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INCARA PHARMACEUTICALS CORP

Form 10-Q

February 14, 2002

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

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. For the quarterly period ended December 31, 2001.

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. For the transition period from _____ to _____.

Commission File Number

0-27410

INCARA PHARMACEUTICALS CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware

56-1924222

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

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

27709

(Address of Principal Executive Office)

(Zip Code)

Registrant's Telephone Number, Including Area Code

919-558-8688

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES X NO

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding as of February 11, 2002
Common Stock, par value \$.001	12,717,093 Shares

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INCARA PHARMACEUTICALS CORPORATION

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INCARA PHARMACEUTICALS CORPORATION

CONSOLIDATED BALANCE SHEETS

(Dollars in thousands, except per share data)

	December 2001

	(Unaudited)

ASSETS	
Current assets:	
Cash and cash equivalents	
Accounts receivable from Incara Development	
Prepays and other current assets	

Total current assets	
Property and equipment, net	
Other assets	

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:	
Accounts payable	
Accrued expenses	
Accumulated losses of Incara Development in excess of investment	
Current portion of capital lease obligations	
Current portion of notes payable	

Total current liabilities	
Long-term portion of capital lease obligations	
Long-term portion of notes payable	
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 \$12,881)	
Series B convertible preferred stock, 600,000 shares authorized;	
28,457 shares issued and outstanding	
Common stock, \$.001 par value per share, 40,000,000 shares authorized,	
12,717,093 shares issued and outstanding	
Additional paid-in capital	
Restricted stock	
Accumulated deficit	

Total stockholders' equity	

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

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INCARA PHARMACEUTICALS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended December 31,	
	2001	2000
	-----	-----
Revenue:		
Cell processing revenue	\$ 35	\$ -
	-----	-----
Costs and expenses:		
Research and development	2,073	1,807
General and administrative	663	683
	-----	-----

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Total costs and expenses	2,736	2,490
	-----	-----
Loss from operations	(2,701)	(2,490)
Equity in loss of Incara Development	(338)	-
Investment income, net	2	84
Other income	150	767
	-----	-----
Net loss	(2,887)	(1,639)
Preferred stock dividend accreted	(214)	-
	-----	-----
Net loss attributable to common stockholders	\$ (3,101)	\$ (1,639)
	=====	=====
Net loss per common share:		
Basic and diluted	\$ (0.25)	\$ (0.24)
	=====	=====
Weighted average common shares outstanding:		
Basic and diluted	12,501	6,924
	=====	=====

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

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

	Three Months Ended December 31,	
	2001	2000
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (2,887)	\$ (1,639)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	96	26
Equity in loss of Incara Development	397	-
Gain on settlement of accrued liability	-	(767)
Noncash compensation	140	30
Change in assets and liabilities:		
Accounts receivable from Incara Development	607	-
Prepays and other assets	59	(90)
Accounts payable and accrued expenses	(360)	142
	-----	-----
Net cash used in operating activities	(1,948)	(2,298)
	-----	-----

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Cash flows from investing activities:		
Investment in Incara Development	(857)	-
Proceeds from sales and maturities of marketable securities	-	3,072
Purchases of property and equipment	(172)	(36)
	-----	-----
Net cash provided by (used in) investing activities	(1,029)	3,036
	-----	-----
Cash flows from financing activities:		
Proceeds from notes payable	1,437	-
Principal payments on notes payable	(37)	(27)
Principal payments on capital lease obligations	(6)	(5)
	-----	-----
Net cash provided by (used in) financing activities	1,394	(32)
	-----	-----
Net increase (decrease) in cash and cash equivalent	(1,583)	706
Cash and cash equivalents at beginning of period	5,453	1,877
	-----	-----
Cash and cash equivalents at end of period	\$ 3,870	\$ 2,583
	=====	=====
Supplemental disclosure of financing activities:		
Series C preferred stock dividend accreted	\$ 214	\$ -
	=====	=====
Common stock issued in settlement of accrued liability	\$ -	\$ 416
	=====	=====

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

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INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. Basis of Presentation

The Company is developing therapies focused on tissue protection, repair and regeneration. In particular, the Company is focused on developing adult liver cell therapy for the treatment of liver failure. The Company is also conducting research and development of a series of catalytic antioxidant molecules and, in collaboration with Elan Corporation, plc, an Irish company, and its subsidiaries ("Elan"), is conducting a Phase 2/3 clinical trial of deligoparin, an ultra-low molecular weight heparin for the treatment of ulcerative colitis. Deligoparin was previously known as OP2000.

