INCARA PHARMACEUTICALS CORP Form 10-Q February 13, 2001

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

FORM 10-Q

V	Out to the control of	3	15/d) of the Committee				
X 	Quarterly report pursuant to Section 13 or 15(d) of the Securities						
	Exchange Act of 1934. For the 2000.	e quarterly pe	eriod ended December 31,				
	Transition report pursuant to Section 13 or 15(d) of the Securi Exchange Act of 1934. For the transition period from to						
	Commission F	File Number 7410					
	INCARA PHARMACEUT	ICALS CORPORAT	CION				
	(Exact Name of Registrant as	Specified in	its Charter)				
	Delaware		56-1924222				
	other jurisdiction of ation or organization)	(I.R.S.	Employer Identification Number)				
	14287 Highway 54 Building, Suite 300						
Research ?	Triangle Park, NC		27709				
	of Principal Executive Office)		(Zip Code)				
Registrant	t's Telephone Number, Including	g Area Code	919-558-8688				
to be file the preced to file su	by check mark whether the registed by Section 13 or 15(d) of the ding 12 months (or such shorter uch reports), and (2) has been 90 days. YES X NO	ne Securities period that	Exchange Act of 1934 during the registrant was required				
	the number of shares outstandinock, as of the latest practical	-	the issuer's classes of				
	Class	Outstanding a	s of February 8, 2001				
Common Sto	Common Stock, par value \$.001 8,365,849 Shares						

INCARA PHARMACEUTICALS CORPORATION

INDEX TO FORM 10-Q

			PAGE
PART I.	FINANCIAL	INFORMATION	
	Item 1.	Financial Statements	
		ted Balance Sheets as of December 31, 2000 (unaudited) mber 30, 2000	. 3
		ted Statements of Operations for the Three Months ended 31, 2000 and 1999 (unaudited)	. 4
		ted Statements of Cash Flows for the Three Months ended 31, 2000 and 1999 (unaudited)	. 5
	Notes to	Consolidated Financial Statements	. 6
	Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	. 9
PART II.	OTHER INF	ORMATION	
	Item 2.	Changes in Securities and Use of Proceeds	. 12
	Item 4.	Submission of Matters to a Vote of Security Holders	. 12
	Item 6.	Exhibits and Reports on Form 8-K	. 12
	SIGNATURE		. 14

2

INCARA PHARMACEUTICALS CORPORATION

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

	December 2000	•	September 2000
	(Unaudit	ed)	
ASSETS			
Current assets:			
Cash and cash equivalents	\$	2,583	\$
Marketable securities		1,606	
Accounts receivable		105	
Prepaids and other current assets		488	
Total current assets		4,782	
Property and equipment, net		203	

	\$	4,985	\$
	====		=====
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$	578	\$
Accrued expenses		728	
Current portion of capital lease obligations		23	
Current portion of notes payable		_	
Total current liabilities		1,329	
Long-term portion of capital lease obligations		37	
Stockholders' equity:			
Common stock, \$.001 par value per share, 40,000,000 shares authorized, 7,540,849 and 7,365,849 shares issued and			
outstanding at December 31, 2000 and September 30, 2000,			
respectively		8	
Additional paid-in capital		89,366	
Restricted stock		(209)	
Accumulated deficit		(85,546)	
Total stockholders' equity		3,619	
	\$	4 , 985	\$

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

3

INCARA PHARMACEUTICALS CORPORATION

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

	Three Months Ended December 31,			
	200	 0	19 	99
Revenue:				
Contract revenue	\$ 	-	\$ 	100
Costs and expenses:				
Research and development		1,807		2,379
General and administrative		683		562
Total costs and expenses		2 , 490		2 , 941
Loss from operations		(2,490)		(2,841)

=====

Gain on sale of division Gain on settlement of accrued liability Investment income, net		- 767 84		9,751 - 13
Net income (loss)	\$ ====	(1,639)	\$	6 , 923
Net income (loss) per common share: Basic	\$	(0.22)	\$	1.33
Diluted	\$	(0.22)	\$ =====	1.26
Weighted average common shares outstanding: Basic	====	7 , 387	====	5 , 222
Diluted	====	7 , 387	====	5 , 489

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

4

INCARA PHARMACEUTICALS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Three Months Ended December 31,		
	 2000		1999
Cash flows from operating activities: Net income (loss) Adjustments to reconcile net income (loss) to net cash	\$ (1,639)	\$	6,
used in operating activities: Depreciation and amortization Gain on sale of division Gain on settlement of accrued liability Noncash compensation Change in assets and liabilities: Accounts receivable Prepaids and other assets	26 - (767) 30 (5) (85)		(9,
Accounts payable and accrued expenses Net cash used in operating activities	 142 (2,298)		(2,
Cash flows from investing activities: Proceeds from sale of division Proceeds from sales and maturities of marketable securities Purchases of property and equipment	3,072 (36)		11, 2,

