INCYTE CORP
Form 10-K
February 22, 2012

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 0-27488

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3136539**
(State of other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
Experimental Station, Route 141 & Henry Clay Road, Building E336, Wilmington, DE 19880	
(Address of principal executives offices)	**(302) 498-6700** (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of exchange on which registered**
Common Stock, $.001 par value per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15 (d) of the Act. Yes o No ý

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý

The aggregate market value of Common Stock held by non-affiliates (based on the closing sale price on The NASDAQ Global Market on June 30, 2011) was approximately $2.2 billion.

As of February 21, 2012 there were 127,333,906 shares of Common Stock, $.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2012 Annual Meeting of Stockholders to be held on May 30, 2012.

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Item 1. ***Business***

This report contains forward-looking statements that involve risks and uncertainties. These statements relate to future periods, future events or our future operating or financial plans or performance. Often, these statements include the words "believe," "expect," "target," "anticipate," "intend," "plan," "seek," "estimate," "potential," "project," or words of similar meaning, or future or conditional verbs such as "will," "would," "should," "could," "might," or "may," or the negative of these terms, and other similar expressions. These forward-looking statements include statements as to:

the discovery, development, formulation, manufacturing and commercialization of our compounds, our product candidates and JAKAFI;

conducting clinical trials internally, with collaborators, or with clinical research organizations;

our collaboration and strategic relationship strategy; anticipated benefits and disadvantages of entering into collaboration agreements;

our licensing, investment and commercialization strategies, including our plans to commercialize JAKAFI;

the regulatory approval process, including obtaining U.S. Food and Drug Administration and other international health authorities approval for our products in the United States and abroad;

the safety, effectiveness and potential benefits and indications of our product candidates and other compounds under development;

the timing and size of our clinical trials; the compounds expected to enter clinical trials; timing of clinical trial results;

our ability to manage expansion of our drug discovery and development operations;

future required expertise relating to clinical trials, manufacturing, sales and marketing;

obtaining and terminating licenses to products, compounds or technology, or other intellectual property rights;

the receipt from or payments pursuant to collaboration or license agreements resulting from milestones or royalties;

plans to develop and commercialize products on our own;

plans to use third party manufacturers;

expected expenses and expenditure levels; expected uses of cash; expected revenues and sources of revenues;

expected losses; fluctuation of losses;

our profitability; the adequacy of our capital resources to continue operations;

the need to raise additional capital;

the costs associated with resolving matters in litigation;

our expectations regarding competition;

our investments, including anticipated expenditures, losses and expenses;

our patent prosecution and maintenance efforts; and

our indebtedness, and debt service obligations.

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These forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. These risks and uncertainties could cause actual results to differ materially from those projected and include, but are not limited to:

our ability to successfully commercialize JAKAFI;

our ability to maintain at anticipated levels, reimbursement for JAKAFI from government health administration authorities, private health insurers and other organizations;

our ability to establish and maintain effective sales, marketing and distribution capabilities;

the risk of reliance on other parties to manufacture JAKAFI, which could result in a short supply of JAKAFI, increased costs, and withdrawal of regulatory approval;

our ability to maintain regulatory approvals to market JAKAFI;

our ability to successfully identify patients and achieve a significant market share in order to achieve or maintain profitability;

the risk of civil or criminal penalties if we market JAKAFI in a manner that violates health care fraud and abuse and other applicable laws, rules and regulations;

our ability to discover, develop, formulate, manufacture and commercialize our other product candidates;

the risk of unanticipated delays in research and development efforts;

the risk that previous preclinical testing or clinical trial results are not necessarily indicative of future clinical trial results;

risks relating to the conduct of our clinical trials;

changing regulatory requirements;

the risk of adverse safety findings;

the risk that results of our clinical trials do not support submission of a marketing approval application for our product candidates;

the risk of significant delays or costs in obtaining regulatory approvals;

risks relating to our reliance on third party manufacturers, collaborators, and clinical research organizations;

risks relating to the development of new products and their use by us and our current and potential collaborators;

risks relating to our inability to control the development of out-licensed drug compounds or drug candidates;

risks relating to our collaborators' ability to develop and commercialize product candidates;

costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights;

our ability to maintain or obtain adequate product liability and other insurance coverage;

the risk that our product candidates may not obtain or maintain regulatory approval;

the impact of technological advances and competition;

the ability to compete against third parties with greater resources than ours;

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risks relating to changes in pricing and reimbursements in the markets in which we may compete;

competition to develop and commercialize similar drug products;

our ability to obtain patent protection and freedom to operate for our discoveries and to continue to be effective in expanding our patent coverage;

the impact of changing laws on our patent portfolio;

developments in and expenses relating to litigation;

our ability to in-license potential drug compounds or drug candidates or other technology;

our substantial leverage and limitations on our ability to incur additional indebtedness and incur liens on our assets imposed by our debt obligations;

our ability to obtain additional capital when needed;

fluctuations in net cash provided and used by operating, financing and investing activities;

our history of operating losses; and

the risks set forth under "Risk Factors."

