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 where pharmaceutical companies do not do so, their patents might not be enforceable to prevent generic competition. Some major pharmaceutical companies have greatly reduced prices for their drugs in certain developing countries. If certain countries do not permit enforcement of any of our patents, sales of our products in those countries, and in other countries by importation from low-price countries, could be reduced by generic competition or by parallel importation of our product. Alternatively, governments in those countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products in those countries, thereby reducing our product sales, or we could respond to governmental concerns by

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reducing prices for our products. In all of these situations, our results of operations could be adversely affected.

**Government Regulation**

Our ongoing research and development activities and any manufacturing and marketing of JAKAFI and our product candidates are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Before marketing in the United States, any drug developed by us must undergo rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA under the United States Food, Drug and Cosmetic Act and its implementing regulations. The FDA regulates, among other things, the research, development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution and import and export, of these products.

*FDA Review and Approval Process*

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate's safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application (IND), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may commence;
- performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication;
- submission of a new drug application to the FDA for review;
- random inspections of clinical sites to ensure validity of clinical data around safety and efficacy;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices;
- FDA approval of the NDA; and
- payment of user and establishment fees, if applicable.

Similar requirements exist within foreign agencies as well. The time required to satisfy FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions about safety issues such as the

conduct of the clinical trials as outlined in the IND. In the latter case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence.

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Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. These regulations require all research subjects to provide informed consent. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND and each trial must be reviewed and approved by an independent ethics committee or institutional review board (IRB) before it can begin.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion.

Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications.

Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling.

We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the IRB, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

As a separate amendment to an IND, a clinical trial sponsor may submit a request for a special protocol assessment (SPA) from the FDA. Under the SPA procedure, a sponsor may seek the FDA's agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins, except in limited circumstances, such as when a substantial scientific issue essential to determining the safety and effectiveness of a product candidate is identified after a Phase III clinical trial is commenced and agreement is obtained with the FDA. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. The FDA, however, may make an approval decision based on a number of factors, including the degree of clinical benefit, and the FDA is not obligated to approve an NDA as a result of an SPA, even if the clinical outcome is positive.

Even after initial FDA approval has been obtained, post-approval trials, or Phase IV studies, may be required to provide additional data, and will be required to gain approval for the sale of a product as a treatment for clinical indications other than those for which the product was initially tested and approved. Also, the FDA will require post-approval reporting to monitor the side effects of the drug. Results of post-approval programs may limit or expand the indication or indications for which the drug product may be marketed. Further, if there are any requests for modifications to the initial FDA approval for the drug, including changes in indication, manufacturing process, labeling or manufacturing facilities, a supplemental NDA may be required to be submitted to the FDA.

The length of time and related costs necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or cause the costs of these clinical trials to increase, include:

- slow patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors;

- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;

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delays in approvals from a study site's IRB;

longer than anticipated treatment time required to demonstrate effectiveness or determine the appropriate product dose;

lack of sufficient supplies of the drug candidate for use in clinical trials;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the drug candidate being tested.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level, and at any time in the course of animal studies designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or in clinical trials of our potential products. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates, and could ultimately prevent their marketing approval by the FDA or foreign regulatory authorities for any or all targeted indications.

The FDA's fast track program is intended to facilitate the development and expedite the review of drug candidates intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for these conditions. Under this program, the FDA can, for example, review portions of an NDA for a fast track product before the entire application is complete, thus potentially beginning the review process at an earlier time.

We cannot guarantee that the FDA will grant any of our requests for fast track designation, that any fast track designation would affect the time of review or that the FDA will approve the NDA submitted for any of our drug candidates, whether or not fast track designation is granted. Additionally, FDA approval of a fast track product can include restrictions on the product's use or distribution (such as permitting use only for specified medical conditions or limiting distribution to physicians or facilities with special training or experience). Approval of fast track products can be conditioned on additional clinical trials after approval.

