Incyte Reports Second-Quarter 2013 Financial Results; Increases Revenue Guidance; Updates Shareholders on Key Clinical Programs

August 1, 2013

- *$54.1 million of second-quarter net product revenues from Jakafi, reflecting solid growth in underlying demand*
- *2013 guidance for Jakafi net product revenues increased to range of $220 million to $230 million*
- *New data presented for Jakafi suggest an impact on bone marrow fibrosis and provide further evidence of a survival advantage in myelofibrosis patients*
- *New dosing guidance for myelofibrosis patients with low platelet counts added to prescribing information for Jakafi*

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

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 1, 2013-- Incyte Corporation (Nasdaq: INCY) today reported second-quarter 2013 financial results, including revenue from Jakafi® (ruxolitinib), which is approved by the U.S. Food & Drug Administration (FDA) for the treatment of patients with intermediate or high-risk myelofibrosis (MF). The Company also increased its 2013 net product revenue guidance to a range of $220 million to $230 million, a change from the previous range of $210 million to $225 million; highlighted additional positive data recently presented at key scientific meetings for its lead JAK1 and JAK2 inhibitors, Jakafi and baricitinib, and its novel immunotherapy, INCB24360, an oral IDO1 inhibitor; and described progress for several other clinical programs, including additional potential indications for Jakafi.

“The underlying demand for Jakafi was strong in the second quarter, leading to our decision to increase guidance for 2013,” stated Paul A. Friedman, M.D., Incyte’s President and Chief Executive Officer. “Looking forward, we expect the positive data recently presented at the European Hematology Association meeting regarding the overall survival advantage seen in COMFORT-II compared to best available therapy to continue to generate confidence in the therapeutic value of Jakafi.”

In the three-year follow-up analysis of COMFORT-II, a 52 percent reduction in risk of death was observed in the patients treated with Jakafi as compared to patients treated with best available therapy, and the estimated probability of overall survival at three years in patients with intermediate or high-risk myelofibrosis treated with Jakafi was 81 percent.

2013 Second-Quarter Financial Results and Guidance Updates

Cash Position

As of June 30, 2013, cash, cash equivalents and marketable securities totaled $277.5 million compared to $228.4 million as of December 31, 2012.

Revenues

Total revenues for the quarter ended June 30, 2013, were $101.7 million as compared to $86.5 million for the comparable period in 2012. Total revenues for the six months ended June 30, 2013, were $172.8 million as compared to $122.7 million for the comparable period in 2012.

Jakafi net product revenues were $54.1 million for the quarter ended June 30, 2013, as compared to $29.7 million for the comparable period in 2012. For the six months ended June 30, 2013, Jakafi net product revenues were $102.4 million as compared to $49.0 million for the comparable period in 2012.

The Company now expects that 2013 net product revenues from Jakafi will be in the range of $220 million to $230 million, an increase from the previous range of $210 million to $225 million. This range excludes any product royalty revenues received from Novartis on sales of Jakavi®.

Product royalties from sales of Jakavi outside the United States from Novartis for the quarter and six months ended June 30, 2013, were $5.8 million and $11.7 million, respectively; there were no product royalties earned in the comparable periods in 2012.

Also included in revenues for the second quarter of 2013 were contract revenues of $41.7 million, which included a $25.0 million milestone from Novartis for our c-MET program, as compared to $56.7 million for the comparable period in 2012, which included a $40.0 million milestone from Novartis for Jakavi. For the six months ended June 30, 2013, contract revenues were $58.5 million as compared to $73.5 million for the comparable period in 2012.

Net Income (Loss)

Net loss for the quarter ended June 30, 2013, was $2.6 million, or $0.02 per basic and diluted share, as compared to net income of $4.0 million, or $0.03 per basic and diluted share, for the same period in 2012. For the six months ended June 30, 2013, net loss was $18.2 million, or $0.13 per basic and diluted share, as compared to a net loss of $41.4 million, or $0.32 per basic and diluted share, for the same period in 2012. Included in the net loss for the quarter and six months ended June 30, 2013, was a one-time cash charge of $9.8 million, or $0.07 per basic and diluted share, related to the exchange of the Company’s 4.75% Convertible Senior Notes (4.75% Senior Notes) due 2015 described below.