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by federal securities laws, we undertake no obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

In this report all references to "Incyte," "we," "us," "our" or the "Company" mean Incyte Corporation and our subsidiaries, except where it is made clear that the term means only the parent company.

Incyte is our registered trademark and JAKAFI is our trademark. We also refer to trademarks of other corporations and organizations in this Annual Report on Form 10-K.

Overview

Incyte is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary small molecule drugs to treat serious unmet medical needs. We began our drug discovery and development operations in 2001 and have focused our research efforts primarily in the areas of oncology and inflammation where we believe our expertise in medicinal chemistry, target selection, and preclinical and clinical development can be most effectively leveraged.

Our most advanced compound, JAKAFI (ruxolitinib), also known as INCB18424 and INC424, is an oral Janus associated kinase (JAK) inhibitor that was recently approved by the U.S. Food and Drug Administration (FDA) as a treatment for patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. MF is a serious, life-threatening blood cancer that belongs to a group of diseases known as myeloproliferative neoplasms that include polycythemia vera and essential thrombocythemia.

JAKAFI is the first FDA-approved JAK inhibitor, and is part of a potentially important new oral drug class to treat cancer and chronic inflammatory diseases. The JAK pathway, which consists of four tyrosine kinases JAK1, JAK2, JAK3 and Tyk2, is dysregulated in many oncologic and inflammatory conditions. This can occur through mutations that activate JAK2 or through other mechanisms such as overexpression of cytokines that activate JAK1 and JAK2. JAKAFI works by selectively inhibiting the overactive JAK1 and JAK2 signaling.

The FDA has also granted JAKAFI orphan drug status for MF as well as two related myeloproliferative neoplasms: polycythemia vera and essential thombocythemia. The European

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Commission has also granted the compound orphan drug status for MF. In addition, we hold patents that cover the formulation and use of JAKAFI through 2026, excluding potential patent term extensions.

JAKAFI is subject to a collaboration agreement with Novartis International Pharmaceutical Ltd. in which Novartis received exclusive development and commercialization rights to the product outside of the United States for all hematologic and oncology indications, including hematological malignancies, solid tumors and myeloproliferative neoplasms. Pursuant to the terms of the collaboration agreement with Novartis, we retained all development and commercialization rights to JAKAFI in the United States and are eligible to receive development milestones and royalties from product sales outside the United States.

Following the FDA approval of JAKAFI as a treatment for patients with intermediate or high-risk MF in November 2011, we began its commercialization in the United States. We believe there are between 16,000 and 18,500 total myelofibrosis patients in the United States. Based on the modern prognostic scoring systems referred to as International Prognostic Scoring System and Dynamic International Prognostic Scoring System, we believe intermediate and high-risk patients represent 80 percent to 90 percent of all MF patients in the United States and encompass patients over the age of 65, or patients who have or have ever had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts, or platelet counts less than 100,000 per microliter of blood.

In addition to its development as a treatment for MF, Incyte and Novartis believe ruxolitinib may have potential as a treatment for other cancers. Several additional clinical programs are ongoing, including a global Phase III trial in patients with advanced polycythemia vera, a Phase II trial in patients with pancreatic cancer, and Phase II trials in several other hematologic cancers being conducted as investigator sponsored trials.

We have a second oral JAK1 and JAK2 inhibitor, LY3009104 (INCB28050), which is subject to a collaboration agreement with Eli Lilly and Company in which Lilly received exclusive worldwide development and commercialization rights for the compound for inflammatory and autoimmune diseases. We could receive tiered, double-digit royalty payments on future global sales of products subject to the agreement with rates ranging up to 20% if the products are successfully commercialized. This collaboration also contains an option for us to co-develop compounds for any inflammatory and autoimmune disease, whereby we fund 30% of development costs from Phase IIb through regulatory approval for that indication in exchange for tiered royalties ranging up to the high twenties on potential future sales. We exercised our co-development option for the development of LY3009104 in rheumatoid arthritis in 2010. This compound is currently in Phase IIb trials in patients with rheumatoid arthritis and moderate-to-severe psoriasis.