Net cash provided by investing activities		3 , 036		13,
Cash flows from financing activities:		(27)		
Principal payments on notes payable		(27)		
Principal payments on capital lease obligations		(5)		
Net cash used in financing activities		(32)		
Net increase in cash and cash equivalents		706		10,
Cash and cash equivalents at beginning of period		1,877		2,
Cash and cash equivalents at end of period	\$	2,583	\$	13,
	=====		====	
Supplemental disclosure of financing activities:				
Common stock issued in settlement of accrued liability	\$	416	\$	
	=====		====	

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

5

INCARA PHARMACEUTICALS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. Basis of Presentation

The "Company" refers collectively to Incara Pharmaceuticals Corporation ("Incara") and its wholly owned subsidiaries, Aeolus Pharmaceuticals, Inc., a Delaware corporation ("Aeolus"), and Renaissance Cell Technologies, Inc., a Delaware corporation ("Renaissance").

The Company conducts discovery and development programs in three areas: (1) inflammatory bowel disease, using an ultra-low molecular weight heparin; (2) liver disorders, using hepatic progenitor cell therapy; and (3) small molecule antioxidants for disorders such as stroke and heart attack.

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, 2000 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, 2000 and in the Company's other Securities and Exchange Commission ("SEC") filings. Results for the interim

period are not necessarily indicative of the results for any other interim period or for the full fiscal year.

B. Recent Accounting Pronouncements

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

6

C. Net Loss Per Common Share

The Company computes basic net loss per common share using the weighted average number of shares of common stock outstanding during the period. The Company computes diluted net loss per common share using the weighted average number of shares of common and dilutive potential common shares outstanding during the period. Potential common shares consist of stock options using the treasury stock method and are excluded if their effect is antidilutive. For the three-month period ended December 31, 2000, the weighted average shares outstanding used in the calculation of net loss per common share did not include potential shares outstanding because they had the effect of reducing net loss per common share.

D. Commitments and Contingencies

In December 1999, Incara sold IRL, its anti-infectives division, to a private pharmaceutical company. Incara remains contingently liable through May 2007 on some remaining debt and lease obligations of approximately \$7,900,000 assumed by the purchaser, including the IRL facility lease in Cranbury, New Jersey.

In January 2001, Incara entered into a five-year non-cancelable operating lease for additional office and laboratory facilities. The future minimum payments under the new lease total \$1,926,000.

E. Knoll Settlement

On December 20, 2000, Incara entered into a Settlement Agreement and Release with Knoll AG ("Knoll") to resolve a dispute regarding a payable owed by us to Knoll for a discontinued program. As of the settlement date, the accrued liability, net of related receivables, on our financial statements was \$1,250,000. We agreed to pay Knoll 150,000 Deutsche marks (approximately \$70,000) and to issue to Knoll 175,000 shares of our common stock (with a value of approximately \$416,000) in exchange for a full release of all amounts owed by us to Knoll. This settlement eliminated the accrued liability owed to Knoll and reduced our net loss by \$767,000 for the quarter ended December 31, 2000.

F. Elan Transaction

On January 22, 2001, Incara closed on a collaborative transaction with Elan

Corporation, plc, an Irish company ("Elan"), Elan International Services, Ltd., a Bermuda company ("Elan International"), and Elan Pharma International Limited, an Irish company ("Elan Pharma"). As part of the transaction, Elan International and Incara formed a Bermuda corporation, Incara Development, Ltd. ("Incara Development"), to develop OP2000. Incara owns all of the common stock of Incara Development and 60.2% of the non-voting preferred shares of Incara Development and Elan International owns 39.8% of the non-voting preferred shares of Incara Development. Of the outstanding combined common and non-voting preferred shares of Incara Development, Incara owns 80.1% and Elan International owns 19.9%.

7

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

Elan International also purchased shares of Incara Series C convertible exchangeable non-voting preferred stock ("Series C Stock") for an aggregate purchase price of \$12,015,000. The Series C Stock bears an annual mandatory stock dividend of 7%, compounded annually. The Series C Stock is convertible into shares of Incara's Series B Stock at the rate of \$64.90 per share. Six years after its issuance, Incara will have the option to either redeem the Series C Stock for cash or for shares of Incara common stock or Series B Stock having a then fair market value of the amount due. The redemption price will be the original issue price plus the compounded 7% annual stock dividend. The proceeds from the Series C Stock issuance were used to fund Incara's obligation to purchase the securities of Incara Development.

