



Incyte Provides Update on Most Advanced Discovery and Development Programs; Announces 2004 Financial Results and Provides 2005 Guidance

February 28, 2005

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 28, 2005--

Conference Call and Webcast Scheduled for 4:30 p.m. ET Today

Incyte Corporation (Nasdaq:INCY) today announced 2004 financial results and 2005 financial guidance and reported on the company's most advanced drug discovery and development programs including Reverset(TM), its Phase II compound for human immune deficiency virus (HIV), INCB3284, its CCR2 antagonist for inflammation, and INCB7839, its sheddase inhibitor for cancer.

Recent accomplishments include:

- Completion of patient enrollment in Study 203, a six month Phase IIb trial designed to evaluate the use of Reverset in 180 treatment-experienced HIV patients who are failing their current treatment regimens
- Completion of an interim analysis of Study 203 demonstrating that Reverset has been generally well-tolerated at all doses studied for as long as 24 weeks. Based on the viral load reductions seen in patients receiving Reverset, and assuming these positive interim trends continue, the company intends to proceed with preparations for an end-of-Phase II meeting with the FDA at which time it would expect to finalize plans for Phase III
- Completion of a Phase I single- and multiple-dose trial for INCB3284, Incyte's lead orally-available CCR2 antagonist, demonstrating that the compound was well-tolerated with good pharmacokinetic properties and supporting its advancement into Phase II in a range of inflammation-driven conditions, including rheumatoid arthritis (RA) and insulin resistance/Type II diabetes
- Filing and acceptance of an investigational new drug application (IND) for INCB7839, Incyte's lead orally-available sheddase inhibitor that has potential in the treatment of multiple solid tumor types
- The sale of its Proteome subsidiary assets to BIOBASE, a German company focused on the development and licensing of commercial biological databases. This sale completes the transition of Incyte to a drug discovery and development company
- Strengthening its cash position through the sale of 9 million shares of common stock in a public offering at \$9.75 per share, resulting in net proceeds of \$83.3 million

Paul Friedman, M.D., Incyte's president and CEO, stated, "I am encouraged by the results of the interim analysis which support our belief that Reverset has the potential to be an important new therapy for treatment-experienced HIV patients. We look forward to completing Study 203 and, assuming the final analysis remains consistent with the interim analysis, reviewing our plans for Phase III with the FDA at our end-of-Phase II meeting and initiating our Phase III program later this year."

Dr. Friedman added, "With acceptance of the IND for INCB7839, our novel sheddase inhibitor, Incyte's pipeline now includes three compounds in clinical development in areas in which we have a great deal of expertise - HIV, inflammation and cancer."

Update on Drug Discovery and Development Programs

Reverset: Nucleoside-Analogue Reverse Transcriptase Inhibitor (NRTI)

We recently completed patient enrollment for Study 203, a six-month double-blind clinical trial designed to compare three once-daily doses of Reverset (50, 100 and 200 mg) to placebo in 180 treatment-experienced HIV-infected individuals. In addition to comparing antiviral activity in these four groups of patients, who are failing their current treatments on entry to the study, other goals are to select a dose for Phase III and to evaluate the safety and tolerability of Reverset in patients failing their current treatment regimens.

Study 203 also included an interim analysis which involved approximately 140 patients. Top-line results from the interim analysis suggest that Reverset can provide sustained anti-viral activity in patients with multiple resistance mutations, including thymidine analog mutations (TAMS), as well as the M184V and K65R mutations.

Reverset has also been generally well tolerated over the course of the study. The only adverse effect of note to date has been a higher than anticipated incidence of asymptomatic hyperlipasemia in patients who are also receiving didanosine. Didanosine, also known as ddI, is an approved HIV therapy associated with hyperlipasemia, a marker of pancreatic inflammation. Certain other NRTIs have also been shown to result in an increased incidence of hyperlipasemia when used in combination with ddI.

Study 203 is ongoing; all patients are scheduled to complete 16 weeks of therapy by June. This is expected to allow the company to schedule its end-of-Phase II meeting with the FDA and initiate Phase III in 2005. The company also intends to present the results of Study 203 at future scientific meetings.

INCB3284: Oral CCR2 Antagonist for Inflammation-driven Diseases

During the fourth quarter, we completed a Phase I single- and multiple-dose study of INCB3284 in healthy volunteers. The compound was extremely well-tolerated at all doses studied and demonstrated an excellent pharmacokinetic profile. The study also included a surrogate test of pharmacological

activity in the form of a delayed type hypersensitivity (DTH) skin test. The decreases in DTH responses in this clinical study were similar to those seen in prior animal studies.