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We have several other orally available small molecule compounds that are in various stages of development. We intend to continue our investment in drug discovery to expand our pipeline. Our current clinical pipeline includes the following compounds:

Target/Drug Compound	Indication	Status
JAK1 and JAK2		
JAKAFI(1)	Intermediate or High-Risk Myelofibrosis(5)	FDA Approved Marketed
Ruxolitinib(INCB18424)(1)	Polycythemia Vera	Phase III
Ruxolitinib(INCB18424)(1)	Essential Thrombocythemia	Phase II
Ruxolitinib(INCB18424)(1)	Pancreatic Cancer	Phase II
Ruxolitinib(INCB18424)(1)	Solid Tumors and Other Hematologic Malignancies(6)	Phase I and Phase II
LY3009104(INCB28050)(2)	Rheumatoid Arthritis	Phase IIb
LY3009104(INCB28050)(3)	Psoriasis	Phase IIb
c-MET		
INCB28060(4)	Solid Tumors	Phase I
IDO		
INCB24360	Solid Tumors	Phase I

(1) We licensed rights outside the United States to Novartis and retained U.S. rights.

(2) We licensed worldwide rights to Lilly and have elected to co-develop with Lilly and we retain a co-promotion option.

(3) We licensed worldwide rights to Lilly and retained co-development and co-promotion options.

(4) We licensed worldwide rights to Novartis and retained co-development and co-promotion options.

(5) Several clinical trials in patients with myelofibrosis are ongoing, including long-term extension studies, a joint global Phase II trial with Novartis in patients with low platelet counts, and an Incyte-sponsored Phase II trial in patients with low platelet counts.

(6) These studies are investigator sponsored trials.

JAKAFI

JAKAFI became commercially available in the United States in November 2011 and is being marketed in the United States through our own 60 person specialty sales force and commercial team, which has relevant expertise in the promotion, distribution and reimbursement of oncology drugs.

The wholesale acquisition cost for a 30-day supply of JAKAFI, across all dosage strengths, is $7,000. To help ensure that all eligible MF patients have access to JAKAFI, we have established a patient assistance program called IncyteCARES (CARES stands for Connecting to Access, Reimbursement, Education and Support). IncyteCARES helps ensure that any patient with intermediate or high-risk MF who meets certain eligibility criteria and is prescribed JAKAFI has access to the product regardless of ability to pay and has access to ongoing support and educational resources during their treatment. In addition, IncyteCARES works closely with payers to help facilitate insurance coverage of JAKAFI.

JAKAFI is distributed through a network of specialty pharmacy providers that work closely with IncyteCARES and allow for efficient delivery of the medication by mail directly to patients or direct delivery to the patient's pharmacy of choice. Our distribution process uses a model that is well-established and familiar to physicians who practice within the oncology field.

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To further support appropriate utilization and future development of JAKAFI, our Medical Affairs department, which is comprised of experienced personnel, is responsible for providing appropriate scientific and medical education and information to physicians, preparing scientific presentations and publications, and overseeing the process for supporting investigator sponsored trials.

Novartis filed the Marketing Authorization Application for INC424 with the European Medicines Agency in June 2011 and, if the product is approved, expects to begin commercializing the product in its territories in the second half of 2012.

Clinical Programs

JAK Programs for Myeloproliferative Neoplasms, Oncology and Inflammation

The JAK family is composed of four tyrosine kinases JAK1, JAK2, JAK3 and Tyk2 that are involved in the signaling of a number of cytokines and growth factors. JAKs are central to a number of biologic processes, including the formation and development of blood cells and the regulation of immune functions. Dysregulation of the JAK-STAT signaling pathway has been associated with a number of diseases, including myeloproliferative neoplasms (MPNs), other hematological malignancies, solid tumors, rheumatoid arthritis, psoriasis and other chronic inflammatory diseases. MPNs are a closely related group of blood diseases in which blood cells, specifically platelets, white blood cells, and red blood cells, grow or act abnormally in the bone marrow. These diseases include myelofibrosis, polycythemia vera and essential thrombocythemia.

We have discovered multiple potent, selective and orally bioavailable JAK inhibitors that are selective for JAK1 and JAK2. Our lead JAK inhibitor for hematologic and oncology indications, JAKAFI (ruxolitinib), is FDA-approved for use in patients with intermediate or high-risk MF and is in Phase III development for polycythemia vera. The compound is also in Phase II development for solid tumors and other hematologic malignancies, and we have completed a Phase II trial in patients with essential thrombocythemia. We also have a topical formulation of ruxolitinib and have completed a Phase IIb trial in patients with mild to moderate psoriasis. We are seeking a partner for this program and do not intend to advance the topical formulation into Phase III on our own.

Myelofibrosis. Myelofibrosis is a rare, life-threatening condition. MF, considered the most serious of the MPNs, can occur either as primary MF, or as secondary MF that develops in some patients who previously had polycythemia vera or essential thrombocythemia.

Most MF patients have enlarged spleens and many suffer from debilitating symptoms, including abdominal discomfort, pruritus (itching), night sweats and cachexia (involuntary weight loss). There were no FDA-approved therapies for MF until the approval of JAKAFI.

