We refer to the former Transcell operation as Incara Research Laboratories, or IRL. We accounted for the purchase of Interneuron's 77.9% interest in Transcell by Incara in a manner similar to a "pooling-of-interests," because it represented a transfer of stock between entities under common control, as Interneuron also owned a majority of our stock at the time. We accounted for the acquisition of the non-Interneuron ownership interest by using the purchase method of accounting. We have combined all of Transcell's past results of operations with our consolidated results of operations. We issued stock in the Transcell merger in three installments. We issued the first installment upon the closing of the merger in May 1998. In lieu of the second installment payment due to Interneuron in connection with the merger, Interneuron retained 281,703 shares of Incara common stock as part of a corporate restructuring between Interneuron and Incara. In August 1999, Incara issued 867,583 shares of Incara common stock to the other former Transcell stockholders as payment for their second installment of the merger. We issued the third and final installment of 856,861 shares of Incara common stock to the former Transcell stockholders, including Interneuron, in February 2000. We calculated the number of shares issued using a formula based on the market price of Incara common stock prior to the stock issuance date. The issuance of these additional shares did not impact our operating results because we included the value of these shares in the determination of the purchase price of Transcell in fiscal 1998.

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We had net losses attributable to common stockholders of \$6,665,000 and \$9,778,000 for the fiscal year ended September 30, 2000 and for the six months ended March 31, 2001, respectively. We had an accumulated deficit of \$93,685,000 at March 31, 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.

### RESULTS OF OPERATIONS

Six Months Ended March 31, 2001 Compared to Six Months Ended March 31, 2000

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We incurred net losses attributable to common stockholders of \$9,778,000 and \$1,537,000 for the six months ended March 31, 2001 and 2000, respectively. The net loss for the six months ended March 31, 2001 includes equity losses in Incara Development of \$5,669,000 related to operating losses for Incara Development's initial quarter and the immediate write-off of the contributed technology. The net loss for the six months ended March 31, 2001 was reduced by a \$767,000 gain recognized on the settlement of a disputed accrued liability for a discontinued program and the net loss for the six months ended March 31, 2000 was reduced by the \$9,751,000 gain on the sale of IRL.

We had cell processing revenue of \$3,000 for the six months ended March 31, 2001. This revenue resulted from fees we earned for processing liver cells that are used for research purposes by other companies. Contract revenue of \$100,000 for the six months ended March 31, 2000 resulted from a collaboration that we sold with our IRL division in December 1999.

Our research and development, or R&D, expenses decreased \$250,000, or 7%, to \$3,375,000 for the six months ended March 31, 2001 from \$3,625,000 for the six months ended March 31, 2000. R&D expenses for the six months ended March 31, 2000 included \$1,376,000 of expenses for IRL, which was sold in December 1999.

R&D expenses for our liver cell program increased \$511,000, or 104%, to \$1,004,000 for the six months ended March 31, 2001 from \$493,000 for the six months ended March 31, 2000. Expenses were higher this fiscal year due to increased activity in the program, including increases in consultants, sponsored research, headcount and patent fees.

R&D expenses for our antioxidant program increased \$740,000, or 129%, to \$1,314,000 for the six months ended March 31, 2001 from \$574,000 for the six months ended March 31, 2000. In February 2001, we announced the selection of a catalytic antioxidant compound for late-stage preclinical development to support an Investigational New Drug, or IND, application for the treatment of ischemic stroke. R&D expenses were higher this fiscal year due to increased activity in the program, including the costs of process improvement and scale-up of the IND compound.

In January 2001, Incara transferred the rights to its OP2000 compound being developed for inflammatory bowel disease to Incara Development. R&D expenses incurred prior to December 21, 2000 were on behalf of Incara, while R&D expenses incurred after December 20, 2000 were on behalf of Incara Development. Expenses for OP2000 of \$733,000 for the six months ended March 31, 2000 were included in R&D expenses. Concurrent with Incara's investment in Incara Development, R&D work by Incara for OP2000 is performed on behalf of Incara Development. Amounts billable to Incara Development for OP2000 for expenses incurred and work performed by Incara are netted against R&D expenses. Subsequent to our investment in Incara Development, our expenses associated with OP2000 development are shown as "Equity in loss of Incara Development." While Incara owns 80.1% of the outstanding stock of Incara Development, Elan has retained significant minority investor rights that are considered "participating rights" as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Incara 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's investments, advances and commitments to make future investments in or advances to Incara Development. Further, since Elan can exchange its investment in Incara's Series C preferred stock for Incara's 30.1% preferred interest in Incara Development, Incara will only recognize 50% of any accumulated net earnings of Incara Development. During the six months ended March 31, 2001, our equity in loss of Incara Development was \$5,669,000, which included \$5,496,000 for Incara's interest in the immediate write-off at inception of the contributed technology by Elan to

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Incara Development and \$173,000 for net losses.

Purchase of in-process research and development expenses for the six months ended March 31, 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 \$194,000, or 15%, to \$1,446,000 for the six months ended March 31, 2001 from \$1,252,000 for the six months ended March 31, 2000.

