## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 8-K

## **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report: August 4, 2004 (Date of earliest event reported)

## **INCYTE CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 0-27488

(Commission File Number)

94-3136539 (IRS Employer Identification No.)

Route 141 & Henry Clay Road, Building E336, Wilmington, DE 19880 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (302) 498-6700

#### Item 12. Results of Operations and Financial Condition.

The information in this Current Report is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

On August 4, 2004, Incyte Corporation ("Incyte") issued a press release regarding Incyte's financial results for its fiscal quarter ended June 30, 2004. The full text of Incyte's press release is furnished herewith as Exhibit 99.1.

## Exhibits.

Exhibit 99.1 Press release issued by Incyte Corporation dated August 4, 2004.

## 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 hereunto duly authorized.

Dated: August 4, 2004.

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By: /s/ Patricia A. Schreck

Patricia A. Schreck Executive Vice President and General Counsel

## INDEX TO EXHIBITS

Exhibit Number Description

99.1 Press release issued by Incyte Corporation dated August 4, 2004



#### FOR IMMEDIATE RELEASE

Pamela M. Murphy Vice President, Investor Relations & Corporate Communications (302) 498-6944

Incyte Announces Second Quarter Financial Results

Provides Update on Reverset™ and

INCB3284, Incyte's Phase I CCR2 Antagonist

Conference Call and Webcast Scheduled for 8:30 a.m. ET Today

WILMINGTON, DE —August 4, 2004— Incyte Corporation (Nasdaq:INCY) announced today its financial results for the second quarter ended June 30, 2004 and updated shareholders on its most recent corporate accomplishments, including:

- Initiation of patient enrollment for a Phase IIb trial using Reverset in combination with other antiviral agents involving 180 treatment-experienced HIV-infected individuals and 22 clinical sites in the United States and Europe.
- Presentation of positive Reverset results from a 10-day Phase II trial that involved 30 treatment-naive and 10 treatment-experienced HIV patients. In this study, Reverset was well-tolerated and achieved potent antiviral effects in both the treatment-naive and treatment-experienced HIV patients.
- Initiation of patient enrollment for a Phase I trial for INCB3284, Incyte's internally-developed oral CCR2 antagonist for the treatment of chronic inflammation-driven diseases, including rheumatoid arthritis, multiple sclerosis and atherosclerosis. Preliminary results for the Phase I trial are expected to be available in the fourth quarter of 2004.

Paul Friedman, M.D., Incyte's president and chief executive officer, stated, "During the first half of 2004 we have accomplished a number of our key objectives for the year, including the initiation of a Phase IIb study for Reverset and a Phase I trial for our oral CCR2 antagonist. We expect that the data from the Phase IIb Reverset trial will allow us to establish the optimal dose and begin a pivotal Phase III trial in mid-2005. If the Phase I CCR2 antagonist study is positive, we expect to begin Phase II by the end of 2004."

#### **Second Quarter Financial Results**

Cash Position: As of June 30, 2004, cash and short-term investments totaled approximately \$474 million compared to \$294 million as of December 31, 2003. The company continues to expect to use between \$130 and \$140 million in cash in 2004, excluding any possible in-license or purchase of products in clinical development, or any debt repurchases. Revenues for the quarter ended June 30, 2004 were \$5.2 million as compared to \$11.0 million for the same period in 2003. Year to date 2004 revenue was \$11.8 million as compared to \$23.6 million for the same period in 2003. Revenue guidance for the full year 2004 is now expected to be in the range of \$12.0 million to \$14.0 million, which represents an increase from prior guidance of \$7.0 million to \$9.0 million.

The net loss for the second quarter ended June 30, 2004 was \$63.6 million, or \$0.87 per share, as compared to \$26.9 million, or \$0.37 per share, in the second quarter of 2003. The net loss for the six months ended June 30, 2004 was \$101.3 million, or \$1.39 per share, as compared to \$82.7 million, or \$1.17 per share, for the same period in 2003. Included in the 2004 net loss for the second quarter and year to date were restructuring and related charges of \$34.5 million and \$42.7 million, respectively, which were primarily associated with the closure of the company's facilities in Palo Alto. The company is maintaining its prior guidance of up to \$47 million for restructuring charges in 2004. Also included in the net loss for the six months ended June 30, 2004 is a charge of \$2.7 million recorded as a result of certain write-downs related to reduced market valuations in strategic investments that Incyte holds in other companies. This charge was recorded in the first quarter and is included in interest and other income, net. Included in the net loss for the six months ended June 30, 2003 was a charge of \$28.1 million for purchased in-process research and development expense related to the acquisition of Maxia Phamaceuticals, Inc.