Non-Cash Stock Option Expense

Non-cash expense related to employee stock options for the second quarter of 2013 was $9.9 million, of which $6.7 million was included in research and development expenses and $3.2 million was included in selling, general and administrative expenses. For the year to date, non-cash expense related to employee stock options was $19.1 million, of which $13.2 million was included in research and development expenses and $5.9 million was included in selling, general and administrative expenses.

Operating Expenses

Research and development expenses for the quarter and six months ended June 30, 2013, were $61.0 million and $113.7 million, respectively, as compared to $51.6 million and $100.5 million, respectively, for the same periods in 2012.

Selling, general and administrative expenses for the quarter and six months ended June 30, 2013, were $23.2 million and $45.5 million, respectively, as compared to $19.7 million and $41.1 million, respectively, for the same periods in 2012.

Interest Expense and 4.75% Convertible Senior Notes

Interest expense for the quarter and six months ended June 30, 2013, was $10.3 million and $22.0 million, respectively, as compared to $11.4 million and $22.7 million, respectively, for the comparable periods in 2012. Also included in interest expense for the quarter and six months ended June 30, 2013, were $6.2 million and $13.2 million, respectively, of non-cash charges to amortize the discount on the 4.75% Senior Notes, as compared to $6.7 million and $13.2 million, respectively, for the same periods in 2012.

During the second quarter the Company entered into separately negotiated agreements with certain holders of the Company's 4.75% Senior Notes pursuant to which such holders agreed to exchange $143.7 million in aggregate principal amount of the 4.75% Senior Notes for the shares of the Company's stock into which the 4.75% Senior Notes were convertible, aggregating 16.4 million shares, and $9.8 million in cash. The Company recorded the $9.8 million in debt exchange expense in the second quarter.

As a result of the reduction in the outstanding principal balance of the 4.75% Senior Notes, the Company now expects interest expense to be approximately $38 million for 2013, including non-cash charges of $23 million to amortize the discount on the 4.75% Senior Notes, a decrease from previous guidance of $47.0 million, which included $28.0 million of non-cash charges to amortize the discount on the 4.75% Senior Notes.

Recent Clinical Highlights

Jakafi® (ruxolitinib) - a JAK1 and JAK2 Inhibitor

- Myelofibrosis

  Three-year data from the Phase III COMFORT-II trial presented at the 18th Congress of the European Hematology Association (EHA) in Stockholm, Sweden, showed sustained spleen reductions and improved overall survival among patients treated with Jakafi as compared to best available therapy.

  The U.S. Food and Drug Administration approved a supplemental New Drug Application for expanded dosing language stating that the recommended starting dose for patients with baseline platelet counts between 50-100 x 10^9/L is 5 mg twice daily and providing guidance for subsequent dose titrations based on safety and efficacy.

  In an exploratory analysis of long-term data from an ongoing Phase I/II trial presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, researchers found evidence that bone marrow fibrosis, a hallmark of worsening disease in MF, stabilized or reversed after 24 and 48 months of Jakafi treatment in the majority of patients. By contrast, a separate historical database analysis of hydroxyurea-treated patients showed the majority of these patients had increasing levels of fibrosis by 48 months, and none in the hydroxyurea-treated group had evidence of reversal. In a second presentation at EHA, the researchers observed a similar contrast between Jakafi-treated patients and those treated with best available therapy. Additional research is needed to understand the clinical impact of these findings.

