# UNITED STATES 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: November 1, 2005** (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 (I.R.S. Employer Identification Number)

Experimental Station, Route
141 & Henry Clay Road,
Building E336
Wilmington, DE
(Address of principal executive
offices)

**19880** (Zip Code)

#### (302) 498-6700

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On November 1, 2005, Incyte Corporation issued a press release announcing financial results for its fiscal quarter ended September 30, 2005. The full text of the press release is furnished as Exhibit 99.1.

#### ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

- (c) Exhibits
  - 99.1 Press release issued by Incyte Corporation dated November 1, 2005.

2

## **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: November 1, 2005

By: /s/ Patricia A. Schreck

Patricia A. Schreck Executive Vice President and General Counsel



#### FOR IMMEDIATE RELEASE

Pamela M. Murphy Vice President, Investor Relations/Corporate Communications 302/498-6944

#### Incyte Announces Third Quarter 2005 Results; Provides Update on Most Advanced Drug Development Programs and Reduces Cash Use Guidance for 2005

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

**Wilmington, DE, November 1, 2005** — Incyte Corporation (Nasdaq:INCY) today announced its third quarter 2005 financial results, revised its 2005 financial guidance and updated shareholders on recent developments, including:

- Incyte's decision to initiate, at the request of the U.S. Food and Drug Administration (FDA), a second Phase IIb trial for Reverset prior to beginning the pivotal Phase III program;
- Progression of two Phase IIa trials in rheumatoid arthritis and obese insulin-resistant patients for INCB3284, Incyte's orally-available CCR2 antagonist. Results from these two trials are expected in late 2005 and early 2006, respectively;
- Initiation of a dose-ranging Phase I/II trial in cancer patients with INCB7839, Incyte's oral sheddase inhibitor that is being developed as a treatment for solid tumors;
- Selection of an internally-discovered oral CCR5 antagonist, INCB9471, which is expected to advance into Phase I development as a potential treatment for HIV in the first half of 2006; and
- Reduction of 2005 cash use guidance from a range of \$120 to \$130 million to a range of \$100 to \$105 million.

#### **Third Quarter Financial Results**

#### **Cash Position**

As of September 30, 2005, cash and short-term investments totaled \$364.0 million, compared to \$469.8 million as of December 31, 2004. The decrease is a result of the company's use of cash of approximately \$75.7 million to support operations and an additional \$35.8 million to repurchase and retire its 5.5% convertible subordinated notes. The repurchase has reduced the outstanding principal amount of these notes to \$91.6 million. The use of cash was partially offset by the sale of a strategic investment in the amount of \$5.7 million.

The company is reducing its 2005 guidance for cash use from a range of \$120.0 to \$130.0 million to a range of \$100.0 to \$105.0 million. This guidance excludes any possible in-license or purchase of products in clinical trials, any activity in connection with strategic investments or any additional debt repurchases the company may make. The reduction in cash guidance for 2005 is primarily the result of the FDA's request that the company conduct a second Phase IIb trial with Reverset rather than advance directly into Phase III trials. The company's use of cash, research and development expense and overall operating results will vary from quarter to quarter depending primarily on the timing of its clinical trials.

In addition, due to higher average cash balances and higher yields on its investment portfolio the company is increasing its 2005 interest income guidance from \$7.0 to \$8.0 million to \$9.0 to \$10.0 million.

#### Revenue

Revenues for the quarter ended September 30, 2005 were \$1.2 million as compared to \$2.3 million for the same period in 2004. Revenues for the nine months ended September 30, 2005 were \$6.8 million as compared to \$11.8 million for the same period in 2004.

#### **Net Loss, Operating Expenses**

The net loss for the quarter ended September 30, 2005 was \$30.2 million, or \$0.36 per share, as compared to \$26.0 million, or \$0.35 per share, for the same period in 2004. Included in the third quarter 2004 net loss was a charge of \$2.5 million, which is included in interest and other income/expense, net, as a result of a writedown related to a reduced market valuation in a strategic investment that Incyte holds in another company.