Research and development expense for the second quarter ended June 30, 2004 was \$25.6 million as compared to \$29.9 million for the same period last year. Research and development expense for the six months ended June 30, 2004 was \$51.7 million as compared to \$60.1 million for the same period last year. The decrease in research and development expense is the result of the company's restructuring efforts at its former Palo Alto facilities, which were partially offset by increased expenses associated with our drug development programs. The company continues to expect its overall research and development expense for 2004 to be in the range of \$91.0 to \$95.0 million.

Selling, general and administrative expenses for the second quarter ended June 30, 2004 were \$6.0 million as compared to \$7.7 million for the same period last year. Selling, general and administrative expenses for the six months ended June 30, 2004 were \$11.8 million, as compared to \$15.1 million for the same period in 2003. The decrease is a result of the company's restructuring efforts at its former Palo Alto facilities. The company continues to expect selling, general and administrative expense for the year to be in the range of \$21 to \$23 million.

#### **Drug Discovery and Development Update**

Positive Phase IIa Results Reported for Reverset: The Reverset Phase IIa study, referred to as Study 202, involved 30 treatment-naive and 10 treatment-experienced HIV patients and showed a clinically significant reduction in viral load for all treatment-naive patients and 7 of 8 patients who had failed previous therapies. The mean reduction in viral load among the treatment-naïve patients who received either the 50 mg, 100 mg or 200 mg once daily dose of Reverset ranged from 1.67 log10 copies/mL to 1.77 log10 copies/mL. The mean reduction in viral load among the treatment-experienced patients was 0.8 log10 copies/mL. Reverset was well tolerated in all patients, with no significant adverse effects observed. No new resistance mutations developed during the 10 days of treatment with Reverset.

Dr. Friedman stated, "Overall, the results from this study were very encouraging and, while the treatment-experienced group included only 8 patients, the results were in line with our expectations and were meaningful for several reasons. The subjects were heavily treatment-experienced, having failed an average of over 5 prior regimens. Additionally, we saw positive responses in subjects who were failing regimens including AZT, 3TC and tenofovir, which is consistent with our preclinical data suggesting that Reverset has a unique resistance profile and may inhibit replication of HIV that is resistant to each of the approved NRTIs."

Phase IIb Trial Initiated: A second Phase II trial, using Reverset in combination with other antiviral agents in 180 treatment-experienced HIV-infected individuals, began enrollment during the second quarter. If results from this Phase IIb trial are positive, Incyte plans to begin two pivotal Phase III studies in mid-2005.

Phase I Study Initiated for Incyte's CCR2 Receptor Antagonist: Incyte filed an investigational new drug (IND) application for INCB3284 on April 6, 2004 and began enrolling healthy volunteers on May 11, 2004. This single-center Phase I trial involves single and multiple doses and will include a pharmacological "proof-of-principle" component that has the potential to confirm the anti-inflammatory effects of INCB3284 in humans.

Early-Stage Programs: Progress in the company's sheddase inhibitor program during the second quarter included the initiation of GLP toxicology trials for INCB7839, our lead compound for this program. If results of these trials are acceptable, we intend to initiate Phase I clinical studies for this compound in the first quarter of 2005. A number of additional early-stage discovery efforts, primarily in cancer and diabetes, are also underway. In parallel with its internal discovery efforts, Incyte continues to seek compounds that may be available for in-licensing from other companies.

#### **Conference Call Information**

Incyte will host a conference call on Wednesday, August 4, 2004 at 8:30 a.m. ET to discuss the news contained in this release. The domestic dial in number is 1-877-692-2592 and the international dial in number is 1-973-582-2700. The conference ID # is 5009139. The conference call will also be webcast live and can be accessed at: <a href="https://www.incyte.com/webcasts">www.incyte.com/webcasts</a>.

