

## **Incyte Reports Second Quarter 2011 Financial Results and Provides Update on Key Clinical Programs**

July 28, 2011

- **New Drug Application (NDA) for ruxolitinib as a treatment for myelofibrosis submitted to US Food & Drug Administration (FDA)**
- **Pivotal Phase III results for ruxolitinib demonstrating significant clinical benefit in patients with myelofibrosis presented at ASCO and EHA**
- **Commercialization activities ongoing; sales force recruitment initiated**

***Conference Call Scheduled Today at 8:30 a.m. ET***

WILMINGTON, Del., Jul 28, 2011 (BUSINESS WIRE) --

Incyte Corporation (Nasdaq: INCY) today reported second quarter financial results, provided updated information on key clinical programs and described preparations for the potential launch of ruxolitinib, an oral JAK1 and JAK2 inhibitor, that is being developed as a treatment for patients with myelofibrosis (MF).

"With the NDA now submitted, we are closer to bringing ruxolitinib forward as the first selective JAK1 and JAK2 inhibitor to treat patients with MF, a potentially life-threatening blood cancer for which there are no FDA approved products," stated Paul A. Friedman, M.D., Incyte's President and Chief Executive Officer.

Dr. Friedman added, "In anticipation of the potential product launch of ruxolitinib later this year, we are now actively building the US sales team, focusing on the recruitment of approximately 60 sales professionals with prior experience in the sales and marketing of hematology/oncology treatments."

### **Clinical Program Highlights:**

#### **JAK1 and JAK2 Inhibitor: ruxolitinib (also known as INCB18424 or INC424)**

- The Marketing Authorization Application for ruxolitinib as a treatment for MF was submitted to the European Medicines Agency by Novartis, our collaboration partner outside of the US, in June.
- Results from both Phase III trials, COMFORT-I and COMFORT-II, were presented in June at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting and the 16<sup>th</sup> Congress of the European Hematology Association (EHA) in London. The clinical data demonstrated that ruxolitinib provided a statistically significant reduction in spleen size in patients with MF, the primary endpoint for both studies, when compared to either placebo or best-available therapy. The safety profile of ruxolitinib was consistent with prior studies.
- Several Incyte-sponsored Phase II trials with ruxolitinib continued throughout the quarter, including a study in MF patients with platelet counts between 50,000/uL and 99,000/uL and a study evaluating a sustained-release formulation of ruxolitinib in patients with MF. A randomized Phase II trial in patients with pancreatic cancer was initiated in July.
- Regarding RESPONSE, the global Phase III trial with ruxolitinib in patients with advanced polycythemia vera, enrollment is behind schedule and we are taking steps to work with the FDA to amend the protocol so as to accelerate patient recruitment.
- Multiple investigator-sponsored trials evaluating ruxolitinib are also underway, including two Phase I/II trials in adults with advanced hematologic malignancies (acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome and chronic myelogenous leukemia) and relapsed or refractory acute leukemia, and a Phase I/II trial in children with hematologic malignancies and solid tumors. An investigator-sponsored trial in patients with non-Hodgkin lymphoma is expected to be initiated in the second half of the year.

#### **JAK1 and JAK2 Inhibitor: LY3009104 (formerly known as INCB28050)**

- Enrollment continues in a six-month dose-ranging Phase IIb trial in patients with rheumatoid arthritis, conducted by our collaboration partner Lilly. The three-month, double-blind, placebo-controlled phase of the trial is expected to be completed in early 2012.

#### **Sheddase Inhibitor: INCB7839**

- Efforts to complete the tissue analyses for the p95 assay validation are ongoing and once completed will be used to finalize interpretation of the Phase II data in HER2-positive breast cancer patients. These data, together with a thorough assessment of the current breast cancer market, will be used to determine whether moving into Phase III development is warranted.

#### **c-MET Inhibitor: INCB28060 (also known as INC280)**

- The initial Phase I trial in patients with solid tumors is ongoing and expected to continue until a maximum-tolerated or maximum-feasible dose is identified. This program is part of the Incyte-Novartis collaboration.

#### **IDO Inhibitor: INCB24360**

- The dose-escalation phase of a Phase I trial is ongoing and we expect to initiate a Phase II trial in the first half of 2012.

### **Second Quarter 2011 Financial Results**

#### **Cash Position**

As of June 30, 2011, cash, cash equivalents and marketable securities totaled \$364.1 million compared to \$424.2 million as of December 31, 2010. These amounts exclude \$28.5 million and \$37.9 million, respectively, of restricted cash and investments held in an escrow account reserved for interest payments through October 2012 on the 4.75% Convertible Senior Notes due 2015. The Company used \$89.5 million of cash during the first six months of 2011. Excluded from this amount is \$14.4 million of proceeds from stock option exercises and a \$15 million milestone payment received from Novartis for our c-MET inhibitor, INCB28060.