The net loss for the nine months ended September 30, 2005 was \$75.5 million, or \$0.91 per share, as compared to \$127.3 million, or \$1.74 per share, for the same period in 2004. Included in the net loss for the nine months ended September 30, 2005 were:

- a gain of \$2.8 million from the sale of a strategic investment, included in interest and other income, net; and
- a gain of \$0.5 million from the repurchase of \$36.5 million principal amount of our 5.5% convertible subordinated notes.

Included in the net loss for the nine months ended September 30, 2004 were:

- restructuring and related charges of \$42.5 million, which were primarily associated with the closure of the company's facilities in Palo Alto;
   and
- charges of \$5.2 million as a result of certain write-downs related to reduced market valuations in strategic investments that Incyte holds in
  other companies, included in interest and other income/expense, net.

Research and development expense for the quarter ended September 30, 2005 was \$27.4 million as compared to \$17.6 million for the same period last year. Research and development expense for the nine months ended September 30, 2005 was \$71.7 million as compared to \$67.2 million for the same period last year. The increase in research and development expense is the result of the increased spending on the company's clinical development programs. The company is lowering its research and development expense guidance for the year from a range of \$98.0 to \$102.0 million to a range of \$90.0 to \$95.0 million, due primarily to the FDA's recent decision regarding Reverset. The company expects its research and development expenses to vary from quarter to quarter, primarily due to timing of its clinical development activities.

Selling, general and administrative expenses for the quarter ended September 30, 2005 were \$2.7 million as compared to \$4.9 million for the same period last year. Selling, general and administrative expenses for the nine months ended September 30, 2005 were \$8.2 million, as compared to \$16.0 million for the same period in 2004. The decrease is primarily the result of the company's restructuring efforts. Due to the company's continued focus on minimizing its selling, general and administrative expenses, it is reducing its 2005 guidance for these expenses from a range of \$12 to \$14 million to a range of \$11 to \$12 million.

## **Update on Drug Development Programs**

#### Reverset (dexelvucitabine, DFC)

In a meeting with the FDA on September 27, 2005, the agency asked the company to conduct a second Phase IIb trial with Reverset to confirm the positive results from Study 203. These results were presented at the 3<sup>rd</sup> International AIDS Society (IAS) meeting in July and demonstrated that Reverset provided sustainable and clinically relevant antiviral potency in treatment-experienced HIV patients. Results from Study 203 also determined that the 200 mg once-aday was the most effective dose for Reverset and identified the groups of patients for whom Reverset is most likely to provide the greatest benefits. While the company expects that the decision to conduct a second Phase IIb trial will cause a 12 to 18 month delay in the Reverset program, the company is confident that Reverset warrants further development and believes this trial, if positive, could serve as one of the two required registration trials.

Paul Friedman, M.D., Incyte's president and CEO stated, "We are working with the FDA to finalize the design of the second Phase IIb trial and continue to believe we can initiate the trial toward the end of this year or early in 2006."

Calvin Cohen, M.D., M.S., the presenting clinical investigator at IAS and Research Director for both Harvard Vanguard Medical Associates and Community Research

Initiative of New England, stated, "Many of us who are familiar with Reverset, and who actively treat HIV patients, see the potential for Reverset as a critically important addition to our existing NRTI therapies. I look forward to participating in its continued development and potential commercialization."

The company also stated that the FDA indicated that the proposed brand name for the product, Reverset, will not be acceptable. As a result, Incyte will cease using the name Reverset for this product. The company is working now to develop an alternative brand name and will, in the interim, refer to the compound by its generic name, dexelvucitabine, or DFC.