If you are unable to participate, a replay of the conference call will be available through August 30, 2004 (12:00 midnight ET). The replay dial-in number for the U.S. is 877-519-4471 and dial-in number for international callers is 973-341-3080. The replay pin number is 5009139.

#### **About Incyte**

Incyte Corporation is a Wilmington, Delaware based drug discovery and development company with a growing pipeline of oral compounds to treat HIV, inflammation, cancer and diabetes. The company's most advanced product candidate, Reverset, is an oral, once-a-day therapy in Phase II clinical trials to treat patients with HIV infections. The company's lead internal compound, INCB3284, is a proprietary, oral CCR2 antagonist in Phase I development that may have therapeutic value in a number of chronic inflammatory diseases. Incyte has several other early drug discovery programs underway and a proteomic information business based in Beverly, Massachusetts.

#### Forward Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements as to plans to establish the optimal dose for Reverset and move Reverset through to Phase III studies during 2005, the expected resistance and tolerability profile of Reverset, the expected utility of Incyte's CCR2 compounds as anti-inflammatory therapies in multiple indications, plans to begin a Phase II study by the end of 2004 for Incyte's lead orally available, small molecule CCR2 compound and expected Phase I results in the fourth quarter of 2004, plans to enter its lead sheddase inhibitor compound into human testing in the first quarter of 2005, the expected cash impact in 2004 from restructuring related charges, Incyte's expected reduction in annual operating expenses associated with this restructuring and financial guidance as to expected cash utilization, revenues and expenses for 2004, are all forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the results of further research and development, the impact of competition and of technological advances and the ability of Incyte to compete against parties with greater financial or other resources, unanticipated delays, unanticipated cash requirements and the ability to raise additional capital, the ability to implement technological improvements, unanticipated costs and transition risks associated with restructuring plans, unexpected attrition in the company's Delaware and Massachusetts facilities, Incyte's ability to obtain regulatory approval for its products or to conduct clinical trials for its product

candidates, its ability to enroll a sufficient number of patients for its clinical trials and its ability to obtain effective patent protection for its discoveries and to continue to be effective in expanding its patent coverage, and other risks detailed from time to time in Incyte's Quarterly Report on Form 10-Q for the three months ended March 31, 2004 and other filings with the Securities Exchange Commission. Incyte assumes no obligation and expressly disclaims any duty to update the information contained in this presentation.

**Financial Statements Follow** 

## INCYTE CORPORATION

## **Condensed Consolidated Statements of Operations**

(in thousands, except per share amounts)

		nths Ended e 30,		Six Months Ended June 30,	
	2004	2003	2004	2003	
Revenues	\$ 5,163	\$ 11,036	\$ 11,804	\$ 23,545	
Costs and expenses:					
Research and development	25,565	29,870	51,749	60,056	
Selling, general and administrative	6,004	7,694	11,804	15,071	
Purchased in-process research and development	<del>_</del>	_	_	28,116	
Other expenses	34,537	290	42,671	1,393	
Total costs and expenses	66,106	37,854	106,224	104,636	
Loss from operations	(60,943)	(26,818)	(94,420)	(81,091)	
Interest and other income, net	2,387	2,490	1,974	3,723	
Interest expense	(4,868)	(2,439)	(8,388)	(4,878)	
Gain/(loss) on certain derivative financial instruments, net	(77)	108	(254)	63	
Loss before income taxes	(63,501)	(26,659)	(101,088)	(82,183)	
Provision for income taxes	99	241	227	501	
Net loss	\$ (63,600)	\$ (26,900)	\$(101,315)	\$ (82,684)	
Basic and diluted net loss per share:	\$ (0.87)	\$ (0.37)	\$ (1.39)	\$ (1.17)	
	70.000	71.005	72.796	70.411	
Shares used in computing basic and diluted net loss per share	72,929	71,895	72,786	70,441	

# INCYTE CORPORATION Condensed Consolidated Balance Sheet Data

(in thousands)

	June 30, 2004	December 31, 2003
Cash, cash equivalents, and marketable securities	\$ 473,555	\$ 293,807
Total assets	538,118	379,545
Convertible subordinated notes	417,578	167,786
Total stockholders' equity	52,632	154,333