The FDA approval was based on results from two randomized Phase III trials (COMFORT-I and COMFORT-II), which demonstrated that patients treated with JAKAFI experienced significant reductions in splenomegaly (enlarged spleen). The COMFORT-I trial, conducted by Incyte, compared JAKAFI to placebo in 309 patients with primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. The trial met the primary endpoint, showing that 41.9 percent of patients treated with JAKAFI experienced a 35 percent or greater reduction in spleen volume at 24 weeks, compared with 0.7 percent of patients taking placebo ($p<0.0001$). A 35 percent reduction in spleen volume correlates to approximately a 50 percent reduction in spleen size on palpation. COMFORT-I also demonstrated improvements in symptoms as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) v.2.0 electronic diary and the MFSAF Total Symptom Score (TSS) comprised of six specific symptoms (abdominal discomfort, pain under the left ribs, an early feeling of fullness, night sweats, bone and muscle pain, and itching) all of which contributed to the overall benefit. At week 24, the percentage of patients with a greater than or equal to 50 percent improvement in the TSS was 45.9 percent and 5.3 percent in

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patients treated with JAKAFI and placebo, respectively (p<0.0001), with a median time to response of less than four weeks. Most patients taking placebo experienced worsening of these same parameters.

The COMFORT-II trial, conducted by Novartis, compared JAKAFI to best available therapy in 219 patients with primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF. This trial also met the primary endpoint, showing that 28.5 percent of patients treated with JAKAFI experienced a 35 percent or greater reduction in spleen volume at 48 weeks, compared with 0 percent of patients in the best available therapy arm (p<0.0001).

The most common adverse reactions in both trials were thrombocytopenia and anemia. These events rarely led to discontinuation of JAKAFI treatment. The most common non-hematologic adverse reactions were bruising, dizziness and headache.

Further analyses from the global, pivotal Phase III clinical program of JAKAFI were presented at the 2011 American Society of Hematology (ASH) Annual Meeting in December. Included in these presentations was a survival analysis from a planned safety update in COMFORT-I highlighting that there were 13 (8.4%) deaths in the JAKAFI group and 24 (15.7%) in the placebo group (HR=0.50; 95% CI, 0.25-0.98). While COMFORT-I was not designed or powered to show a statistically significant difference in overall survival, the data presented suggest that JAKAFI may provide an overall survival benefit as compared to placebo.

Polycythemia Vera and Essential Thrombocythemia. Polycythemia vera is a rare but serious myeloproliferative neoplasm and occurs when the bone marrow produces too many blood cells, especially red blood cells. Patients with polycythemia vera can have symptoms similar to myelofibrosis, including enlarged spleens and debilitating symptoms such as fatigue, abdominal discomfort, pruritus (itching), night sweats and cachexia (involuntary weight loss). While there are currently no FDA-approved therapies for polycythemia vera, several treatments are used to manage the signs and symptoms of the disease, including the removal of blood (phlebotomy) and treatment with myelosuppressive therapies. About a third of patients can become resistant to or intolerant of these approaches, and there is an unmet medical need for new therapies to treat this subset of patients. We estimate, based on the available literature and published databases, that there are currently 95,000 patients with polycythemia vera in the United States.

In September 2010, we reached a special protocol assessment (SPA) agreement with the FDA for a Phase III clinical trial for ruxolitinib in patients with advanced polycythemia vera. The SPA was subsequently amended with FDA agreement in the fourth quarter of 2011. This global, randomized, open-label trial, being conducted by Incyte and Novartis, will compare the efficacy and safety of ruxolitinib to best available therapy. The primary dual endpoint is phlebotomy independence and at least a 35 percent spleen volume reduction at week 32. Key secondary endpoints include the proportion of patients who maintain the primary endpoint response for 48 weeks from randomization and the proportion of patients achieving complete hematologic remission at week 32. The trial is expected to include approximately 200 patients.

In December 2010, we presented long-term clinical results from an ongoing open-label Phase II trial for ruxolitinib in patients with advanced polycythemia vera or essential thrombocythemia. The data, showing long-term clinical activity, including reduction in spleen size, phlebotomy independence (in patients with polycythemia vera) and improvement in blood counts lasting up to 27 months, were presented in an oral session at the 52nd American Society of Hematology Annual Meeting. With a median duration of 21 months of follow-up, clinical responses observed in 34 patients enrolled with polycythemia vera included durable improvements in splenomegaly (spleen enlargement), hematocrit control and symptomatic burden, including pruritus (itching), night sweats and bone pain. Clinical responses seen in 39 patients enrolled with essential thrombocythemia included long-term reductions in elevated platelet and white blood cell counts, and, when present, splenomegaly and constitutional symptoms. Ruxolitinib was well-tolerated in this trial.