#### INCB3284: Oral CCR2 Antagonist for Inflammation-Driven Diseases

Recruitment of two one-month, double-blind, placebo-controlled Phase IIa trials of INCB3284 progressed during the third quarter. The first trial is in 48 rheumatoid arthritis (RA) patients with active disease who are also receiving methotrexate. This trial is now fully enrolled and will therefore be completed in the fourth quarter with top-line results expected to be available by year-end. The second trial is scheduled to include 120 obese insulin-resistant patients. Enrollment is expected to be completed in January with top-line results available in the first quarter of 2006.

#### **INCB7839: Oral Sheddase Inhibitor for Cancer**

Based on results from single-dose-rising and multiple-dose-rising Phase I trials of INCB7839 in healthy volunteers, Incyte has initiated a double-blind placebo-controlled Phase I/II dose-ranging trial in cancer patients. This trial will include patients with a variety of solid tumors such as breast, non-small cell lung, prostate, colorectal and head and neck cancers, all of which can be associated with excessive signaling of epidermal growth factor receptors (HER1, HER2, HER3).

#### **CCR5** Antagonist

The company has selected an oral CCR5 antagonist compound, INCB9471, for clinical development. INCB9471 is an internally-developed proprietary compound that appears to have very potent anti-HIV activity in cell culture and has excellent pharmacokinetic properties. Like other CCR5 antagonists in development, INCB9471 is active in cell culture against viruses resistant to nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors. Incyte expects to complete the IND for INCB9471 and initiate a Phase I trial in the first half of 2006.

#### **Conference Call Information**

Incyte will host a conference call on Tuesday, November 1, 2005 at 8:30 a.m. ET to discuss the news contained in this release. The domestic dial-in number is 877-692-2592 and the international dial-in number is 973-582-2700. The conference ID number is 6620513.

If you are unable to participate, a replay of the conference will be available for thirty days. The replay dial-in number for the U.S. is 877-519-4471 and the dial-in

number for international callers is 973-341-3080. The replay pin number is 6620513.

The conference call will also be webcast live and can be accessed at www.incyte.com under Investor Relations, Events and Webcasts.

#### **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, dexelvucitabine, DFC (formerly Reverset) is an oral, once-a-day therapy in Phase IIb clinical development to treat patients with HIV infections. The company's lead internal compounds include INCB3284, a proprietary oral CCR2 antagonist that is in Phase II development for a number of inflammation-driven diseases, and INCB7839, a proprietary oral sheddase inhibitor that is in Phase I development as a potential treatment for cancer. Incyte has several other early drug discovery programs underway in the areas of cancer, inflammation, diabetes and HIV.

#### **Forward Looking Statements**

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to revised financial guidance regarding expected cash utilization, revenues and expenses for 2005, interest income guidance, the timing and initiation of a second Phase IIb trial for DFC, the potential benefits and expected resistance and tolerability profile of DFC, the length of the expected delay in the DFC program, the potential use of a second Phase IIb trial as a registration trial for DFC, the expected utility of Incyte's CCR2 compounds as anti-inflammatory therapies in multiple indications, timelines and expected availability of results for the one-month Phase IIa trials for INCB3284, and the plans and expectations for a Phase I/II trial for Incyte's lead sheddase inhibitor compound, and the expected utility of Incyte's CCR5 compound INCB9471, Incyte's plans and timing for IND submission and a Phase I trial for Incyte's CCR5 compound INCB9471, 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 possibility that the FDA might reach different conclusions as to the second Phase IIb trial regarding DFC, results of the second DFC Phase IIb trial will not confirm the potential shown by the first Phase IIb trial, the high degree of risk associated with drug development and clinical trials, results of further research and development, the impact of competition and of technological advances and the ability to raise additional capital, the ability to implement technological improvements, Incyte's ability to enroll a sufficient number of patients for its clinical trials, and other risks detailed from time to time in Incyte's filings with the Securities Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2005. Incy