We intend to proceed with the initiation of two one-month Phase IIa trials in the first half of 2005. The first study will be in patients with RA; the second in obese insulin-resistant patients. In RA, the severity of disease correlates well with the presence of macrophages in the synovial tissue of patients' joints. Furthermore, antagonism of CCR2 signaling through a variety of means, including oral administration of an Incyte CCR2 antagonist, has shown efficacy in multiple animal models of RA.

Insulin resistance occurs in Type II diabetes patients, the majority of whom are overweight/obese. There is growing evidence of a positive correlation between increased macrophage number in the adipose tissue of these patients, with the resulting accumulation of pro-inflammatory mediators, and the degree of insulin resistance. We believe that use of a CCR2 antagonist in this setting can reduce macrophage influx into the adipose tissue, thus improving insulin sensitivity. This hypothesis is supported by the efficacy of one of our CCR2 antagonists in animal models of obesity-related insulin resistance. The trial in insulin resistant subjects is the first step in assessing whether a CCR2 antagonist has the potential to be used in Type II diabetes patients and patients with a related disorder known as metabolic syndrome.

While both of these one-month trials are primarily focused on safety, efficacy measures will be monitored, and positive and potentially relevant trends may emerge.

INCB7839: Oral Sheddase Inhibitor for Cancer

We filed the IND for our oral sheddase inhibitor, INCB7839, on December 28. We have now received clearance to begin a Phase I study in healthy volunteers, which is scheduled to start in March 2005. We plan to initiate Phase II trials in the second half of 2005 in breast cancer and possibly other cancers such as non-small cell lung cancer, colon cancer, or head and neck cancer that are associated with excessive signaling of epidermal growth factor receptors (HER1, HER2, HER3).

Early-Stage Discovery Programs

Incyte is also pursuing a number of additional early stage discovery efforts, primarily in cancer, diabetes, inflammation and HIV. In parallel with our internal discovery efforts, we continue to seek compounds in our core therapeutic areas that may be available for in-licensing from other companies.

2004 Financial Results

Cash Position

As of December 31, 2004, cash and short-term investments totaled \$469.8 million as compared to \$293.8 million as December 31, 2003. During 2004, the company used \$111.5 million in cash. This figure does not include cash used to repurchase and retire \$38.4 million of its 5.5% Convertible Subordinated Notes in the third quarter of 2004.

Discontinuation of Proteome Subsidiary Operation and Sale of Assets

As a result of the discontinuation of operations and sale of assets of its Proteome subsidiary in Beverly, Massachusetts in January 2005, the company reclassified all of the financial results for Proteome to discontinued operations and therefore will record the following changes to its 2004 and 2003 financial statements:

- a reclassification of 2004 revenues of \$1.0 million and \$4.4 million for the fourth quarter and full year ended December 31, 2004, respectively, and \$1.3 million and \$5.9 million for the quarter and full year ended December 31, 2003, respectively
- a reclassification of research and development expense of \$1.0 million and \$4.2 million for the fourth quarter and full year ended December 31, 2004, respectively, and \$1.1 million and \$4.8 million for the quarter and full year ended December 31, 2003, respectively
- a reclassification of total selling, general and administrative expense of \$0.3 million and \$1.4 million for the fourth quarter and full year ended December 31, 2004, respectively, and \$0.2 million and \$1.0 million for the quarter and full year ended December 31, 2003, respectively

The reclassification of these amounts is reflected in the following 2004 and 2003 financial results:

Revenues

Total revenues for the fourth quarter and full year ended December 31, 2004 were \$2.3 million and \$14.1 million, respectively, as compared to \$9.0 million in the fourth quarter of 2003 and \$41.2 million for the year ending December 31, 2003.

Net Loss

The company's net loss for the fourth quarter and full year 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 includes 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 2004 net loss are restructuring and related charges of \$42.1 million, which were primarily associated with the closure of the company's facilities in Palo Alto. Also included in our net loss for the year is a charge of \$5.2 million, recorded as a result of write downs related to reduced market valuations in strategic investments that Incyte holds in other companies. This charge is included in interest income and other income, net.

The net loss for the fourth quarter and full year 2003 was \$40.8 million, or \$0.56 per share and \$166.5 million or \$2.33 per share and included restructuring and related charges of \$14.5 million of which \$11.5 million was a result of the company's decision to reduce headcount and write-down certain assets related to its genomic information product line. This charge is included in other expenses. Also included in the fourth quarter 2003 net loss is a charge of \$1.9 million, which is included in interest income and other income and expense, net, as a result of a write-down related to a reduction in the market valuation in a strategic investment Incyte has in another company.