- Polycythemia Vera

  RESPONSE, a Phase III study being conducted under a Special Protocol Assessment (SPA) in collaboration with Novartis, is evaluating ruxolitinib in patients with polycythemia vera (PV), and results are expected in early 2014. Completion of this pivotal trial, if positive, would allow for the filing of a supplemental new drug application submission in the first half of 2014. The FDA has granted fast track designation for ruxolitinib for the treatment of patients with PV who are resistant to or intolerant of hydroxyurea.

  RELIEF is an ongoing Phase III trial measuring disease-related symptoms in patients with PV, and not being part of the SPA agreement with the FDA, it is not required for approval. Once completed, the trial results are expected to be submitted to support labeling claims regarding the symptomatic benefit of ruxolitinib in PV.

- Pancreatic Cancer

  A randomized Phase II trial of ruxolitinib in combination with capecitabine is ongoing with approximately 135 patients with recurrent or treatment refractory metastatic pancreatic cancer (the RECAP trial). The primary endpoint is overall survival, and top-line results are expected later in the third quarter of 2013.

- Other Potential Indications

  Multiple investigator-sponsored trials evaluating ruxolitinib in oncologic indications are ongoing.

Baricitinib - a JAK1 and JAK2 Inhibitor

The 52-week efficacy and safety data from the open-label, long-term extension of the Phase IIb JADA study of baricitinib in patients with

active rheumatoid arthritis, conducted by the Company's collaboration partner Eli Lilly and Company, were presented at the European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology in Madrid, Spain. Among patients completing the open-label extension, the statistically significant clinical improvements in the signs and symptoms of rheumatoid arthritis observed at week 24 were sustained at the end of 52 weeks, with no new safety signals observed with longer treatment.

The Phase III clinical program to evaluate baricitinib in rheumatoid arthritis is ongoing. Two Phase II trials in patients with moderate-to-severe psoriasis and in patients with diabetic nephropathy are also underway.

INC280 (formerly INCB28060) – a c-MET Inhibitor

Under the Incyte-Novartis licensing agreement, further development of this compound is being conducted by Novartis. INC280 is currently in several clinical trials: as monotherapy in patients with advanced hepatocellular carcinoma and in patients with c-MET dependent advanced solid malignancies, as well as combination therapy with gefitinib in patients with non-small-cell lung cancer.

INCB24360 – an IDO1 Inhibitor

Final results from the Phase I clinical trial of INCB24360, which were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, demonstrate that this novel oral immunotherapy achieves greater than 90 percent inhibition of IDO1 at generally well-tolerated doses and may represent a new treatment option for advanced malignancies either as monotherapy or in combination with other cancer treatments.

INCB24360 is currently in Phase I/II clinical development for metastatic melanoma in combination with ipilimumab and as monotherapy for ovarian cancer.

INCB39110 – a JAK1 Inhibitor

Three proof-of-concept studies evaluating INCB39110 in patients with myelofibrosis, psoriasis and rheumatoid arthritis are underway, with results expected in the second half of 2013. The results of these studies are expected to provide information about the most appropriate indications for further development.

INCB47986 – a JAK1 Inhibitor

A second JAK1 inhibitor, INCB47986, is currently in Phase I clinical development, and future studies will focus on its use in hematology and oncology indications.

Conference Call Information

Incyte will hold its second-quarter 2013 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, 417382.

If you are unable to participate, a replay of the conference call will be available for 30 days. The replay dial-in number for the United States 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 identification number, 417382.

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 biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

Important Safety Information

Jakafi can cause serious side effects including:

Low blood counts: Jakafi may cause your platelet, red blood cell, or white blood cell counts to be lowered. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will perform blood tests to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you experience unusual bleeding, bruising, fatigue, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection while taking Jakafi. Tell your healthcare provider if you develop symptoms such as chills, nausea, vomiting, aches, weakness, fever, or painful skin rash or blisters.

The most common side effects of Jakafi include dizziness and headache.