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Incara accreted \$214,000 of dividends on its Series C preferred stock during the six months ended March 31, 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, Incara will accrete the Series C preferred stock from its recorded value up to its face value plus the 7% dividend, compounded annually.

### 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 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 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. All of this revenue 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.

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.

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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.

### Fiscal Year Ended September 30, 1999 Compared To Fiscal Year Ended September 30, 1998

Our net loss of \$19,598,000 for fiscal 1999 was \$452,000, or 2%, greater than the \$19,146,000 net loss for fiscal 1998.

Contract and license fee revenue for fiscal 1999 was \$2,088,000, as compared to \$6,121,000 for fiscal 1998. Contract and license fee revenue for fiscal 1999 primarily resulted from our collaboration with Merck. During fiscal 1999, we received a \$1,500,000 milestone payment from Merck for compounds that demonstrated specific activity in laboratory tests using both resistant and sensitive bacterial strains. Merck also funded \$563,000 of research and development costs at IRL during fiscal 1999.

Contract and license fee revenue for fiscal 1998 included (1) a \$4,000,000 payment from Astra Pharmaceuticals, L.P. received pursuant to the termination of a collaboration with Astra Merck Inc. for the development, manufacturing and marketing of bucindolol in the United States, (2) \$833,000 of U.S. bucindolol development support from Astra Merck prior to the termination of the Astra Merck collaboration, and (3) \$1,138,000 of revenue recognized in conjunction with the Merck

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collaboration.

Our research and development expenses increased \$2,197,000, or 13%, to \$18,996,000 in fiscal 1999 from \$16,799,000 in fiscal 1998.

Expenses for the development of bucindolol and general R&D expenses increased \$2,885,000, or 59%, to \$7,807,000 for fiscal 1999 from \$4,922,000 for fiscal 1998. Our expenses increased after funding from the Astra Merck collaboration ended in September 1998 and also increased as a result of the costs of expanded European clinical trials for bucindolol during fiscal 1999. Pursuant to the Astra Merck collaboration, during fiscal 1998 Astra Merck paid for most expenses related to the development of the twice-daily formulation of bucindolol for the United States, including liabilities assumed by Astra Merck on our behalf of approximately \$6,065,000. This additional amount did not flow through our statements of operations, because it was offset against related

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expenses. Because we terminated the Astra Merck collaboration in September 1998, we absorbed all of the U.S. development expenses for bucindolol in fiscal 1999. In addition, we expanded the European bucindolol clinical program with BASF Pharma/Knoll AG during fiscal 1999, resulting in expense of approximately \$2,326,000 in fiscal 1999 versus approximately \$1,309,000 in fiscal 1998. We terminated the development of bucindolol in the last quarter of fiscal 1999 and all estimated costs of termination were accrued as of September 30, 1999.

R&D expenses for IRL remained relatively constant, increasing by only \$44,000, or 1%, to \$8,245,000 for fiscal 1999 from \$8,201,000 for fiscal 1998. During fiscal 1999 IRL incurred increased expenses for license fees paid to Princeton University and patent preparation fees. These increased expenses were offset by lower depreciation costs, because in fiscal 1998 we expensed \$856,000 of Transcell property and equipment that did not meet our capitalization criteria.

R&D expenses for our antioxidant program increased by \$96,000, or 5%, to \$2,112,000 for fiscal 1999 from \$2,016,000 for fiscal 1998, primarily due to an increase in contract services for research and preclinical studies.

R&D expenses for our liver cell program increased by \$172,000, or 26%, to \$832,000 for fiscal 1999 from \$660,000 for fiscal 1998, primarily due to increased fees for patent preparation and a fee to the University of North Carolina for the license of technology developed under the research agreement with UNC.

During fiscal 1998, we paid and expensed a \$1,000,000 license fee for a development compound licensed from Opocrin S.p.A.

In conjunction with the Transcell merger, we incurred a charge of \$5,343,000 for the purchase of in-process research and development during fiscal 1998, because feasibility of the in-process research and development acquired was not yet established and we had no alternative future use for the technology. This charge represents the market value of the shares of Incara stock issued to the former minority interest owners of Transcell.

General and administrative expenses decreased by \$464,000, or 13%, to \$3,045,000 for fiscal 1999 from \$3,509,000 for fiscal 1998, primarily due to the elimination of IRL administrative personnel and functions at IRL in conjunction with the Transcell merger.

### LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2001, we had cash and cash equivalents and marketable securities of \$4,954,000, a decrease of \$1,601,000 from September 30, 2000. Cash decreased primarily due to operating expenses of \$4,821,000 for the six months, offset by \$4,000,000 received from the net effect of investment transactions with Elan. We believe that this \$4,954,000 of cash, along with anticipated borrowings of cash under an existing note arrangement that we have with Elan, will only be adequate to fund our operations through September 30, 2001, the end of our fiscal year.

During the past 18 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 in our next fiscal year 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 these cash requirements, we

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will need to raise significant additional funds during our next fiscal year and beyond.