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Additional Clinical Activities in Oncology. Additional clinical studies to evaluate the use of ruxolitinib in other malignant diseases are either underway or planned. We initiated a Phase II trial in pancreatic cancer in 2011 that is expected to include approximately 138 patients. The primary endpoint of the trial is overall survival. Secondary endpoints include tumor response rate and patient-reported quality of life measures and pain status.

An investigator-sponsored trial evaluating ruxolitinib in patients with lymphoma was initiated in 2011, and several other investigator-sponsored trials evaluating ruxolitinib are ongoing, including 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.

Rheumatoid Arthritis. Rheumatoid arthritis is an autoimmune disease characterized by aberrant or abnormal immune mechanisms that lead to joint inflammation and swelling and, in some patients, the progressive destruction of joints. Rheumatoid arthritis can also affect connective tissue in the skin and organs of the body.

Current rheumatoid arthritis treatments include the use of non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs, such as methotrexate, and the newer biological response modifiers that target pro-inflammatory cytokines, such as tumor necrosis factor, implicated in the pathogenesis of rheumatoid arthritis. None of these approaches to treatment is curative; therefore, there remains an unmet need for new safe and effective treatment options for these patients. Rheumatoid arthritis is estimated to affect about 1 percent of the world population.

We have a second JAK1 and JAK2 inhibitor, LY3009104 (INCB28050), which is the lead compound in our inflammation program and subject to our collaboration agreement with Lilly. In November 2010, at the 2010 American College of Rheumatology Annual Scientific Meeting, we presented the final six-month clinical data from the dose-ranging, placebo-controlled Phase IIa trial of LY3009104 in patients with active rheumatoid arthritis.

Results from the 125-patient Phase IIa trial demonstrated that all three doses (4, 7 and 10 milligrams once a day) of oral LY3009104 improved on the primary endpoint, the percent of patients achieving an American College of Rheumatology (ACR) 20 response, over the full 24-week treatment period. Evidence of improvement was seen as early as the first assessment at two weeks, and efficacy results continued to improve from week 12 to week 24 across ACR response categories. Responses were similar in both biologic-experienced and biologic-naïve patients, and adverse events for all three doses were predominantly mild-to-moderate with frequencies similar to placebo.

In October 2010, Lilly initiated a Phase IIb trial in 270 patients with rheumatoid arthritis poorly controlled on methotrexate. This global, dose-ranging trial is now fully enrolled with results expected in 2012. Provided the results support further development, we expect that Lilly will advance the compound into Phase III testing. We have exercised our option in rheumatoid arthritis to fund 30% of development costs from Phase IIb through regulatory approval in exchange for increased tiered royalties ranging up to the high twenties on potential future sales.

Psoriasis. LY3009104 is also being developed in psoriasis. Psoriasis is a skin disease that causes visible scaling and inflammation. Most psoriasis patients have patches of thick, red skin with silvery scales that can occur on the elbows, knees, other parts of the legs, scalp, lower back, face, palms, and soles of the feet. Market research suggests that neither physicians nor patients are satisfied with existing psoriasis treatments primarily because these require constant monitoring to balance safety and efficacy outcomes. There is clear unmet need for a better tolerated and effective treatment. The U.S. psoriasis market consists of approximately six million patients, of which moderate-to-severe patients account for approximately 20 percent of the market.

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In December 2011, Lilly initiated a Phase IIb double-blind, placebo-controlled, dose-ranging trial designed to evaluate LY3009104 in patients with moderate-to-severe plaque psoriasis. The trial is expected to include 240 patients randomized to one of four dose groups (2 mg, 4 mg, 8 mg or 10 mg once daily) or placebo. The primary objective of this study is to demonstrate that at least one dose group is superior to placebo at week 12 in the treatment of patients with moderate-to-severe psoriasis as measured by the proportion of patients with at least a 75 percent improvement from baseline in Psoriasis Area and Severity Index (PASI) score. The timeframe for exercising our co-development option for this indication has not yet occurred.

c-MET for Solid Tumors

Solid tumors are named for the type of cells that form them, for example, sarcomas, carcinomas, and lymphomas. Frequently, the term "solid tumors" collectively refers to cancer in major organs. The American Cancer Society estimates that more than 1,500,000 Americans will be diagnosed with cancer in 2011, of which more than 835,000 patients will be diagnosed with solid tumors such as lung, prostate, colon, rectum or breast cancer. The American Cancer Society also estimates that approximately 572,000 U.S. patients are expected ultimately to die from cancer in 2011.

c-MET is a clinically validated receptor kinase cancer target. Abnormal c-MET activation in cancer correlates with poor prognosis. Dysregulation of the c-MET pathway triggers tumor growth, formation of new blood vessels that supply the tumor with nutrients, and causes cancer to spread to other organs. Dysregulation of the c-MET pathway is seen in many types of cancers, including kidney, liver, stomach, breast and brain.