These are not all the possible side effects of Jakafi. Ask your healthcare provider or pharmacist for more information. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Before taking Jakafi, tell your healthcare provider about all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had liver or kidney problems, are on dialysis, or have any other medical condition. Do not drink grapefruit juice while taking Jakafi.

Women should not take Jakafi while pregnant or planning to become pregnant, or if breast-feeding.

Please see the Full Prescribing Information available at www.jakafi.com, which includes a more complete discussion of the risks associated with Jakafi.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements regarding financial guidance about expected net product revenues and interest expense, our plans and expectations with respect to Jakafi (ruxolitinib), including the potential efficacy and therapeutic and commercial value of Jakafi, our expectation that the positive data recently presented at EHA regarding the overall survival advantage seen with long-term use of Jakafi will continue to generate confidence in the therapeutic value of Jakafi, our expectation of results from the RESPONSE trial evaluating ruxolitinib in PV in early 2014 and the filing of a supplemental new drug application in the first half of 2014, our expectation to submit results from the RELIEF trial to support labeling claims on symptomatic benefit of ruxolitinib in PV, our expectation of top-line results from the RECAP trial in the third quarter of 2013, our belief that INCB24360 may represent a new treatment option for advanced malignancies, our expectation of results from the three proof-of-concept studies evaluating INCB39110 in patients with myelofibrosis, psoriasis and rheumatoid arthritis in the second half of 2013 and these results being expected to provide information as to the most appropriate indications for further development, and our expectation that future studies of INCB47986 will focus on its use in hematology and oncology indications, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to the efficacy or safety of Jakafi, the acceptance of Jakafi in the marketplace, risks related to market competition, the results of further research and development, risks and uncertainties associated with sales, marketing and distribution requirements, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, the ability to enroll sufficient numbers of subjects in clinical trials, other market or economic factors and technological advances, unanticipated delays, the ability of Incyte to compete against parties with greater financial or other resources, risks associated with Incyte's dependence on its relationships with its collaboration partners, and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended March 31, 2013.

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 June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
Product revenues, net	$ 54,099	$ 29,727	$102,388	$ 49,006
Product royalty revenues	5,800	-	11,709	-
Contract revenues	41,737	56,737	58,474	73,474
Other revenues	39	78	181	242
Total revenues	101,675	86,542	172,752	122,722
Costs and expenses:				
Cost of product revenues	157	16	308	27
Research and development	60,950	51,588	113,713	100,548
Selling, general and administrative	23,249	19,719	45,509	41,115
Total costs and expenses	84,356	71,323	159,530	141,690
Income (loss) from operations	17,319	15,219	13,222	(18,968)
Interest and other income, net	245	315	444	366
Interest expense	(10,293)	(11,430)	(22,022)	(22,720)
Debt exchange expense	(9,771)	-	(9,771)	-
Income (loss) before income taxes	(2,500)	4,104	(18,127))	(41,322)
Provision for income taxes	71	67	113	67
Net income (loss)	$ (2,571)	$ 4,037	$(18,240))	$(41,389)
Net income (loss) per share				
Basic	$ (0.02)	$ 0.03	$ (0.13)	$ (0.32)
Diluted	$ (0.02)	$ 0.03	$ (0.13)	$ (0.32)
Shares used in computing basic and diluted net income (loss) per share				

Basic	142,284	129,224	138,315	128,214
Diluted	142,284	137,969	138,315	128,214

INCYTE CORPORATION
Condensed Consolidated Balance Sheet Data
(in thousands)

	June 30, 2013	December 31, 2012
Cash, cash equivalents, and short-term marketable securities	277,453	228,418
Accounts receivable, net	27,522	70,951
Total assets	334,219	330,419
Convertible senior notes(1)	214,530	322,043
Convertible subordinated notes	9,287	9,033
Total stockholders' deficit	(27,786)	(174,957)

(1) Net of unamortized debt discount of $41.8 million and $78.0 million at June 30, 2013 and December 31, 2012, respectively.

Source: Incyte Corporation

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