# 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 (Date of earliest event reported): February 16, 2006

## **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)

19880

(Zip Code)

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

(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 February 16, 2006, Incyte Corporation (the "Company") issued a press release announcing financial results for its fiscal year ended December 31, 2005. The full text of the press release is furnished as Exhibit 99.1.

#### ITEM 8.01 OTHER EVENTS.

The Company's 2006 Annual Meeting of Stockholders will be held on May 23, 2006 at such place and time as will be set forth in the Company's proxy statement relating to that meeting. A stockholder proposal not included in the proxy statement for the Company's 2006 Annual Meeting of Stockholders will be ineligible for presentation at the meeting unless the stockholder gives timely notice of the proposal in writing to the Secretary of the Company at the principal executive offices of the Company and otherwise complies with the provisions of the Company's Bylaws. To be timely, the Company's Bylaws provide that the Company must have received the stockholder's notice not less than 60 days nor more than 90 days prior to the scheduled date of such meeting. However, if notice or prior public disclosure of the date of the annual meeting is given or made to stockholders less than 70 days prior to the meeting date, the Company must receive the stockholder's notice by the earlier of (i) the close of business on the 10th day after the earlier of the day the Company mailed notice of the annual meeting date or provided such public disclosure of the meeting date and (ii) two days prior to the scheduled date of

the annual meeting. For the Company's 2006 Annual Meeting of Stockholders, stockholders must submit written notice to the Secretary in accordance with the foregoing Bylaw provisions not later than March 24, 2006.

#### ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

99.1 Press release issued by Incyte Corporation dated February 16, 2006.

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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 hereunto duly authorized.

Dated: February 16, 2006

#### INCYTE CORPORATION

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 2005 Financial Results and Provides 2006 Guidance

#### Initiates Study 204 for DFC in Treatment-Experienced HIV Patients and Receives \$50 Million from CCR2 Alliance with Pfizer

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

WILMINGTON, Del. — Feb. 16, 2006 — Incyte Corporation (Nasdaq:INCY) today announced 2005 financial results and 2006 financial guidance, and reported on the company's most advanced drug discovery and development programs including dexelvucitabine, or DFC, our Phase II compound for human immune deficiency virus (HIV).

#### **Recent accomplishments include:**

- Initiation of Study 204, a six-month Phase IIb trial designed to evaluate the use of DFC in 250 treatment-experienced HIV patients who are failing their current treatment regimens.
- Establishment of a collaborative research and license agreement with Pfizer for the development and commercialization of CCR2 antagonists for which Incyte may receive up to \$803 million in payments, including \$40 million that was received as an upfront payment in January 2006 and \$10 million that was received through the purchase of a Convertible Subordinated Note in February 2006.
- Selection of a follow on CCR2 antagonist for lead optimization and preclinical development which we expect to advance into clinical development as a treatment for multiple sclerosis, one of our retained indications under our agreement with Pfizer.
- Selection of an internally-developed inhibitor of 11-beta hydroxysteroid dehydrogenase type 1 (11BHSD1) for development as a treatment for Type 2 diabetes with Phase I trials expected to begin in the first half of 2006.

#### **2005 Financial Results**

Cash Position

As of December 31, 2005, cash and short-term investments totaled \$345.0 million as compared to \$469.8 million as of December 31, 2004.

During 2005, the company used a total of \$103.8 million in cash, excluding the following:

- \$35.8 million used to retire a portion of our 5.5% Convertible Subordinated Notes;
- \$5.0 million used in the purchase of common stock in connection with the exercise of a put right by a strategic investee in the fourth quarter of 2005;
- \$5.7 million of proceeds received from the sale of a prior strategic investment in the second quarter of 2005; and
- \$14.1 million increase in cash and short-term investments resulting from a reclassification of a strategic investment from long-term assets.

#### Revenues

Total revenues for the fourth quarter and full year ended December 31, 2005 were \$1.0 million and \$7.8 million, respectively, as compared to \$2.3 million and \$14.1 million for the same periods in 2004.

#### Net Loss

The company's net loss for the fourth quarter and full year 2005 was \$27.6 million, or \$0.33 per share, and \$103.0 million, or \$1.24 per share, respectively. Included in interest and other income, net, in the full year ended 2005 is a gain on the sale of a strategic investment of \$2.8 million.

The net loss for the fourth quarter and full year ended 2004 was \$37.5 million, or \$0.47 per share and \$164.8 million, or \$2.21 per share, respectively. The fourth quarter 2004 loss included a charge of \$12.1 million to adjust the carrying value of previously capitalized costs associated with the preparation, prosecution and maintenance of our gene patent portfolio. Included in the full year ended 2004 net loss were restructuring and related charges of \$42.1 million, which were primarily associated with the closure of the company's facilities in Palo Alto, and a charge of \$5.2 million included in interest and other income, net, recorded as a result of write downs related to reduced market valuations in strategic investments that Incyte holds in other companies.

