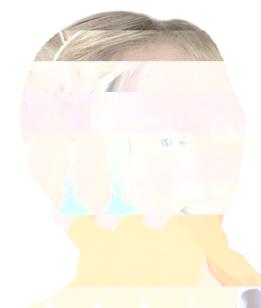
# THE DRIVE TO DISCOVER. THE EXPERIENCE TO DELIVER.

# 2011 ANNUAL REPORT

Imagine being one of the 16,000 to 18,500 people in the U.S. living with myelofibrosis (MF) and having no approved treatments available to you.



The most difficult part emotionally was when I was diagnosed with myelofibrosis. The hard part was that nothing was out there. Jakafi brought us hope, that there is a treatment, there is something that we can do that may benefit us significantly.

> Dan is a patient with MF who has participated in COMFORT-I, our pivotal Phase III U.S. trial

# To Our Stockholders:

The last year was truly significant for Incyte, marked by the FDA approval and the launch of our first product. These key accomplishments attest to our commitment to improving the lives of patients and to establishing Incyte as a commercially successful biopharmaceutical company.

### **ATremendous Achievement**

The FDA approval of Jakafi™ (ruxolitinib) for the treatment of patients with intermediate or high-risk myelofibrosis (MF) provides the first approved medicine for MF and represents a major breakthrough for the people who suffer from this debilitating and life-threatening blood cancer.

In just seven years, our scientific, clinical, regulatory and manufacturing teams have fulfilled our mission of bringing a novel discovery from the laboratory to the market. Our sales and marketing colleagues are now committed to making Jakafi a commercial success.

As the first JAK inhibitor to be approved for any indication, Jakafi is evidence of our leadership position in the discovery and development of this important new class of drugs.

JAK inhibitors have now shown therapeutic value in both oncology and chronic inflammatory diseases, and we are in a strong position to tap into these emerging and potentially major markets.

### Making a Difference in MF

MF has a significant impact on the lives of patients. The loss of their ability to perform certain basic activities of daily living as a result of their enlarged spleens and heavy symptom burden is similar to patients with other advanced cancers, and the prognosis of patients with MF worsens as the disease progresses.

In the largest clinical program ever conducted in MF patients, Jakafi significantly reduced spleen volume and alleviated the most burdensome symptoms. By contrast, patients receiving placebo or best available therapy continued to see their spleens increase in size and their symptoms worsen. Anemia and thrombocytopenia were the most common adverse reactions, but rarely led to discontinuation (only one patient in each treatment group for each event). Non-hematologic adverse reactions that occurred more frequently in the group treated with Jakafi were bruising, dizziness and headache.

We're gratified that the majority of patients treated with Jakafi saw their spleens shrink and their symptoms improve. Additionally, further analysis from the U.S. pivotal study suggests that Jakafi may also have the potential to improve survival as compared to placebo. These data were presented at the American Society of Hematology 2011 Annual Meeting and recently published in *The New England Journal of Medicine.* 

## Close Collaboration with the FDA-A Key Success Factor

By working closely with the FDA, we were able to demonstrate why spleen reduction and improvement in symptoms were clinically meaningful endpoints to support approval in MF. Further, we developed a symptom measurement tool specific to MF that captured patient-reported outcomes in a manner that was not only acceptable to the FDA, but also praised as "remarkable" by the agency.

Our collaborative approach, combined with a compelling clinical efficacy and safety profile, enabled us to gain a priority review for the treatment of intermediate or

high-risk MF, which our market research indicates includes 80 percent to 90 percent of all patients with the disease.

## Favorable Market Response to Jakafi

Within one week of approval, our experienced commercial team launched Jakafi. They are meeting with thousands of physicians across the country who treat patients with MF, and we are encouraged by the enthusiasm expressed by both physicians and patients. We expect acceptance of Jakafi to continue at a steady, gradual pace as physicians witness the benefits of Jakafi and acknowledge the value of treating intermediate or high-risk MF patients. Because we want all appropriate patients who can benefit from Jakafi to have access to the drug, we have established a comprehensive patient assistance and education program called IncyteCARES, and the program has already been widely used and well-received.

Beyond the product launch of Jakafi in the U.S., our strategic partner Novartis has filed regulatory applications for ruxolitinib in its key markets and expects to hear from regulatory authorities in the second half of 2012.