Upon the later of the completion of enrollment of a Phase 2/3 clinical trial or December 21, 2001, Elan International will purchase \$1,000,000 of Incara's Series B Stock at a per share price that will be ten times the greater of (a) the average per share price of Incara common stock for the day prior to the purchase, or (b) 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, both as reported on the Nasdaq National Market. In addition, as part of the \$1,000,000 payment, Incara will issue to Elan International a five-year warrant for 20% of the shares of Series B Stock purchased by Elan International. The exercise price of the Series B Stock under this warrant will be equal to twice the per share purchase price of the Series B Stock purchased on the same date.

Elan International and Incara may provide Incara Development's required funding on a pro rata basis based on Elan International's and Incara's respective percentage ownership of the outstanding common and preferred stock of Incara Development. Subject to mutual agreement, Elan Pharma will lend Incara up to \$4,806,000 to fund Incara's pro rata share of development funding for Incara Development. In return, Incara issued a convertible promissory note that bears interest at 10% compounded semi-annually on the amount outstanding thereunder. This note will mature in six years, when it will be payable in an amount equal to the outstanding principal plus accrued interest. Incara has the option to repay the note either in cash or in shares of Series B Stock having a then fair market value of the amount due. The note will be convertible at the option of Elan Pharma at any time after two years into shares of Series B Stock at \$43.27 per share.

As part of the transaction, Elan, Elan Pharma and Incara entered into license agreements under which Incara licensed to Incara Development the OP2000

compound and Elan Pharma licensed to Incara Development its proprietary MEDIPAD(R) Drug Delivery System technology. Incara Development paid Elan \$15,000,000 for a fully paid license to the MEDIPAD Drug Delivery System.

8

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 wholly owned subsidiaries, Aeolus Pharmaceuticals, Inc. and Renaissance Cell Technologies, Inc.

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" or "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 early stage of products under development, uncertainties relating to clinical trials and regulatory reviews, the need for additional funds, 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 conduct discovery and development programs in three areas: (1) inflammatory bowel disease, using an ultra-low molecular weight heparin; (2) liver disorders, using hepatic progenitor cell therapy; and (3) small molecule antioxidants for disorders such as stroke and heart attack.

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 Incara's anti-infectives division and the assumption by the purchaser of certain related liabilities. We remain contingently liable through May 2007 on some remaining debt and lease obligations of approximately \$7,900,000 assumed by the purchaser, including the IRL facility lease in Cranbury, New Jersey. We recognized a gain of \$9,751,000 on the sale of IRL, which was recorded as other income in the first quarter of fiscal 1999.

Results of Operations

We had a net loss of \$1,639,000 for the three months ended December 31, 2000 versus net income of \$6,923,000 for the three months ended December 31, 1999. The net income for the three months ended December 31, 1999 was the net effect of recognizing a \$9,751,000 gain on the sale of IRL, offset by operating expenses of \$2,941,000. 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.

Contract revenue was \$100,000 for the three months ended December 31, 1999. This revenue resulted from a collaboration that we sold with our IRL division in December 1999.

Our research and development, or R&D, expenses decreased \$572,000 (24%) to \$1,807,000 for the three months ended December 31, 2000 from \$2,379,000 for the three months ended December 31, 1999. R&D expenses were lower this fiscal year because of the sale of IRL in December 1999, offset by increases in other R&D areas. R&D expenses for IRL were \$1,376,000 for the three months ended December 31, 1999.

R&D expenses for OP2000, our compound in development for inflammatory bowel disease, increased \$63,000 (23%) to \$335,000 for the three months ended December 31, 2000 from \$272,000 for the three months ended December 31, 1999. Expenses were higher due to an investigator meeting that we held during the quarter ended December 31, 2000 in preparation for our Phase 2/3 clinical trial.

R&D expenses for Renaissance increased \$274,000 (125%) to \$493,000 for the three months ended December 31, 2000 from \$219,000 for the three months ended December 31, 1999. Our research and development of liver disorders, using hepatic progenitor cell therapy, is conducted through Renaissance. Expenses were higher this year due to increased activity in the program, including increases in consultants, patent fees, sponsored research and headcount.

R&D expenses for Aeolus increased \$379,000 (143%) to \$644,000 for the three months ended December 31, 2000 from \$265,000 for the three months ended December 31, 1999. Our research and development of small molecule antioxidants for disorders such as stroke and heart attack, is conducted through Aeolus. Expenses were higher this year due to increased activity in the program, including increases in sponsored research and preclinical testing.

General R&D expenses (expenses not allocated to R&D projects) increased \$88,000 (36%) to \$334,000 for the three months ended December 31, 2000 from \$246,000 for the three months ended December 31, 1999 due to increased salaries and headcount.