Several small molecule c-MET kinase inhibitors have demonstrated clinical efficacy in a number of cancers; however, these molecules have limited potency and are relatively non-selective, which could lead to off-target toxicities. We believe our lead c-MET inhibitor, INCB28060, which is licensed to Novartis, has the requisite properties to overcome these limitations, including greater selectivity, improved potency and more effective inhibition of c-MET. Under our agreement, Novartis received worldwide exclusive development and commercialization rights to INCB28060 and certain back-up compounds in all indications. We initiated a Phase I/II clinical trial in early 2010 and expect to transition the program to Novartis in 2012.

IDO for Solid Tumors

The enzyme, indoleamine 2, 3-dioxygenase, IDO, is a key regulator of the mechanisms that are responsible for allowing tumors to escape from a patient's immune surveillance. IDO expression by tumor cells, or by antigen presenting cells such as macrophages and dendritic cells in tumors, creates an environment in which tumor specific cytotoxic T lymphocytes are rendered functionally inactive or are no longer able to attack a patient's cancer cells. By inhibiting IDO, it is proposed that this "brake" on the anti-tumor immune response is removed, allowing anti-tumor specific cytotoxic T cells, generated in a patient spontaneously in response to the tumor, or through a therapy designed to stimulate the immune response, to have greater anti-tumor efficacy.

We believe our compound, INCB24360, represents a novel, potent and selective inhibitor of the enzyme IDO. It is efficacious in multiple mouse models of cancer and has been well-tolerated in preclinical safety studies. We initiated a dose-escalation Phase I/II clinical trial in patients with solid tumors in the third quarter of 2010 and expect to begin two Phase II trials in 2012, one in patients with melanoma and a second in patients with ovarian cancer.

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Discovery

We have a number of early discovery programs at various stages of preclinical and clinical testing. We intend to disclose these programs once we have obtained clinical proof-of-concept and established that a compound within a specific program warrants further development.

License Agreements

Novartis

In November 2009, we entered into a Collaboration and License Agreement with Novartis. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to ruxolitinib and certain back-up compounds for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to JAKAFI (ruxolitinib) in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our c-MET inhibitor compound INCB28060 and certain back-up compounds in all indications. We retained options to co-develop and to co-promote INCB28060 in the United States.

Under this agreement, we received an upfront payment and immediate milestone payment totaling $210 million and were initially eligible to receive additional payments of up to approximately $1.1 billion if defined development and commercialization milestones are achieved. We also could receive tiered, double-digit royalties on future ruxolitinib sales outside of the United States. Each company is responsible for costs relating to the development and commercialization of the JAK inhibitor compound in its respective territories, with costs of collaborative studies shared equally. Novartis is responsible for all costs relating to the development and commercialization of the c-MET inhibitor compound after the initial Phase I clinical trial.

The Novartis agreement will continue on a program-by-program basis until Novartis has no royalty payment obligations with respect to such program or, if earlier, the termination of the agreement or any program in accordance with the terms of the agreement. The agreement may be terminated in its entirety or on a program-by-program basis by Novartis for convenience. The agreement may also be terminated by either party under certain other circumstances, including material breach.

Lilly

In December 2009, we entered into a License, Development and Commercialization Agreement with Lilly. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to LY3009104 and certain back-up compounds for inflammatory and autoimmune diseases. We received an initial payment of $90 million, and were initially eligible to receive additional payments of up to $665 million based on the achievement of defined development, regulatory and commercialization milestones. We also could receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20% if the product is successfully commercialized.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly will be responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial through regulatory approval. We would receive an incremental royalty rate increase across all tiers resulting in effective royalty rates ranging up to the high twenties on potential future global sales for compounds and/or indications that we elect to co-develop. We also retained an option to co-promote products in the United States. In July 2010, we elected to co-develop LY3009104 with Lilly in rheumatoid arthritis and we are responsible for funding 30% of the associated future global development costs for this indication from the initiation of a

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Phase IIb trial through regulatory approval. LY3009104 is also being developed in psoriasis. The timeframe for exercising our co-development option for this indication has not yet occurred. The Lilly agreement will continue until Lilly no longer has any royalty payment obligations or, if earlier, the termination of the agreement in accordance with its terms. The agreement may be terminated by Lilly for convenience, and may also be terminated under certain other circumstances, including material breach.