# Unlocking the Full Potential of JAK Inhibitors

There is a growing body of evidence that implicates the JAK pathway in multiple disease settings in both oncology and inflammation. For this reason, and in partnership with Novartis, we are studying Jakafi in a number of indications outside

of MF, including polycythemia vera (PV), another related blood cancer.

We expect results from a global Phase III study in patients with advanced PV in 2013; provided these data are positive, FDA approval in this second indication could occur in 2014. Early Phase II trials are also underway to evaluate Jakafi in leukemia, lymphoma and pancreatic cancer – all of which could add significantly to the therapeutic and commercial value of Jakafi.

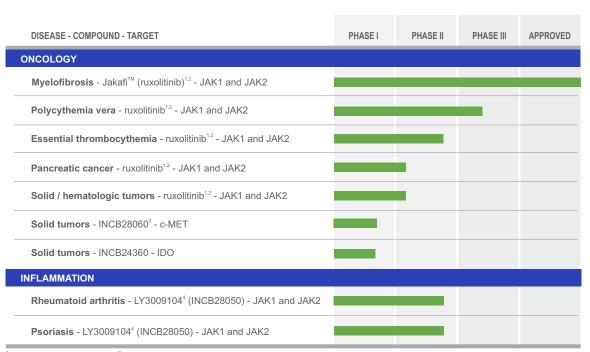


Our second JAK1 and JAK2 inhibitor is currently in development for the treatment of rheumatoid arthritis (RA) and psoriasis. Given the broad market potential associated with chronic inflammatory diseases, we elected to license this program to Eli Lilly and Company. Because of our confidence in this compound and its potential commercial value, we are funding 30 percent of the associated global development costs in RA in exchange for tiered royalty rates ranging up to the high twenties on potential future global sales. We expect Lilly to initiate Phase III trials in RA later this year.

#### Our Pipeline Continues to Grow

In addition to our JAK inhibitor programs, we have a robust and growing pipeline in oncology and inflammatory diseases. Our c-MET inhibitor INCB28060, partnered with Novartis, exhibits greater selectivity and improved potency compared to other known c-MET inhibitors in development. This compound is nearing completion of an initial Phase I trial in patients with solid tumors, after which, Novartis will be responsible for its development. We have retained co-development and copromotion rights and Incyte will receive royalties on any potential future sales of INCB28060.

Our indoleamine 2, 3-dioxygenase (IDO) inhibitor, INCB24360, is a novel immunomodulatory therapeutic that has shown in pre-clinical studies that it can significantly increase the efficacy of various chemotherapeutic agents in controlling tumor growth. The compound has been welltolerated in our Phase I program, and Phase II studies to treat patients with melanoma and ovarian cancer are scheduled to begin this year.



<sup>1</sup>Formerly INCB18424 (INC424) <sup>2</sup>Incyte: U.S. rights; Novartis: ex U.S. rights <sup>3</sup>Novartis: worldwide rights <sup>4</sup>Lilly: worldwide rights

We have several other clinical programs underway in oncology and inflammation as we continue to expand our pipeline with additional differentiated, best-in-class compounds.

#### Continuing Our Drive to Discover

Our goal to discover and develop proprietary new compounds with the requisite characteristics to become important new medicines remains a key driver for our decisions and activities. With our recognized core competency in medicinal chemistry, a proven ability to select clinically relevant targets, an experienced and talented clinical development team and now a commercial group with substantial experience in the promotion of new oncology therapies, I am confident we are in a strong position to build significant, sustainable shareholder value. In closing, I want to thank John Niblack for his service on our Board of Directors. His extensive experience in managing R&D at Pfizer has been of great value over the past six years as we sought to prioritize our efforts and accelerate our most promising programs.

I also want to thank our employees for their commitment to rigorous science, effective teamwork and disciplined program execution which has enabled us to bring Jakafi to market – a success I am confident we can replicate and build on in the years to come.