Operating Expenses

Research and development expense during the fourth quarter and full year ended 2004 was \$21.1 million and \$88.3 million, respectively, versus \$26.4 million and \$111.4 million for the same periods in 2003. The decrease in research and development expense results from the company's restructuring efforts at its Palo Alto facilities, which were partially offset by increased expenses associated with the company's Wilmington-based drug discovery and development programs.

Selling, general and administrative expense during the fourth quarter and full year ended 2004 was \$4.6 million and \$20.6 million, respectively, versus \$6.5 million and \$29.4 million for the same periods in 2003. The decrease in selling, general and administrative expense is a result of staff reductions from our restructuring in February 2004.

2005 Financial Guidance

Cash

The company expects its cash use to range from \$120 million to \$130 million in 2005, which includes the use of approximately \$6 million for net lease-related costs in our closed California facilities. This guidance does not include any possible in-license or purchase of products or the repurchase of any of the company's 5.5% Convertible Subordinated Notes.

Revenue

Based on contractual commitments, the company expects 2005 revenues to be in the range of \$2 to \$4 million.

Operating Expenses

The company expects research and development expense to range from \$98 to \$102 million in 2005. The company expects selling, general and administrative expense to be in the range of \$12 to \$14 million in 2005. The company's operating expense guidance does not include the impact of SFAS 123(R), Share-Based Payment, which requires public companies to measure a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans.

Other Income/Expense

The company expects interest income to range from \$6 to \$7 million in 2005 while interest expense is expected to be approximately \$18 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.

Conference Call Information

Incyte will host a conference call on Monday, February 28, 2005 at 4:30 p.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 5701823.

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 5701823.

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, Reverset, is an oral, once-a-day therapy in Phase II clinical trials to treat patients with HIV infections. The company's lead internal compounds include INCB3284, a proprietary oral CCR2 antagonist that is entering Phase II development for a number of chronic inflammatory conditions and INCB7839, a proprietary, oral sheddase inhibitor that is entering Phase I development as a potential treatment for solid cancers. 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 as to the timing and results of Study 203, the timing and results of an end of Phase II meeting with the FDA regarding Study 203, plans to move Reverset through to Phase III studies during 2005, the potential benefits and 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 Phase II studies for Incyte's lead orally-available CCR2 compound, plans for Phase I and Phase II studies for Incyte's lead sheddase inhibitor compound, and financial guidance as to expected cash utilization, revenues and expenses for 2005, 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 final analysis of the Reverset Phase IIb studies will not confirm the potential shown by the interim results reported in this press release, 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 three months ended September 30, 2004. Incyte disclaims any intent or obligation to update these forward-looking statements.

Financial Statements Follow

INCYTE CORPORATION
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Revenues	\$2,325	\$9,002	\$14,146	\$41,197
Costs and expenses:				
Research and development	21,061	26,438	88,271	111,404
Selling, general and administrative	4,573	6,490	20,551	29,370
Purchased in-process research and development	-	(414)	-	33,952
Other expenses	11,639	14,508	54,177	15,823
Total costs and expenses	37,273	47,022	162,999	190,549
Loss from operations	(34,948)	(38,020)	(148,853)	(149,352)
Interest and other income (expense), net	2,192	(450)	3,563	(7,988)
Interest expense	(4,230)	(2,384)	(17,241)	(9,561)
Gain (loss) on certain derivative financial instruments, net	(15)	(112)	(454)	151
Gain (loss) on repurchase of convertible subordinated notes	-	-	(226)	706
Loss from continuing operations before income taxes	(37,001)	(40,966)	(163,211)	(166,044)
Provision for income taxes	271	(269)	453	342
Loss from continuing operations	(37,272)	(40,697)	(163,664)	(166,386)
Loss from discontinued operation	(254)	(70)	(1,153)	(77)
Net loss	\$(37,526)	\$(40,767)	\$(164,817)	\$(166,463)
Basic and diluted net loss per share:				
Continuing operations	\$(0.47)	\$(0.56)	\$(2.19)	\$(2.33)
Discontinued operation	-	-	(0.02)	-
	\$(0.47)	\$(0.56)	\$(2.21)	\$(2.33)
Shares used in computing basic and diluted net loss per share	79,289	72,411	74,555	71,369

INCYTE CORPORATION
 Condensed Consolidated Balance Sheet Data
 (in thousands)

December 31, December 31,
 2004 2003

Cash, cash equivalents, and marketable securities	\$469,764	\$293,807
Total assets	516,919	379,545
Convertible subordinated notes	378,766	167,786
Total stockholders' equity	78,517	154,333

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SOURCE: Incyte Corporation