#### **Operating Expenses**

Research and development expense during the fourth quarter and full year ended 2005 was \$23.9 million and \$95.6 million, respectively, versus \$21.1 million and \$88.3 million for the same periods in 2004. The increase in research and development expense results from the company's expanded drug discovery and development activities. The company expects its research and development expense to vary from year to year, primarily due to timing of its clinical development activities.

Selling, general and administrative expense during the fourth quarter and full year ended 2005 was \$3.4 million and \$11.7 million, respectively, versus \$4.6 million and \$20.6 million for the same periods in 2004. The decrease in selling, general and administrative expense is a result of the company's restructuring and cost reduction efforts.

#### 2006 Financial Guidance

#### Cash

The company expects its cash use in 2006 to range from \$98 million to \$105 million, which includes the use of approximately \$6 million for net lease-related costs in its closed California facilities. This guidance excludes the in-license or purchase of products, the repurchase of

any of its 5.5% Convertible Subordinated Notes, any funds received from its collaboration with Pfizer and any activity related to its strategic investments.

#### Revenue

The company expects its 2006 revenue to be in the range of \$20 to \$25 million. Included in this guidance is approximately \$20 million of revenue as a result of the upfront payment received from Pfizer in January 2006 in connection with the collaborative research and license agreement. Incyte will record the \$40 million upfront non-refundable payment as revenue ratably over a 24 month period.

#### **Operating** Expenses

The company expects research and development expense to be in the range of \$92 to \$98 million in 2006, including a non-cash expense of \$5 to \$6 million related to the impact of expensing share-based payments, including employee stock options.

The company expects selling, general and administrative expense to be in the range of \$15 to \$16 million in 2006 including a non-cash expense of \$2 to \$3 million related to the impact of expensing share-based payments, including employee stock options.

The impact of expensing share-based payments, including employee stock options, is dependent upon the level of share-based payments issued, as well as the market price and other judgmental assumptions used in estimating the fair value of such instruments.

#### Other Income/Expense

The company expects interest income to be in the range of \$8 to \$9 million in 2006 while interest expense is expected to be approximately \$16 million. This guidance does not include any potential adjustments related to strategic investments in other companies which may occur during the year, or the impact of any potential repurchase of the company's 5.5% Convertible Subordinated Notes.

#### Update on Drug Discovery and Development

#### HIV Portfolio

#### DFC: Nucleoside-Analogue Reverse Transcriptase Inhibitor (NRTI)

We have initiated a second Phase IIb trial, Study 204, to confirm the positive results we saw in our first Phase IIb trial, Study 203. These results were presented at the 3rd International AIDS Society (IAS) meeting in July 2005, and demonstrated that 200 mg once-a-day of DFC was the most effective dose and that DFC provided the greatest benefit in patients not receiving 3TC or FTC, two approved NRTIs. Study 203 also demonstrated that DFC should not be used with ddI, also an approved NRTI.

Study 204 is expected to involve 250 treatment-experienced HIV patients and over 100 clinical sites in the U.S., Europe and South America. The trial is designed to compare DFC treated patients to patients treated with 3TC. The primary endpoint for the study is the percent of patients who achieve at least a 1.0 log or greater drop in viral load at the end of 24 weeks.

Paul Friedman, M.D., Incyte's president and CEO stated, "Study 204 is designed to confirm the positive results we saw in Study 203 and demonstrate DFC's potential value as a new therapy for treatment-experienced HIV patients. Provided the study is positive, I am hopeful that the FDA would require only one Phase III trial for approval."

#### INCB9471: CCR5 Antagonist

Our oral once-a-day CCR5 antagonist compound, INCB9471, is expected to begin Phase I clinical testing in healthy volunteers in the first half of 2006. INCB9471 is an internally-developed proprietary compound that in preclinical studies has shown potent anti-HIV activity in cell culture as well as excellent pharmacokinetic properties. We expect to complete Phase I testing in healthy volunteers in the second half of 2006.