Sponsors submit the results of product development, preclinical studies and clinical trials to the FDA as part of an NDA. NDAs must also contain extensive manufacturing information and proposed labeling. Upon receipt, the FDA initially reviews the NDA to determine whether it is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. If the FDA accepts the submission for substantive review, the FDA typically reviews NDAs within an accepted time frame. Under the Prescription Drug User Fee Act, the FDA agrees to review NDAs under either a standard review or priority review. FDA procedures provide for priority review of NDAs submitted for drugs that, compared to currently marketed products, offer a significant improvement in the treatment, diagnosis or prevention of a disease. The FDA seeks to review NDAs that are granted priority status more quickly than NDAs given standard review status. The FDA's stated policy is to act on 90% of priority NDAs within six months of receipt. Although the FDA historically has not met these goals, the agency has made significant improvements in the timeliness of the review process. NDA review often extends significantly beyond anticipated completion dates due to FDA requests for additional data or clarification, the FDA's decision to have an advisory committee review and make recommendations on approval of the NDA, and difficulties in scheduling an advisory committee meeting. The recommendations of an advisory committee are not binding on the FDA.

To obtain FDA approval to market a product, we must demonstrate that the product is safe and effective for the patient population that will be treated. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is safe and effective, as demonstrated through clinical trials. Marketing or promoting a drug for an unapproved indication is prohibited. Furthermore, approval may entail ongoing requirements for post-marketing studies or risk

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evaluation and mitigation strategies, including the need for patient and/or physician education, patient registries, medication or similar guides, or other restrictions on the distribution of the product. If an NDA does not satisfy applicable regulatory criteria, the FDA may deny approval of an NDA or may issue a complete response, and require, among other things, additional clinical data or analyses.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union, or EU, registration procedures are available to companies wishing to market a product in more than one EU member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization may be granted. This foreign regulatory approval process involves all of the risks associated with FDA approval discussed above and may also include additional risks.

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven year exclusive marketing period in the United States for the orphan drug indication. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven year exclusive marketing period. We believe that the commercial success of any orphan drug product that we may commercialize depends more significantly on the associated safety and efficacy profile and on the price relative to competitive or alternative treatments and other marketing characteristics of the product than on the exclusivity afforded by the Orphan Drug Act. Additionally, these products may be protected by patents and other means.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

*Regulation of Manufacturing Process*

Even if FDA regulatory approval is obtained, a marketed product, such as JAKAFI, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on this product, manufacturer or facility, including costly recalls or withdrawal of the product from the market. Manufacturing facilities are always subject to inspection by the applicable regulatory authorities.

We and our third-party manufacturers are subject to current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the FDA and the European Medicines Agency. Similar regulations are in effect in other countries. Manufacturing facilities are subject to inspection by the applicable regulatory authorities. These facilities, whether our own or our contract manufacturers, must be approved before we can use them in commercial manufacturing of our related products. We or our contract manufacturers may not be able to comply with applicable Good Manufacturing Practices and FDA or other regulatory requirements. If we or our contract manufacturers fail to comply, we or our contract manufacturers may be subject to legal or regulatory action, such as suspension of manufacturing, seizure of product, or voluntary recall of product. Furthermore, continued compliance with applicable Good Manufacturing Practices will require continual

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expenditure of time, money and effort on the part of us or our contract manufacturers in the areas of production and quality control and record keeping and reporting, in order to ensure full compliance.

*Post-Approval Regulation*

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug and other reporting, advertising and promotion restrictions. The FDA's rules for advertising and promotion require, among other things, that we not promote our products for unapproved uses and that our promotion be fairly balanced and adequately substantiated by clinical studies. We must also submit appropriate new and supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. On its own initiative, the FDA may require changes to the labeling of an approved drug if it becomes aware of new safety information that the agency believes should be included in the approved drug's labeling. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations. The observations may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective and preventive actions in order to address the FDA's concerns.

There are a variety of state laws and regulations that apply in the states or localities where JAKAFI and our product candidates are or will be marketed. For example, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in that state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Any applicable state or local regulations may hinder our ability to market, or increase the cost of marketing, our products in those states or localities.