The "Company" refers collectively to Incara Pharmaceuticals Corporation, a Delaware corporation ("Incara Pharmaceuticals"), its two wholly owned subsidiaries, Aeolus Pharmaceuticals, Inc., a Delaware corporation ("Aeolus"), and Incara Cell Technologies, Inc., a Delaware corporation ("Cell Technologies"), as well as its equity investee, Incara Development, Ltd., a Bermuda corporation ("Incara Development"). As of December 31, 2001, Incara Pharmaceuticals owned 80.1% of Incara Development and 35.0% of CPEC LLC. While Incara Pharmaceuticals owns 80.1% of the outstanding stock of Incara Development, Elan has retained significant minority investor rights, including

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50% control of the management committee which oversees the deligoparin program, that are considered "participating rights" as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, Incara Pharmaceuticals does not consolidate the financial statements of Incara Development, but instead accounts for its investment in Incara Development under the equity method of accounting. Incara Development had net operating expenses and a net loss of approximately \$481,000 for the quarter ended December 31, 2001 and no activity for the quarter ended December 31, 2000.

All significant intercompany activity has been eliminated in the preparation of the consolidated financial statements. The unaudited consolidated financial statements have been prepared in accordance with the requirements of Form 10-Q and Rule 10-01 of Regulation S-X. Some information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to those rules and regulations. In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the consolidated financial position, results of operations and cash flows of the Company. The consolidated balance sheet at September 30, 2001 was derived from the Company's audited financial statements included in the Company's Annual Report on Form 10-K. The unaudited consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2001 and in the

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Company's other SEC filings. Results for the interim period are not necessarily indicative of the results for any other period.

B. Recent Accounting Pronouncements

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

C. Net Loss Per Common Share

The Company computes basic net loss per weighted share attributable to common stockholders using the weighted average number of shares of common stock outstanding during the period. The Company computes diluted net loss per weighted share attributable to common stockholders using the weighted average

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number of shares of common and dilutive potential common shares outstanding during the period. Potential common shares consist of stock options, restricted common stock, warrants and convertible preferred stock, which are excluded if their effect is antidilutive. At December 31, 2001, diluted weighted average common shares excluded incremental shares of approximately 6,052,000 related to stock options, unvested shares of restricted common stock, convertible preferred stock and warrants to purchase common and preferred stock. These shares are excluded due to their antidilutive effect as a result of the Company's loss from operations.

D. Notes Payable

In October 2001, the Company executed a Master Loan and Security Agreement with Transamerica Technology Finance Corporation to finance equipment purchases. In October 2001, the Company borrowed \$565,000 from Transamerica and pledged equipment with a cost of \$686,000 as collateral.

In October 2001, Incara Pharmaceuticals borrowed \$857,000 from Elan pursuant to the terms of a note arrangement that it has with Elan. See "Subsequent Event" (Note F).

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E. Commitments and Contingencies

In December 1999, Incara Pharmaceuticals sold IRL, its anti-infectives division, to a private pharmaceutical company. Incara Pharmaceuticals remains contingently liable through May 2007 on debt and lease obligations of approximately \$6,500,000 assumed by the purchaser, including the IRL facility lease in Cranbury, New Jersey.

F. Subsequent Event

On February 13, 2002, the Company, with Elan's consent, converted \$1,400,000 of principal and accrued interest on a note payable owed by Incara Pharmaceuticals to Elan into 480,000 shares of common stock and 58,883 shares of Series B preferred stock. The \$1,400,000 of principal and accrued interest consisted of \$857,000 of principal outstanding on December 31, 2001, \$518,000 that Incara Pharmaceuticals borrowed under the note payable in February 2002 and \$25,000 of accrued interest on the note payable.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results

of Operations.

Introduction

Unless otherwise noted, the phrase "we" or "our" refers collectively to Incara Pharmaceuticals Corporation and our two wholly owned subsidiaries, Aeolus Pharmaceuticals, Inc. and Incara Cell Technologies, Inc., as well as our equity investee, Incara Development, Ltd. At December 31, 2001, Incara Pharmaceuticals

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owned 80.1% of Incara Development.