Pfizer

In January 2006, we entered into a Collaborative Research and License Agreement with Pfizer Inc. for the pursuit of our CCR2 antagonist program. Pfizer gained worldwide development and commercialization rights to our portfolio of CCR2 antagonist compounds. Pfizer's rights extend to the full scope of potential indications, with the exception of multiple sclerosis and autoimmune nephritides, where we retained worldwide rights, along with certain compounds. We do not have obligations to Pfizer on pre-clinical development candidates we select for pursuit in these indications. The agreement will terminate upon the expiration of the last to expire of patent rights licensed under the agreement. Prior to such expiration, either party can terminate the agreement for the uncured material breach of the agreement by the other party or for the insolvency of the other party. In addition, Pfizer may terminate the agreement at any time upon 90 days' notice. We received an upfront nonrefundable, non-creditable payment of $40.0 million in January 2006 and are eligible to receive additional future development and commercialization milestone payments

Incyte's Approach to Drug Discovery and Development

Our productivity in drug discovery and development is primarily a result of our core competency in medicinal chemistry which is tightly integrated with, and supported by, an experienced team of biologists with expertise in multiple therapeutic areas. We have also built a clinical development and regulatory team. This team utilizes clinical research organizations (CROs), expert scientific advisory boards, and leading consultants and suppliers in relevant drug development areas in an effort to conduct our clinical trials efficiently and effectively, while maintaining strategic control of the design and management of our programs.

To succeed in our objective to create a pipeline of novel, orally available drugs that address serious unmet medical needs, we have established a broad range of discovery capabilities in-house, including target validation, high-throughput screening, medicinal chemistry, computational chemistry, and pharmacological and ADME (absorption, distribution, metabolism and excretion) assessment. We augment these capabilities through collaborations with academic and contract laboratory resources with relevant expertise.

We select drug targets with strong preclinical or clinical validation in areas where we have the potential to generate either first-in-class molecules or compounds that are highly differentiated from existing treatments.

Our chemistry and biology efforts are highly integrated and are characterized by the rapid generation of relevant data on a broad and diverse range of compounds for each therapeutic target we pursue. This process allows our scientists to better understand the potency and selectivity of the compounds, how they are likely to be absorbed and eliminated in the body, and to assess the potential safety profile of the compounds. We believe that this approach, along with stringent criteria for the selection of clinical candidates, allows us to select appropriate candidates for clinical development and assess key characteristics required for success.

Given our chemistry-driven discovery process, our pipeline has grown to encompass multiple therapeutic areas, primarily in the areas of oncology and inflammation. We conduct a limited number of discovery programs in parallel at any one time. This focus allows us to allocate resources to our selected programs at a level that we believe is competitive with much larger pharmaceutical companies. We believe this level of resource allocation, applied to the discovery process outlined above, has been a critical competitive advantage in advancing our product pipeline.

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Additionally, in all of our programs we strive to generate a broad range of proprietary compounds which we believe enhances the overall probability of success for our programs and creates the potential for multiple products.

Once our compounds reach clinical development, our objective, whenever possible, is to rapidly progress the lead candidate into a proof-of-concept Phase II clinical trial to quickly assess the therapeutic potential of the clinical candidate itself and its underlying mechanism. This information is then used to evaluate the commercial potential of the compound, the most appropriate indication or indications to pursue, and whether to pursue any development on our own or seek a strategic relationship for the compound.

Our development teams are responsible for ensuring that our clinical candidates are expeditiously progressed from preclinical development and IND-enabling studies into human testing. Our development teams include employees with expertise in drug development, including clinical trial design, statistics, regulatory affairs, medical affairs, pharmacovigilance and project management. We have also built core internal process chemistry and formulation teams using this same strategy. Rather than build extensive infrastructure, we work with contract manufacturers with expertise in process chemistry, product formulation, and the manufacture of clinical trial supplies to support our drug development efforts. In addition, we use external CROs for later stage clinical trials.

Incyte's Commercial Strategy

Our strategy is to develop and commercialize our compounds on our own in selected markets when we believe a company of our size can successfully compete, such as in myelofibrosis, other myeloproliferative neoplasms, other oncology indications and certain inflammatory conditions. In November 2011, we received regulatory approval of JAKAFI (ruxolitinib) in the United States for the treatment of intermediate or high-risk myelofibrosis. We have built the marketing, medical and operational infrastructure to support commercialization of JAKAFI in this indication in the United States. In 2010 and 2011, the marketing team focused the majority of its efforts on conducting quantitative and qualitative market research among physicians and patients, initiating brand development work, progressing the development of the generic and trade names, developing a patient services hub to assist patients in obtaining access to JAKAFI and developing a distribution network of specialty pharmacies to dispense JAKAFI. We hired approximately 60 sales representatives and 6 regional managers in the second half of 2011 to support the launch of JAKAFI.