The FDA's policies may change and additional government regulations may be enacted which could impose additional burdens or limitations on our ability to market products after approval. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the United States or abroad.

*Marketing Exclusivity*

The FDA may grant five years of exclusivity in the United States for the approval of NDAs for new chemical entities, and three years of exclusivity for supplemental NDAs, for among other things, new indications, dosages or dosage forms of an existing drug if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the supplemental application. Additionally, six months of marketing exclusivity in the United States is available if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. The six month pediatric exclusivity is added to any existing

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patent or non-patent exclusivity period for which the drug is eligible. Orphan drug products are also eligible for pediatric exclusivity if the FDA requests and the company completes pediatric clinical trials.

*Health Law Compliance*

In addition to FDA laws and regulations, we must also comply with various federal and state laws pertaining to healthcare "fraud and abuse" which govern, among other things, our relationships with healthcare providers, and the marketing and pricing of prescription drug products. Among these laws are anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices could be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. In addition, a number of states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Many pharmaceutical and other health care companies have been investigated and prosecuted for alleged violations of these laws. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs (including Medicare and Medicaid), criminal fines, and imprisonment. Companies that have chosen to settle these alleged violations have typically paid multi-million dollar fines to the government and agreed to abide by corporate integrity agreements. Private individuals may bring similar actions.

There are also an increasing number of state laws that require manufacturers to make reports to those states on certain pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the state authorities.

*Healthcare Reform and Reimbursement and Pricing Controls*

There has been an increased focus on drug pricing in recent years in the United States. Although there are no direct government price controls over private sector purchases in the United States, there are rebates and other financial requirements for federal and state health care programs.

The Medicare Modernization Act, enacted in December 2003, established the Medicare Part D outpatient prescription drug benefit, which is provided primarily through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Affordable Care Act, requires drug manufacturers to pay 50% of the Medicare Part D coverage gap, also known as the "donut hole," on prescriptions for branded products filled when the beneficiary reaches this coverage.

The Deficit Reduction Act of 2005 resulted in changes to the way drug prices are reported to the government and the formula using such information to calculate the required Medicaid rebates. The Affordable Care Act increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the

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classes of purchasers included in the calculation, and expanded the entities eligible for discounted pricing under the federal 340B drug pricing program. Current orphan drugs are excluded from the expanded 340B hospitals eligible for discounts and the increased rebates to Medicaid on line extension and sustained release formulations.

The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) is based on the manufacturer's market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U.S. government programs. The Affordable Care Act also contains a number of provisions, including provisions governing the way that health care is financed by both governmental and private insurers, enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government health care programs and will result in the development of new programs.

The Affordable Care Act also contains new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013.

We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

Public and private health care payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. Payers may require physicians to seek approval from them before a product will be reimbursed or covered, commonly referred to as prior authorization. In particular, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare Part D coverage for oncology drugs, the Medicare Modernization Act , with certain exceptions, provides for Medicare coverage of unapproved uses of an FDA-approved drug if the unapproved use is reasonable and necessary and is supported by one or more citations in CMS-approved compendia, such as the National Comprehensive Cancer Network Drugs and Biologics Compendium.

Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on health care costs in general, and prescription drugs in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the United Kingdom which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In

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addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

**Manufacturing**

Our manufacturing strategy is to contract with third parties to manufacture the raw materials, our active pharmaceutical ingredients, or API, and finished solid dose products for clinical and commercial uses. We currently do not operate manufacturing facilities for clinical or commercial production of JAKAFI or our drug candidates. In addition, we expect for the foreseeable future to continue to rely on third parties for the manufacture of commercial supplies of the raw materials, API and finished drug product for any drugs that we successfully develop and are approved for commercial sale. In this manner, we continue to build and maintain our supply chain and quality assurance resources.

*Manufacturing of our Products*

Our supply chain for manufacturing raw materials, API and drug product ready for distribution and commercialization is a multi-step international process. Establishing and managing the supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships.