This Report contains, in addition to historical information, statements by us with respect to expectations about our business and future results, which are "forward-looking" statements under the Private Securities Litigation Reform Act of 1995. These statements and other statements made elsewhere by us or our representatives, which are identified or qualified by words such as "likely," "will," "suggests," "expects," "might," "believe," "could," "should," "may," "estimates," "potential," "predict," "continue," "would," "anticipates," "plans," or similar expressions, are based on a number of assumptions that are subject to risks and uncertainties. Actual results could differ materially from those currently anticipated or suggested due to a number of factors, including those set forth herein, those set forth in our Annual Report on Form 10-K and in our other SEC filings, and including risks relating to the need for additional funds, the early stage of products under development, uncertainties relating to clinical trials and regulatory reviews, competition and dependence on collaborative partners. All forward-looking statements are based on information available as of the date hereof, and we do not assume any obligation to update such forward-looking statements.

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

Results of Operations

We had a net loss attributable to common stockholders of \$3,101,000 for the three months ended December 31, 2001 versus a net loss of \$1,639,000 for the three months ended December 31, 2000. The net loss for the three months ended December 31, 2001 was reduced by a \$150,000 gain recognized on the sale of trademarks for a discontinued program. The net loss for the three months ended December 31, 2000 was reduced by a \$767,000 gain recognized on the settlement of a disputed accrued liability for a discontinued program.

We had cell processing revenue of \$35,000 for the three months ended December 31, 2001. This revenue resulted from fees we earned for processing liver cells that are used for research purposes by other pharmaceutical companies.

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Our research and development, or R&D, expenses increased \$266,000 (15%) to \$2,073,000 for the three months ended December 31, 2001 from \$1,807,000 for the three months ended December 31, 2000. R&D expenses were higher this fiscal quarter primarily due to significant increases in spending on our liver cell therapy program, offset by a reduction in R&D expenses due to how expenses are classified for our deligoparin program.

Deligoparin expenses incurred during the first quarter of fiscal 2001 were \$335,000, which were charged to R&D expenses. In January 2001, Incara Pharmaceuticals transferred the rights to deligoparin to Incara Development. Costs for deligoparin incurred after the transfer are on behalf of Incara Development. Amounts billable to Incara Development for expenses incurred and work performed by Incara Pharmaceuticals for deligoparin are netted against R&D expenses. Subsequent to our investment in Incara Development, our expenses

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associated with development of deligoparin flow through "Equity in loss of Incara Development." For the first quarter of fiscal 2002, our equity in loss of Incara Development was \$338,000. As of January 31, 2002, we had enrolled 91 patients in our Phase 2/3 clinical trial at the 34 clinical sites that are participating in the clinical trial. No unexpected safety issues have been reported as of January 31, 2002.

R&D expenses for Cell Technologies increased \$824,000 (167%) to \$1,317,000 for the three months ended December 31, 2001 from \$493,000 for the three months ended December 31, 2000. Our research and development for the treatment of liver disorders, using liver cell therapy, is conducted through Incara Cell Technologies. Expenses were higher this quarter due to increased activity in the program and the establishment of our own laboratory facility in August 2001. We incurred increases in spending on laboratory supplies, personnel, patent costs and sponsored research.

R&D expenses for Aeolus increased \$54,000 (8%) to \$698,000 for the three months ended December 31, 2001 from \$644,000 for the three months ended December 31, 2000. Our research and development of small molecule antioxidants for disorders such as stroke and other tissue damage, is conducted through Aeolus. Expenses were higher this quarter due to increased preclinical contract services.

General and administrative expenses decreased \$20,000 (3%) to \$663,000 for the three months ended December 31, 2001 from \$683,000 for the three months ended December 31, 2000.

We accreted \$214,000 of dividends on our Series C preferred stock during the quarter ended December 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, we will accrete the Series C preferred stock for the 7% dividend, compounded annually from its recorded value up to its redemption value.

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Liquidity and Capital Resources

At December 31, 2001, we had cash and cash equivalents of \$3,870,000, a decrease of \$1,583,000 from September 30, 2001. Cash decreased primarily due to the net loss of \$2,887,000 for the first quarter offset by \$1,437,000 proceeds from notes payable.