Sincerely,

Paul Q. Shiedman

Paul A. Friedman, M.D. President and Chief Executive Officer April 2012

# 2012 Key Business Goals

- Continue the successful launch of Jakafi for myelofibrosis (MF)
- Increase awareness of the progressive and life-threatening nature of MF
- Complete enrollment of the Phase III study of ruxolitinib in polycythemia vera, in partnership with Novartis
- Continue clinical studies of ruxolitinib in other oncologic indications
- Support the ongoing development of LY3009104 (INCB28050) for rheumatoid arthritis, in partnership with Lilly
- Advance several early development and discovery programs in oncology and inflammation

#### BOARD OF DIRECTORS

Richard U. De Schutter Chairman of the Board Formerly Chairman and Chief Executive Officer DuPont Pharmaceuticals Company

Paul A. Friedman, M.D. President and Chief Executive Officer Incyte Corporation

Barry M. Ariko Formerly President, Chief Executive Officer and Chairman Mirapoint, Inc.

Julian C. Baker Managing Member Baker Bros. Advisors, LLC

Paul A. Brooke Founder and Managing Director venBio LLC

Wendy L. Dixon, Ph.D. Formerly Chief Marketing Officer and President, Global Marketing Bristol-Myers Squibb Company

John F. Niblack, Ph.D. Formerly Vice Chairman and President of Global Research and Development Pfizer Inc.

**Roy A. Whitfield** Formerly Chairman of the Board and Chief Executive Officer Incyte Corporation

#### EXECUTIVE MANAGEMENT

Paul A. Friedman, M.D. President and Chief Executive Officer

Patricia S. Andrews Executive Vice President and Chief Commercial Officer

**David C. Hastings** Executive Vice President and Chief Financial Officer

**Reid M. Huber, Ph.D.** Senior Vice President, Discovery Biology

**Richard S. Levy, M.D.** Executive Vice President and Chief Drug Development and Medical Officer

**Eric H. Siegel** Executive Vice President and General Counsel

Paula J. Swain Executive Vice President, Human Resources

Wenqing Yao, Ph.D. Senior Vice President, Discovery Chemistry

#### STOCKHOLDER INFORMATION

**Transfer Agent and** 

Registrar Computershare PO Box 358015 Pittsburgh, PA 15252-8015 or

480 Washington Boulevard Jersey City, NJ 07310-1900 Phone: 800/851-9677

**TDD for Hearing Impaired:** 800/231-5469

Foreign Shareowners: 201/680-6578

**TDD Foreign Shareowners:** 201/680-6610

www.bnymellon.com/ shareowner/equityaccess

Annual Meeting The Annual Meeting of Stockholders will be held May 30, 2012, at 10:00 a.m., Eastern Daylight Time, at the Hotel du Pont, 11th and Market Streets, Wilmington, Delaware 19801

Outside Counsel Pillsbury Winthrop Shaw Pittman LLP

Independent Registered Public Accounting Firm Ernst & Young LLP

#### Market Information

Incyte's Common Stock trades on The Nasdaq Global Market under the symbol INCY.

#### **Investor Relations**

You can obtain recent press releases and other publicly available information on Incyte by visiting our website at www.incyte.com.

#### Contact

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**Corporate Headquarters** 

Incyte Corporation Experimental Station Route 141 & Henry Clay Road Building E336 Wilmington, Delaware 19880 855/446.2983

# Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this annual report, including statements regarding our plans and expectations with respect to Jakafi™(ruxolitinib) including its potential efficacy and therapeutic and commercial value, anticipated future accomplishments in drug discovery, development and product commercialization, plans and expected timelines regarding our pipeline and advancing our drug candidates through clinical trials and regulatory submissions, potential therapeutic and commercial value, including attributes and indications, of our drug candidates, and our business goals for 2012 contain predictions, estimates and other forward-looking statements.

These forward-looking statements are 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, the high degree of risk and uncertainty associated with drug development, clinical trials and the regulatory approval processes, risks related to the timing of and patient enrollment in clinical trials, the risk that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, unanticipated developments in and risks related to the efficacy or safety of our compounds in clinical trials, risks associated with our dependence on our relationships with our collaboration partners, and other risks detailed from time to time in our reports filed with the Securities and Exchange Commission, including our Form 10-K for the year ended December 31, 2011. Incyte disclaims any intent or obligation to update these forward-looking statements.

Jakafi is a trademark of Incyte Corporation.



WWW.INCYTE.COM



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