We contract with third parties to manufacture our drug candidates and products for clinical and commercial purposes, including JAKAFI. Third-party contract manufacturers, including some in China, supply us with raw materials, and contract manufacturers in the United States convert these raw materials into API or convert the API into final dosage form. For most of our drug candidates, once our raw materials are produced, we rely on one third party to manufacture the API, another to make finished drug product and a third to package and label the finished product. For ruxolitinib phosphate, the API for JAKAFI, we use and rely on multiple third-party contract manufacturers, including raw material suppliers in China and a single third-party contract manufacturer in the United States. We are currently seeking to qualify a second manufacturer for the supply of ruxolitinib phosphate, however, there is no assurance that we will be able to identify and qualify a second source of supply for ruxolitinib phosphate (or any of our other drug candidates or drug products) on a timely basis.

We also rely on third-party contract manufacturers to tablet or capsulate all of our active pharmaceutical ingredients for clinical and commercial uses. For example, we use and rely on a single third-party contract manufacturer to tablet and manufacture the finished product of JAKAFI. Under the commercial supply agreement for the manufacture of JAKAFI, we are permitted to validate a second manufacturing source of JAKAFI, however, there is no assurance that we will be able to identify and qualify a second source to tablet and manufacture the finished product of JAKAFI on a timely basis.

We may not be able to obtain sufficient quantities of any of our drug candidates, drug products, ruxolitinib phosphate, or JAKAFI if our designated manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. If any of these single source suppliers were to become unable or unwilling to supply us with API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply which could have a material adverse effect on our business.

We have established a quality assurance program intended to ensure that our third-party manufacturers and service providers produce materials and provide services, when applicable, in accordance with the FDA's current Good Manufacturing Practices and other applicable regulations.

For our future products, we will continue to establish third-party suppliers to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any product that is approved for commercial sale. If we are unable to contract for large scale manufacturing with third parties on acceptable terms for our future products or develop manufacturing capabilities internally, our ability to conduct large scale clinical trials and meet customer demand for commercial products will be adversely affected.

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*Third-party Manufacturers*

Our third-party manufacturers are independent entities, under contract with us, who are subject to their own unique operational and financial risks which are out of our control. If we or any of our third-party manufacturers fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

We believe the technology used to manufacture our products is proprietary. For products manufactured by our third-party contract manufacturers, we have licensed the necessary aspects of this manufacturing technology that we believe is proprietary to us to enable them to manufacture the products for us. We have agreements with these third-party manufacturers that are intended to restrict these manufacturers from using or revealing our technology, but we cannot be certain that these third-party manufacturers will comply with these restrictions.

While we believe there are multiple third parties capable of providing most of the materials and services we need in order to manufacture ruxolitinib phosphate and distribute JAKAFI, and that supply of materials that cannot be second-sourced can be managed with inventory planning, there is always a risk that we may underestimate demand, and that our manufacturing capacity through third-party manufacturers may not be sufficient. In addition, because of the significant lead times involved in our supply chain for ruxolitinib phosphate, we may have less flexibility to adjust our supply in response to changes in demand than if we had shorter lead times.

*Access to Supplies and Materials*

Our third party manufacturers need access to certain supplies and products to manufacture our products. If delivery of material from their suppliers were interrupted for any reason or if they are unable to purchase sufficient quantities of raw materials used to manufacture our products, they may be unable to ship certain of our products for commercial supply or to supply our product candidates in development for clinical trials. For example, currently raw materials used to manufacture ruxolitinib phosphate, the API in JAKAFI, are supplied by Chinese-based companies. As a result, an international trade dispute between China and the United States or any other actions by the Chinese government that would limit or prevent Chinese companies from supplying these materials would adversely affect our ability to manufacture and supply our products to meet market needs and have a material and adverse effect on our operating results.

**Research and Development**

Since our inception, we have made substantial investments in research and technology development. During 2011, 2010 and 2009, we incurred research and development expenses of $178.7 million, $123.9 million and $119.4 million, respectively.