#### Inflammation Portfolio

#### CCR2 Antagonist Program

## Alliance with Pfizer

In November, we announced a worldwide development and commercialization agreement with Pfizer in which Pfizer has rights to Incyte's portfolio of CCR2 antagonist compounds, the most advanced of which is INCB3284. Pfizer's rights extend to the full scope of potential indications, with the exception of multiple sclerosis and one other undisclosed indication, where we have retained exclusive worldwide rights, along with certain other compounds. In exchange for these rights, in addition to the \$40 million that was received as an upfront payment in January 2006 and \$10 million that was received through the purchase of a Convertible Subordinated Note in February 2006, we have the potential to receive up to \$743 million in future development and milestone payments, as well as royalties on worldwide sales. Additionally, at the time we file an Investigational New Drug Application (IND) in one of our retained indications we have the right, but not the obligation, to receive another \$10 million from the sale of an additional Convertible Subordinated Note to Pfizer. These Notes bear no interest and are convertible into Incyte's common stock at a premium. Pfizer will also provide research funding to support the continued expansion of the CCR2 compound portfolio.

#### Incyte's Retained Indications and CCR2 Compounds

Under our agreement with Pfizer, we have retained exclusive worldwide rights to certain CCR2 antagonist compounds for two indications, MS and a second indication which, for competitive reasons, we have not disclosed. We have no obligations to Pfizer on preclinical development candidates we may pursue in these indications.

We have selected a compound for preclinical development and intend to complete IND-enabling studies and begin a Phase I trial in healthy volunteers in the second half of 2006.

#### New Program

We also have a lead compound in preclinical development for inflammation that is distinct from our CCR2 antagonists. We expect to complete IND-enabling studies for this compound by year-end.

#### **Cancer Portfolio**

#### Sheddase Inhibitor

In October, Incyte initiated a Phase I/II dose-ranging trial in cancer patients. This trial is currently recruiting 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 including HER1, HER2 and HER3. In addition to safety, this study will evaluate a number of pharmacodynamic markers to assess the ability of INCB7839 to inhibit these receptors such as circulating HER2 extracellular domain levels (ECD). High levels of ECD are often associated with poor clinical outcomes in breast cancer

patients. Results from this study are expected in the second half of 2006 and, if positive, will allow us to move the compound into Phase II trials.

#### New Program

We have a lead preclinical candidate for cancer that addresses a different target. We expect to complete IND-enabling studies for this compound by year-end.

#### **Diabetes** Opportunity

#### 11BHSD1 Program

We have recently identified a novel proprietary compound with the potential to treat Type 2 diabetes. The compound, INCB13739, is a selective orallyavailable small molecule inhibitor of 118HSD1 (11-beta hydroxysteroid dehydrogenase type 1). INCB13739 is expected to begin Phase I testing in the first half of 2006.

11ßHSD1 is an enzyme that converts the biologically inactive steroid cortisone into a potent biologically active hormone cortisol. This occurs in the liver, adipose tissue, muscle and pancreas. Unlike the hormone insulin, which is produced by beta-cells in the pancreas and maintains normal blood glucose levels, cortisol elevates blood glucose levels by driving glucose production in the liver and by inhibiting the uptake and disposal of glucose in muscle and adipose tissue. Thus, cortisol acts as an antagonist of insulin action.

Recently published data suggest that 11BHSD1-mediated production of cortisol within adipose tissue and the liver may play a key role in regulating the body's resistance to insulin in people with Type 2 diabetes. By selectively inhibiting 11BHSD1 and reducing the level of cortisol available in multiple tissues, we believe INCB13739 may offer a new approach to treating Type 2 diabetes as well as conditions often associated with this disease, such as dyslipidemia, atherosclerosis, and coronary heart disease.

Dr. Friedman stated, "With DFC and our sheddase inhibitor progressing further in the clinic, and with discovery programs in HIV, inflammation, cancer and diabetes potentially reaching the IND stage, we expect Incyte will complete 2006 with a strong proprietary pipeline capable of building sustainable shareholder value."

#### **Conference Call Information**

Incyte will host a conference call on Thursday, February 16, 2006 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 6967179.

If you are unable to participate, a replay of the conference call 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 6967179.

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 has a broad CCR2 antagonist program that is the subject of a global collaborative research and license agreement with Pfizer. Pfizer's rights extend to the full scope of potential indications, with the exception of multiple sclerosis and one other undisclosed indication, where Incyte retains exclusive worldwide rights, along with certain compounds. The company has a proprietary oral sheddase inhibitor that is in Phase I/II development as a potential treatment for cancer. Incyte has several other early drug discovery programs underway in the areas of HIV, inflammation, cancer and diabetes.