For rights to ruxolitinib outside the United States as well as for pipeline compounds that are outside of our core expertise or would require expensive clinical studies, we have established or are seeking to establish collaborations or strategic relationships to support development and commercialization. We established a collaboration with Novartis in 2009 for rights in certain indications outside of the United States to our JAK oncology program with ruxolitinib and specified backups, as well as worldwide rights to our c-MET inhibitor compound INCB28060. We also established a collaboration with Lilly in 2009 for our JAK inflammation and autoimmune program with LY3009104 and specified back-ups, and with Pfizer in 2005 to advance our CCR2 antagonist program. We believe the key benefits to entering into strategic relationships include the potential to receive upfront payments and future milestones and royalties in exchange for certain rights to our compounds, as well as the potential to expedite the development and commercialization of certain of our compounds.

Patents and Other Intellectual Property

We regard the protection of patents and other enforceable intellectual property rights that we own or license as critical to our business and competitive position. Accordingly, we rely on patent, trade secret and copyright law, as well as nondisclosure and other contractual arrangements, to protect our intellectual property. We have established a patent portfolio of patents and patent applications owned by us that cover aspects of all our drug candidates. The patents and patent applications relating to our drug candidates

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generally include claims directed to the drug candidates, methods of using the drug candidates, formulations of the drug candidates, pharmaceutical salt forms of the drug candidates, and methods of manufacturing the drug candidates. Our policy is to pursue patent applications on inventions and discoveries that we believe are commercially important to the development and growth of our business. The following table sets forth the status of the patents and patent applications in the United States, the European Union, and Japan, covering our drugs and drug candidates in our key programs that have progressed into at least Phase II clinical trials:

Drug/Drug Candidate (Target)	Status of United States Patent Estate (Earliest Anticipated Expirations, Subject to Potential Extensions and Payment of Maintenance Fees)	Status of European Union and Japan Patent Estate (Earliest Anticipated Expirations, Subject to Potential Extensions and Payment of Maintenance Fees)
Ruxolitinib (JAK)	Granted and pending (2026)	Granted and pending (2026)
LY3009104 (JAK)	Applications pending (2026)	Applications pending (2026)

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

We may seek to license rights relating to technologies in connection with our drug discovery and development programs. Under these licenses, we may be required to pay up-front fees, license fees, milestone payments and royalties on sales of future products.

Although we believe our rights under patents and patent applications provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents in the United States or elsewhere from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be valid or enforceable or may not be sufficient to protect the technology owned by or licensed to us or provide us with a competitive advantage. Any patent or other intellectual property rights that we own or obtain may be circumvented, challenged or invalidated by our competitors. Others may have patents that relate to our business or technology and that may prevent us from marketing our product candidates unless we are able to obtain a license to those patents. In addition, litigation or other proceedings may be necessary to defend against claims of infringement, to enforce patents, to protect our other intellectual property rights, to determine the scope and validity of the proprietary rights of third parties or to defend ourselves in patent or other intellectual property right suits brought by third parties. We could incur substantial costs in such litigation or other proceedings. An adverse outcome in any such litigation or proceeding could subject us to significant liability.

With respect to proprietary information that is not patentable, and for inventions for which patents are difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. While we require all employees, consultants and potential business partners to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Competition

Our drug discovery and development activities face, and will continue to face, intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Our major competitors include fully integrated pharmaceutical companies that have extensive drug discovery efforts and are developing novel small molecule

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pharmaceuticals. We face significant competition from organizations that are pursuing pharmaceuticals that are competitive with our potential products.

Many companies and institutions, either alone or together with their collaborative partners, have substantially greater financial resources and larger research and development staffs than we do. In addition, many competitors, either alone or together with their collaborative partners, have significantly greater experience than we do in:

- drug discovery;
- developing products;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing, marketing, distributing and selling products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA and other regulatory approval or commercializing products before we do. If we commence commercial product sales, we will be competing against companies with greater manufacturing, marketing, distributing and selling capabilities, areas in which we have limited or no experience.

In addition, any drug candidate that we successfully develop may compete with existing therapies that have long histories of safe and effective use. Competition may also arise from:

- other drug development technologies and methods of preventing or reducing the incidence of disease;
- new small molecules; or
- other classes of therapeutic agents.

Developments by others may render our drug candidates obsolete or noncompetitive. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to proprietary technology. These competitors, either alone or with their collaborative partners, may succeed in developing products that are more effective than ours.

Our ability to compete successfully will depend, in part, on our ability to:

- develop proprietary products;
- develop and maintain products that reach the market first, are technologically superior to and/or are of lower cost than other products in the market;

attract and retain scientific, product development and sales and marketing personnel;

obtain patent or other proprietary protection for our products and technologies;

obtain required regulatory approvals; and

manufacture, market, distribute and sell any products that we develop.

In a number of countries, including in particular, developing countries, government officials and other groups have suggested that pharmaceutical companies should make drugs available at a low cost. In some cases, governmental authorities have indicated that whe