**Human Resources**

As of December 31, 2011, we had 368 employees, including 234 in research and development, 83 in sales and marketing and 51 in operations support, finance and administrative positions. Of these employees, 115 employees have advanced technical degrees including 13 MDs and 99 Ph.Ds. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

**Available Information**

We were incorporated in Delaware in 1991 and our website is located at *www.incyte.com*. We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

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**Item 1A.** ***Risk Factors***

## RISKS RELATING TO OUR LEAD PRODUCT JAKAFI

**We will depend heavily on our lead product, JAKAFI (ruxolitinib). If we are unable to establish and increase sales of JAKAFI in its approved indication or to successfully obtain regulatory approval for and commercialize ruxolitinib for the treatment of additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.**

In November 2011, we received approval from the U.S. Food and Drug Administration, or FDA, to market JAKAFI in the United States for the treatment of intermediate or high-risk myelofibrosis. JAKAFI is our first product to be approved for sale in the United States. Although we have received this regulatory approval, such approval does not guarantee future revenues. The commercial success of JAKAFI and our ability to generate and maintain revenues from the sale of JAKAFI will depend on a number of factors, including:

- our ability to successfully launch commercial sales of JAKAFI in the United States for the treatment of intermediate or high-risk myelofibrosis;
- the number of patients with intermediate or high-risk myelofibrosis who are diagnosed with the disease and identified to us and the number of such patients that may be treated with JAKAFI;
- the acceptance of JAKAFI by patients and the healthcare community;
- whether physicians, patients and healthcare payors view JAKAFI as therapeutically effective and safe relative to cost and any alternative therapies;
- the ability to obtain and maintain sufficient coverage or reimbursement by third-party payors;
- the ability of our third-party manufacturers to manufacture JAKAFI in sufficient quantities with acceptable quality;
- the ability of our company and our third-party providers to provide marketing and distribution support for JAKAFI;
- the label and promotional claims allowed by the FDA;
- the maintenance of regulatory approval for the treatment of intermediate or high-risk myelofibrosis in the United States; and
- our ability to develop, obtain regulatory approval for and commercialize ruxolitinib in the United States for additional indications.

If we are not successful in commercializing sales of JAKAFI in the United States, or are significantly delayed or limited in doing so, our business may be materially harmed and we may need to delay other product candidate initiatives or even significantly curtail operations.

In addition, whether or not we receive royalties under our collaboration agreement with Novartis for sales of ruxolitinib outside of the United States will depend on the receipt of European marketing authorization and on factors similar to those listed above for jurisdictions outside of the United States.

**If we are unable to obtain, or maintain at anticipated levels, reimbursement for JAKAFI from government health administration authorities, private health insurers and other organizations, our pricing may be affected or our product sales, results of operations or**

**financial condition could be harmed.**

We may not be able to sell JAKAFI on a profitable basis or our profitability may be reduced if we are required to sell JAKAFI at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. JAKAFI is expensive and almost all patients will require some form of third party coverage to afford its cost. Our future revenues and profitability will be adversely affected if we cannot

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depend on government and other third-party payors to defray the cost of JAKAFI to the patient. If these entities refuse to provide coverage and reimbursement with respect to JAKAFI, determine to provide a lower level of coverage and reimbursement than anticipated, or reduce previously approved levels of coverage and reimbursement, then our pricing or reimbursement for JAKAFI may be affected and our product sales, results of operations or financial condition could be harmed.

Changes in pricing or the amount of reimbursement for JAKAFI may also reduce our profitability and worsen our financial condition. In the United States, there have been, and we expect there will continue to be, efforts to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs. A significant reduction in the amount of reimbursement or pricing for JAKAFI in the United States may have a material adverse effect on our business.