During the past two years, we have incurred average operational expenses of approximately \$10,000,000 per year, on an annualized basis, including expenses of our R&D programs, but excluding non-cash charges for the purchase of in-process research and development. We anticipate our annual net operational costs to remain at approximately this level, or slightly higher, during fiscal 2002 and for the foreseeable future, although our ongoing cash requirements will depend on numerous factors, particularly the progress of our R&D programs and our ability to negotiate and complete collaborative agreements. Without additional financing or other funding, at our current spending level, we would run out of cash during the third quarter of fiscal 2002. In order to fund our on-going operating cash requirements, we need to raise significant additional funds during 2002 and beyond. We intend to:

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

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- . sell additional shares of our stock; and
- . borrow additional cash from Elan under the terms of an existing note arrangement that we have with Elan to meet our obligations for Incara Development.

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. In our Proxy Statement for our Annual Meeting to be held in March 2002, we are asking our stockholders to approve the sale of up to \$25 million of our securities. 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 our stockholders.

The continued funding of our operations is affected by our ability to sell additional equity in the form of common or preferred stock. Our common stock is not actively traded and the price of our common stock has fluctuated from \$1.00 to \$11.00 during the last two years. Further, we must meet certain minimum capital requirements set by the Nasdaq National Market. If we fail to meet such listing requirements, our common stock might be delisted and become more illiquid.

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

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rights to technologies, product candidates or markets that we might otherwise develop ourselves.

We may borrow up to \$4,806,000 through December 21, 2003 under the note arrangement with Elan to fund our 80.1% pro rata interest in the operating costs of Incara Development. We borrowed \$857,000 under the note in October 2001 and \$518,000 in February 2002. Advances under the note are subject to the mutual consent of Elan and Incara Pharmaceuticals. The note matures on December 21, 2006.

If we are unable to enter into new collaborations or raise additional capital to continue to support our operations, we will be required to scale back, delay or discontinue one or more of our programs, which could have a material adverse affect on our business. Reduction or discontinuation of any of our programs could result in additional charges, which would be reflected in the period of the reduction or discontinuation.

The following pro forma balance sheet reflects the effects of the borrowing of an additional \$518,000 from Elan in February 2002 pursuant to the note arrangement and the conversion to equity of \$1,400,000 of debt owed to Elan in February 2002, as if the events had taken place as of December 31, 2001.

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

	De

	Actual

ASSETS	
Current assets:	
Cash and cash equivalents	\$ 3,870
Accounts receivable from Incara Development	540
Prepays and other current assets	262

Total current assets	4,672
Property and equipment, net	1,417
Other assets	356

	\$ 6,445
	=====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	\$ 1,241
Accrued expenses	359
Accumulated losses of Incara Development in excess of investment	510
Current portion of capital lease obligations	25
Current portion of notes payable	132

Total current liabilities	2,267
Long-term portion of capital lease obligations	10
Long-term portion of notes payable	1,268
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 \$12,881)	1
Series B convertible preferred stock, 600,000 shares authorized; 28,457	
and 87,340 shares issued and outstanding on an actual and pro forma	
basis, respectively	1
Common stock, \$.001 par value per share, 40,000,000 shares authorized,	
12,717,093 and 13,197,093 shares issued and outstanding on an actual and	
pro forma basis, respectively	13
Additional paid-in capital	112,842
Restricted stock	(84)
Accumulated deficit	(109,873)

Total stockholders' equity	2,900

	\$ 6,445
	=====

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/(a)/Reflects the conversion to equity of \$872 of debt owed to Elan at December 31, 2001

/(b)/Reflects the borrowing of \$518 from Elan in February 2002 and the conversion of the debt to equity

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Part II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits

10.75 Agreement and Fourth Amendment, effective February 13, 2002, by and among Incara Pharmaceuticals Corporation, Elan International Services, Ltd., Elan Pharma International Limited and Elan Pharmaceutical Investments III, Ltd.

(b) No reports on Form 8-K were filed by the Company during the three months ended December 31, 2001.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INCARA PHARMACEUTICALS CORPORATION

Date: February 14, 2002

By:

/s/ Richard W. Reichow

Richard W. Reichow, Executive Vice President,
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

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