# INCYTE CORPORATION Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

|   |    | Septem   | Three Months Ended<br>September 30, |          |    | Nine Months Ended<br>September 30, |    |           |  |
|---|----|----------|-------------------------------------|----------|----|------------------------------------|----|-----------|--|
|   |    | 2005     |                                     | 2004     |    | 2005                               |    | 2004      |  |
| Revenues  | \$ | 1,228    | \$                                  | 2,332    | \$ | 6,818                              | \$ | 11,821    |  |
| Costs and expenses:   |    |          |                                     |          |    |                                    |    |           |  |
| Research and development                                      |    | 27,356   |                                     | 17,648   |    | 71,676                             |    | 67,210    |  |
| Selling, general and administrative                           |    | 2,710    |                                     | 4,898    |    | 8,244                              |    | 15,979    |  |
| Other expenses  |    | 299      |                                     | (132)    |    | 1,088                              |    | 42,538    |  |
| Total costs and expenses                                      |    | 30,365   |                                     | 22,414   |    | 81,008                             |    | 125,727   |  |
|   |    |          |                                     |          |    |                                    |    |           |  |
| Loss from operations  |    | (29,137) |                                     | (20,082) |    | (74,190)                           |    | (113,906) |  |
| Interest and other income (expense), net                      |    | 2,656    |                                     | (571)    |    | 10,228                             |    | 1,403     |  |
| Interest expense  |    | (3,810)  |                                     | (4,623)  |    | (12,257)                           |    | (13,011)  |  |
| Gain (loss) on repurchase of convertible subordinated notes   |    | 85       |                                     | (226)    |    | 506                                |    | (226)     |  |
| Loss on certain derivative financial instruments, net         |    | (1)      |                                     | (216)    |    | (89)                               |    | (470)     |  |
| Loss from continuing operations before income taxes           |    | (30,207) |                                     | (25,718) |    | (75,802)                           |    | (126,210) |  |
|   |    |          |                                     |          |    |                                    |    |           |  |
| Provision (benefit) for income taxes                          |    | _        |                                     | _        |    | (156)                              |    | 182       |  |
| Loss from continuing operations                               |    | (30,207) |                                     | (25,718) |    | (75,646)                           |    | (126,392) |  |
| Income (loss) from discontinued operations                    |    | (3)      |                                     | (258)    |    | 159                                |    | (899)     |  |
| ST. 1   | Ф  | (00.040) | Φ.                                  | (25.050) | Φ. | (55.405)                           | ф  | (405.004) |  |
| Net loss  | \$ | (30,210) | \$                                  | (25,976) | \$ | (75,487)                           | \$ | (127,291) |  |
| Basic and diluted net loss per share:                         |    |          |                                     |          |    |                                    |    |           |  |
| Continuing operations   | \$ | (0.36)   | \$                                  | (0.35)   | \$ | (0.91)                             | \$ | (1.73)    |  |
| Discontinued operations                                       | _  | _        |                                     | _        |    | _                                  |    | (0.01)    |  |
| ·   | \$ | (0.36)   | \$                                  | (0.35)   | \$ | (0.91)                             | \$ | (1.74)    |  |
|   |    |          |                                     |          |    |                                    |    |           |  |
| Shares used in computing basic and diluted net loss per share |    | 83,414   |                                     | 73,323   |    | 83,213                             |    | 72,966    |  |

# INCYTE CORPORATION Condensed Consolidated Balance Sheet Data

(in thousands)

|   | Sept | tember 30,<br>2005 | <b>December 31, 2004</b> |         |  |
|---|------|--------------------|--------------------------|---------|--|
| Cash, cash equivalents, and marketable securities | \$   | 364,038            | \$                       | 469,764 |  |
| Total assets                                      |      | 398,109            |                          | 516,919 |  |
| Convertible subordinated notes                    |      | 341,919            |                          | 378,766 |  |
| Total stockholders' equity                        |      | 3,515              |                          | 78,517  |  |