#### **Forward Looking Statements**

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to expectations of advancing into clinical development a follow on CCR2 antagonist as a treatment for multiple sclerosis, financial guidance regarding expected cash use, revenues, expenses and other income/expense for 2006, expectations regarding the number of patients and sites for Study 204 for DFC, the potential benefits of Study 204 and expectations regarding the number of Phase III trials that would be required for DFC, expectations for the timing of the Phase I clinical trial for Incyte's CCR5 antagonist compound INCB9471, expectations regarding the timing of completion of IND-enabling studies and Phase I clinical trials for the CCR2 antagonist for the treatment of multiple sclerosis, expectations regarding the timing of completion of IND-enabling studies for the new inflammation compound in preclinical development, the plans and expectations for a Phase I/II trial for Incyte's lead sheddase inhibitor compound, expectations for the timing of completion of IND-enabling studies for Incyte's new preclinical candidate for cancer, the expected utility and plans and timing for Phase I clinical testing of INCB13739, and the positioning of the company for growth from internal programs 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 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 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, 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 September 30, 2005. Incyte disclaims any intent or obligation to update these forward-looking statements.

## INCYTE CORPORATION

### **Condensed Consolidated Statements of Operations**

(in thousands, except per share amounts)

|   | Three Months Ended<br>December 31, |   |    | Twelve Months Ended<br>December 31, |    |                    |    |              |
|---|------------------------------------|---|----|-------------------------------------|----|--------------------|----|--------------|
|   |                                    | 2005  |    | 2004                                |    | 2005               |    | 2004         |
| Revenues  | \$                                 | 1,027   | \$ | 2,325                               | \$ | 7,846              | \$ | 14,146       |
| Costs and expenses:   |                                    |   |    |                                     |    |                    |    |              |
| Research and development                                      |                                    | 23,942  |    | 21,061                              |    | 95,618             |    | 88,271       |
| Selling, general and administrative                           |                                    | 3,412   |    | 4,573                               |    | 11,656             |    | 20,551       |
| Other expenses  |                                    | 268   |    | 11,639                              |    | 1,356              |    | 54,177       |
| Total costs and expenses                                      |                                    | 27,622  |    | 37,273                              |    | 108,630            |    | 162,999      |
|   |                                    | (a. c. a. |    | (2.1.0.10)                          |    | (100 <b>-</b> 0 () |    | (1.10.0.0.0) |
| Loss from operations  |                                    | (26,595)                                      |    | (34,948)                            |    | (100,784)          |    | (148,853)    |
| Interest and other income, net                                |                                    | 2,302   |    | 2,162                               |    | 12,527             |    | 3,563        |
| Interest expense  |                                    | (3,796)                                       |    | (4,230)                             |    | (16,052)           |    | (17,241)     |
| Gain (loss) on repurchase of convertible subordinated notes   |                                    |   |    |                                     |    | 506                |    | (226)        |
| Gain (loss) on certain derivative financial instruments, net  |                                    | (17)  |    | 15                                  |    | (106)              |    | (454)        |
| Loss from continuing operations before income taxes           |                                    | (28,106)                                      |    | (37,001)                            |    | (103,909)          |    | (163,211)    |
| Provision (benefit) for income taxes                          |                                    | (395)   |    | 271                                 |    | (552)              |    | 453          |
| Loss from continuing operations                               |                                    | (27,711)                                      |    | (37,272)                            |    | (103,357)          |    | (163,664)    |
| Income (loss) from discontinued operations                    |                                    | 155   |    | (254)                               |    | 314                |    | (1,153)      |
|   | *                                  |   | *  |                                     |    | (100.010)          |    |              |
| Net loss  | \$                                 | (27,556)                                      | \$ | (37,526)                            | \$ | (103,043)          | \$ | (164,817)    |
| Basic and diluted net loss per share:                         |                                    |   |    |                                     |    |                    |    |              |
| Continuing operations   | \$                                 | (0.33)  | \$ | (0.47)                              | \$ | (1.24)             | \$ | (2.19)       |
| Discontinued operations                                       |                                    | _   |    | _                                   |    | _                  |    | (0.02)       |
|   | \$                                 | (0.33)  | \$ | (0.47)                              | \$ | (1.24)             | \$ | (2.21)       |
| Shares used in computing basic and diluted net loss per share |                                    | 83,520  |    | 79,289                              |    | 83,321             |    | 74,555       |
| shares used in computing basic and diluted net loss per share |                                    | 65,520  |    | 79,209                              |    | 65,521             |    | 74,333       |

#### **INCYTE CORPORATION**

**Condensed Consolidated Balance Sheet Data** 

(in thousands)

|   | December 31,<br>2005 |          | December 31,<br>2004 |         |
|---|----------------------|----------|----------------------|---------|
| Cash, cash equivalents, and marketable securities | \$                   | 344,971  | \$                   | 469,764 |
| Total assets                                      |                      | 374,108  |                      | 516,919 |
| Convertible subordinated notes                    |                      | 341,862  |                      | 378,766 |
| Total stockholders' equity (deficit)              |                      | (19,397) |                      | 78,517  |