To meet our operating cash requirements for our next fiscal year we intend to

- o sell up to \$10,000,000 of our common stock through this offering;
- o sell shares of our common stock under an equity financing line we currently have with Torneaux Fund Ltd.;
- o establish new collaborations for our current research programs that include initial cash payments and on-going research support; and
- o borrow cash from Elan under the terms of an existing note arrangement that we have with Elan to meet our obligations for Incara Development.

To meet our operating cash requirements after September 30, 2002, we intend to

- o receive additional research support, milestone and other cash payments from collaborations;
- o sell additional shares of our stock through equity offerings; and
- o continue to borrow cash from Elan under the existing note to meet our obligations for Incara Development.

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's 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. However, advances under the note are subject to the mutual consent of Elan and Incara. 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 a month. As of June 25, 2001, we could sell up to \$1,750,000 of our common stock, based on the closing sales price of our stock on that day of \$2.05 per share. However, assuming the price of our stock does not increase to \$3.00 or higher, we are limited to selling a maximum of \$250,000 worth of our stock at any one time. Consequently, assuming our stock price remains at its current level, the amount of stock we could sell to Torneaux at June 26, 2001 will decrease by approximately \$219,000 each month. In addition, in order to sell stock to Torneaux, the price of our common stock must not be less than \$2.00. On July 9, 2001, the closing price of our common stock was \$1.89.

If we are unable to enter into new collaborations or raise additional capital to support our operations after September 30, 2001, we might be required to scale back, delay or discontinue one or more of our programs, or obtain funds on terms that are not favorable to us, 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.

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## BUSINESS

### General

Incara is developing therapies focused on tissue protection, repair and regeneration. In particular, we are focused on developing 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 areas of cell therapy. In collaboration with Elan, we are conducting a Phase 2/3 clinical trial of an ultra-low molecular weight heparin for the treatment of ulcerative colitis.

### Human Liver Progenitor Cell Transplant

Hepatic progenitor cells are cells in the liver that can differentiate into a variety of daughter cells that provide liver function. These are the early cells in the maturation of the liver and include the liver stem cells and their early descendants. We are developing human liver progenitor cells as a potential treatment for liver failure.

Incara established its liver 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 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 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 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 \$300,000. Over 17,500 patients are on the liver transplant waiting list, an increase of more than 100% over the last four years and up from 1,500 ten years ago. Furthermore, there are a total of approximately 100,000 adults with severe cirrhosis and other forms of chronic liver failure 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



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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 beneficial results 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 where benefit occurred, 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 severe 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 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

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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 isolate the liver progenitor cells from whole donor organs not suitable for transplant. Human liver progenitor cells, unlike mature liver 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 may 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

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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.

[DIAGRAM 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. 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 nine traditional organ donor programs for procurement of livers and are pursuing relationships with over 30 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 donor liver does not provide enough liver progenitor cells for multiple recipients, commercialization of our program will be adversely affected.

### Development Strategy

We have successfully demonstrated scale-up of the liver progenitor cell isolation and selection process. This step includes establishing isolation and 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 compliant with cGMP.

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### Clinical Trials

Incara is exploring two patient populations for the initial clinical trials of progenitor cell transplantation. The first 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

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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. Incara plans to file in late 2001 an IND to begin these initial Phase 1 clinical trials. Clinical investigators from several leading research hospitals have expressed interest in participating in our clinical trials. Some of these investigators have experience with cell transplants using unfractionated human liver cells.

### 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. Progenitor cells, because of their extensive expansion potential, may be suitable to produce continued gene expression. 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

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, pharmaceutical companies have difficulty obtaining a consistent supply of human liver cells for toxicity testing. As a result of our supply of human livers, we collect non-progenitor liver cells as a byproduct of our stem cell isolation procedure. This allows us to supply human liver cells for a processing fee to pharmaceutical companies for use in toxicology testing of the drugs they are developing. We have recently established material transfer agreements with several major pharmaceutical companies which allow them, but do not require them, to receive human liver cells from us for a processing fee.

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,

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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.

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### Liver Assist Device

Incara's liver progenitor cell technology has potential application in the development of a liver assist device, or LAD. LADs are 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. Attempts at clinically useful LADs by others have utilized 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 pig hepatocytes, while easily obtained, have limitations such as potential immune reactions to secreted pig proteins, 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. Functioning human liver cells from donor organs have not been a viable alternative due to the scarcity of donor livers.

We believe that a LAD using our human liver progenitor cells could overcome some of the problems experienced to date. Proteins secreted by these cells will be of human origin, so immune reactions may be minimized. The progenitor cells can divide extensively in culture, so that cells from one donor liver may be able to supply cells for many LADs. Most importantly, these cells should display the wide range of liver functions necessary for clinical utility. We are currently developing a prototype cartridge that could be used 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 and might not prove to be superior to LADs using pig or other cell types, or even be feasible for human therapy at all.

### Commercialization

There are approximately 120 liver transplant programs in hospitals in the United States. We believe that marketing to these hospitals could