General and administrative expenses increased \$121,000 (22%) to \$683,000 for the three months ended December 31, 2000 from \$562,000 for the three months ended December 31, 1999.

Liquidity and Capital Resources

At December 31, 2000, we had cash and cash equivalents and marketable securities of \$4,189,000, a decrease of \$2,366,000 from September 30, 2000. Cash decreased primarily due to the operating expenses of \$2,561,000 for the first quarter. In January 2001, our cash

10

balance increased by \$4,000,000 from the net effect of investment transactions with Elan Corporation, plc. We believe we have adequate financial resources to fund our current operations at least through fiscal 2001.

Our cash requirements for subsequent periods will depend on numerous

factors, particularly the progress of our R&D programs. We intend to use proceeds from an equity financing line with Torneaux Fund Ltd. to help fund operations. Significant additional funds will be required for the development activities of Aeolus and Renaissance, the cost of new equipment and leasehold improvements for a new laboratory facility for Renaissance and for us to continue our clinical program evaluating the use of OP2000, a low-weight molecular heparin, in the treatment of inflammatory bowel disease. Subject to the mutual consent of Elan and Incara, Elan will lend Incara up to \$4,806,000 to fund our portion of OP2000 development costs.

To execute our business plan, we intend to seek the necessary additional capital through one or more potential sources, including the sale of common or preferred stock in private or public equity offerings and from new collaborations related to one or more of our product development programs. We have filed a shelf registration with the SEC for the sale of up to \$10,000,000 of our securities, however, we might not be able to sell our securities under this registration statement, 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. If we are successful in obtaining collaborations for any of our programs, we expect to relinquish rights to technologies, product candidates or markets which we might otherwise develop ourselves. If we are unable to enter into new collaborations or raise additional capital to support our current level of operations, we might be required to scale back, delay or discontinue one or more of our R&D 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 R&D programs could result in additional charges, which would be reflected in the period of the reduction or discontinuation.

11

Part II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

On December 20, 2000, Incara issued 175,000 shares (the "Shares") of its common stock, par value \$.001, to Knoll AG ("Knoll") pursuant to a Settlement Agreement and Release in settlement of a dispute regarding a payable owed by Incara to Knoll for a discontinued program. The Shares had a value of approximately \$416,000. The Shares were issued pursuant to an exemption from registration under Section 4(2) of the Securities Act of 1933, as amended (the "Act"). As part of the transaction, Incara agreed to register the Shares under the Act so the Shares would be freely tradable. Incara registered the Shares under the Act by filing a registration statement with the Securities and Exchange Commission, which declared the registration statement effective in January 2001.

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

A Special Meeting of Stockholders of the Company was held on October 19, 2000. At the meeting, the stockholders approved a private equity financing facility of up to \$18,900,000, based on availability, with Torneaux Fund Ltd., pursuant to which Incara would issue common stock and warrants exercisable for common stock. Stockholders representing 4,021,342 shares (55.5% of the shares then outstanding) voted for approval, 18,125 shares voted against approval and 10,072 shares abstained.

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

(a) Exhibits

- 3.4 Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock and Series C Convertible Exchangeable Preferred Stock
- 4.3 Warrant to Purchase Shares of Series B Preferred Stock issued to Elan International Services, Ltd.
- 10.56* License Agreement dated November 17, 2000 between National Jewish Medical and Research Center and Aeolus Pharmaceuticals, Inc.
- 10.57 Office Lease between Highwoods Realty Limited Partnership and Incara Pharmaceuticals Corporation, dated January 25, 2001
- 10.58* Subscription, Joint Development and Operating Agreement dated January 19, 2001 among Elan Corporation, plc, Elan Pharma International Ltd., Elan International Services, Ltd., Incara Pharmaceuticals Corporation and Incara Development, Ltd.
- 10.59* License Agreement dated January 19, 2001 between Incara Pharmaceuticals Corporation and Incara Development, Ltd.
- 10.60* License Agreement dated January 19, 2001 between Elan Corporation, plc, Elan Pharma International Ltd. and Incara Development, Ltd.
- 10.61 Convertible Promissory Note dated December 21, 2000 issued by Incara Pharmaceuticals Corporation to Elan Pharma International Ltd.

12

- 10.62 Registration Rights Agreement dated December 21, 2000 among Incara Pharmaceuticals Corporation, Elan International Services, Ltd. and Elan Pharma International Ltd.
- (b) No reports on Form 8-K were filed by the Company during the three months ended December 31, 2000.

13

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

^{*} Confidential treatment requested.

Date: February 13, 2001 By: /s/ Richard W. Reichow

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

14