#### **Net Income/Net Loss**

Net loss for the quarter ended June 30, 2011 was \$51.9 million, or \$0.41 per basic and diluted share, as compared to net income of \$3.0 million, or \$0.03 and \$0.02 per basic and diluted share, respectively, for the same period in 2010. Included in net income for the quarter ended June 30, 2010 was a \$30 million milestone payment from Lilly in connection with a milestone for the JAK1/JAK2 inhibitor, LY3009104, and a \$3 million milestone payment from Pfizer for the CCR2 antagonist program.

The net loss for the six months ended June 30, 2011 was \$78.4 million, or \$0.63 per basic and diluted share, as compared to a net loss of \$32.7 million, or \$0.27 per basic and diluted share, for the same period in 2010. Included in net loss for the six months ended June 30, 2011 was a \$15 million milestone payment received from Novartis for INCB28060. Included in net income for the six months ended June 30, 2010 was \$33.0 million of milestone payments from Lilly and Pfizer.

Included in net loss for the quarter and for the six months ended June 30, 2011 were \$7.2 million and \$14.1 million, respectively, of non-cash expense related to the impact of expensing employee stock options, as compared to \$3.6 million and \$6.7 million, respectively, for the same periods in 2010.

#### **Revenues**

Total revenues for the quarter ended June 30, 2011 were \$16.8 million as compared to \$49.8 million for the same period in 2010. The decrease was primarily the result of the recognition of \$33.0 million of milestone payments from Lilly and Pfizer in the quarter ended June 30, 2010.

Total revenues for the six months ended June 30, 2011 were \$48.8 million as compared to \$67.1 million for the same period in 2010. The decrease was primarily the result of the \$33.0 million of milestone payments from Lilly and Pfizer recognized in the six months ended June 30, 2010, partially offset by a \$15 million milestone payment from Novartis for INCB28060 recognized in the six months ended June 30, 2011.

#### **Operating Expenses**

Research and development expenses for the quarter and six months ended June 30, 2011 were \$46.0 million and \$82.3 million, respectively, as compared to \$28.9 million and \$60.3 million, respectively, for the same periods last year.

Included in research and development expenses for the quarter and the six months ended June 30, 2011 were \$4.8 million and \$9.2 million, respectively, of non-cash expense related to the impact of expensing employee stock options, as compared to \$2.4 million and \$4.7 million, respectively, for the same periods in 2010.

The increase in research and development expenses for the quarter and six months ended June 30, 2011 was due to advancement of the Company's pipeline and increased non-cash employee stock option expense. The Company expects its research and development expenses to vary from quarter to quarter, primarily due to the timing of its clinical development activities.

Selling, general and administrative expenses for the quarter and six months ended June 30, 2011 were \$11.9 million and \$22.7 million, respectively, as compared to \$7.5 million and \$13.3 million, respectively, for the same periods last year. Increased selling, general and administrative expenses for the quarter and six months ended June 30, 2011 reflected the Company's preparation for the potential commercialization of ruxolitinib for MF.

Also included in selling, general and administrative expenses for the quarter and six months ended June 30, 2011 were \$2.4 million and \$4.9 million, respectively, of non-cash expense related to the impact of expensing employee stock options, as compared to \$1.2 million and \$2.0 million, respectively, for the same periods in 2010.

#### **Interest Expense**

Interest expense for the quarter and six months ended June 30, 2011 was \$10.9 million and \$21.6 million, respectively, as compared to \$10.4 million and \$22.2 million, respectively, for the comparable periods last year. Included in interest expense for the quarter and six months ended June 30, 2011, was \$6.1 and \$12.1 million, respectively, of non-cash charges to amortize the discount on the Company's convertible notes, as compared to \$5.6 million and \$11.8 million, respectively, for the same periods in 2010. The decrease from the six months ended June 30, 2010 is primarily due to interest

expense incurred in 2010 on the Company's 3<sup>1</sup>/<sub>2</sub>% convertible notes through their redemption date in February 2010.

## Conference Call Information

Incyte will hold its second quarter 2011 financial results conference call this morning at 8:30 a.m. ET. To access the conference call, please dial 877-407-8037 for domestic callers or 201-689-8037 for international callers. When prompted, provide the conference identification number, 375487.

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 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay you will need the conference account number 278 and the identification number 375487.

The conference call will also be webcast live and can be accessed at [www.incyte.com](http://www.incyte.com) under Investor Relations, Events and Webcasts.

## About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, visit the Company's web site at [www.incyte.com](http://www.incyte.com).

## Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to Incyte being closer to bringing ruxolitinib forward as the first selective JAK1 and JAK2 inhibitor to treat patients with MF and the anticipation of the potential product launch of ruxolitinib later this year, our plans to work with the FDA to amend the protocol for RESPONSE, the global Phase III trial with ruxolitinib in patients with advanced polycythemia vera, so as to accelerate patient recruitment, the expectation that an investigator-sponsored trial with ruxolitinib in patients with non-Hodgkin lymphoma will be initiated in the second half of this year, for the JAK1 and JAK2 inhibitor LY3009104, the expectation that the three-month, double-blind, placebo-controlled phase of the six-month dose-ranging Phase IIb trial in patients with rheumatoid arthritis, conducted by our collaboration partner Lilly, will be completed in early 2012, for the Sheddase inhibitor INCB7839, our plans to use the tissue analyses for the p95 assay validation to finalize interpretation of the Phase II data in HER2-positive breast cancer patients and to use these data, together with a thorough assessment of the current breast cancer market, to determine whether moving into Phase III development is warranted, for the c-MET inhibitor INCB28060, the expectation that the initial Phase I trial in patients with solid tumors will continue until a maximum-tolerated or maximum-feasible dose is identified, and for the IDO inhibitor INCB24360, the expectation that we will initiate a Phase II trial in the first half of 2012, 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 high degree of risk and uncertainty associated with drug development and clinical trials, the uncertainty associated with the regulatory approval processes, risks related to the timing of and patient enrollment in clinical trials, unanticipated developments in and risks related to the efficacy or safety of Incyte's compounds in clinical trials, the results of further research and development, risks associated with Incyte's dependence on its relationships with its collaboration partners, risks and uncertainties that may cause the parties not to achieve some or all of the commercial and developmental milestones set forth in the collaborative agreements, the risks related to market competition, changes in the timing of expenditures related to clinical development and sales and marketing activities, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2011. 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 |           | Six Months Ended |           |
|-------------------------------------|--------------------|-----------|------------------|-----------|
|                                     | June 30,           |           | June 30,         |           |
|                                     | 2011               | 2010      | 2011             | 2010      |
| Revenues:                           |                    |           |                  |           |
| Contract revenues                   | \$ 16,737          | \$ 49,737 | \$ 48,475        | \$ 66,474 |
| License and royalty revenues        | 74                 | 110       | 309              | 661       |
| Total revenues                      | 16,811             | 49,847    | 48,784           | 67,135    |
| Costs and expenses:                 |                    |           |                  |           |
| Research and development            | 46,047             | 28,883    | 82,329           | 60,322    |
| Selling, general and administrative | 11,858             | 7,485     | 22,683           | 13,280    |
| Other expenses                      | 20                 | (145)     | 712              | (260)     |
| Total costs and expenses            | 57,925             | 36,223    | 105,724          | 73,342    |
| Income (loss) from operations       | (41,114)           | 13,624    | (56,940)         | (6,207)   |
| Interest and other income, net      | 132                | 142       | 204              | 338       |
| Interest expense                    | (10,888)           | (10,391)  | (21,647)         | (22,170)  |
| Loss on debt redemption             | -                  | -         | -                | (3,988)   |

|                                                                        |                   |                 |                   |                   |
|------------------------------------------------------------------------|-------------------|-----------------|-------------------|-------------------|
| Income (loss) before income taxes                                      | (51,870)          | 3,375           | (78,383)          | (32,027)          |
| Provision for income taxes                                             | -                 | 331             | -                 | 658               |
| Net income (loss)                                                      | <u>\$(51,870)</u> | <u>\$ 3,044</u> | <u>\$(78,383)</u> | <u>\$(32,685)</u> |
| Net income (loss) per share                                            |                   |                 |                   |                   |
| Basic                                                                  | \$ (0.41)         | \$ 0.03         | \$ (0.63)         | \$ (0.27)         |
| Diluted                                                                | \$ (0.41)         | \$ 0.02         | \$ (0.63)         | \$ (0.27)         |
| Shares used in computing basic and diluted net income (loss) per share |                   |                 |                   |                   |
| Basic                                                                  | 125,330           | 121,630         | 124,399           | 120,679           |
| Diluted                                                                | 125,330           | 128,291         | 124,399           | 120,679           |

**INCYTE CORPORATION**  
**Condensed Consolidated Balance Sheet Data**  
(in thousands)

|                                                   | June 30,<br>2011 | December 31,<br>2010 |
|---------------------------------------------------|------------------|----------------------|
| Cash, cash equivalents, and marketable securities | \$ 364,110       | \$ 424,168           |
| Total assets                                      | 416,663          | 489,581              |
| Convertible senior notes                          | 287,067          | 276,445              |
| Convertible subordinated notes                    | 17,467           | 16,987               |
| Total stockholders' deficit                       | (136,284)        | (88,644)             |



SOURCE: Incyte Corporation

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