**We are dependent upon a limited number of specialty pharmacies for a significant portion of any revenues from JAKAFI, and the loss of, or significant reduction in sales to, any one of these specialty pharmacies could adversely affect our operations and financial condition.**

We sell JAKAFI to specialty pharmacies, which in turn dispense JAKAFI to patients in fulfillment of prescriptions. We do not promote JAKAFI to specialty pharmacies, and specialty pharmacies will not set or determine demand for JAKAFI. Our ability to successfully commercialize JAKAFI will depend, in part, on the extent to which we are able to provide adequate distribution of JAKAFI to patients. Although we have contracted with a number of specialty pharmacies, such specialty pharmacies are expected generally to carry a very limited inventory and may be reluctant to be part of our distribution network in the future if demand for the product does not increase. Further, it is possible that these specialty pharmacies could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to carry smaller volume products such as JAKAFI, or cause higher product costs, lower margins or the need to find alternative methods of distributing our product. Although we believe we can find alternative channels to distribute JAKAFI on a relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace any such specialty pharmacies. The loss of any large specialty pharmacies, a significant reduction in sales we make to specialty pharmacies, or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations and financial condition.

**If we are unable to establish and maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will not be able to successfully commercialize JAKAFI.**

We have no experience selling and marketing drug products and with pricing and obtaining adequate third-party reimbursement for drug products. Under our collaboration and license agreement with Novartis, we have retained commercialization rights to JAKAFI in the United States. We have established commercial capabilities in the United States, but cannot guarantee that we will be able to maintain our own capabilities or enter into and maintain any marketing, distribution or third-party logistics agreements with third-party providers on acceptable terms, if at all. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell JAKAFI. Establishing and maintaining sales, marketing and distribution capabilities are expensive and time-consuming. Competition for personnel with experience in sales and marketing can be high. Our expenses associated with building up and maintaining the sales force and distribution capabilities may be disproportional compared to the revenues we may be able to generate on sales of JAKAFI. We cannot guarantee that we will be successful in commercializing JAKAFI.

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**Our reliance on other parties to manufacture JAKAFI could result in a short supply of JAKAFI, increased costs, and withdrawal of regulatory approval.**

We do not currently operate manufacturing facilities for commercial production of JAKAFI. Accordingly, we will be subject to the risks described below under " Other Risks Relating to Our Business Our reliance on other parties to manufacture our drug candidates could result in a short supply of the drugs, delays in clinical trials or drug development, increased costs, and withdrawal or denial of a regulatory authority's approval."

**If we fail to comply with continuing regulations, we could lose our approval to market JAKAFI or be subject to other governmental enforcement activity.**

We cannot guarantee that we will be able to maintain regulatory approval to market JAKAFI in the United States. If we do not maintain our regulatory approval to market JAKAFI, our results of operations will be materially harmed. We and our current collaborators, third-party manufacturers and suppliers are subject to rigorous and extensive regulation by the FDA and other federal and state agencies. These regulations continue to apply after product marketing approval, and cover, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, risk mitigation, and adverse event reporting requirements.

Our commercialization of JAKAFI will be subject to post-regulatory approval surveillance, and JAKAFI may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing for JAKAFI, and JAKAFI may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity.

Failure to comply with the laws and requirements, including statutes and regulations, administered by the FDA or other agencies could result in:

- administrative and judicial sanctions, including, warning letters;
- fines and other civil penalties;
- withdrawal of regulatory approval to market JAKAFI;
- interruption of production;
- operating restrictions;
- product recall or seizure;
- injunctions; and
- criminal prosecution.

The occurrence of any such event may have a material adverse effect on our business.

**If the use of JAKAFI harms patients, or is perceived to harm patients even when such harm is unrelated to JAKAFI, our regulatory approval could be revoked or otherwise negatively impacted or we could be subject to costly and damaging product liability claims.**

The testing of JAKAFI and the manufacturing, marketing and sale of JAKAFI expose us to product liability and other risks. Side effects and other problems experienced by patients from the use of JAKAFI could:

lessen the frequency with which physicians decide to prescribe JAKAFI;

encourage physicians to stop prescribing JAKAFI to their patients who previously had been prescribed JAKAFI;

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cause serious harm to patients that may give rise to product liability claims against us; and

result in our need to withdraw or recall JAKAFI from the marketplace.

If JAKAFI is used by a wide patient population, new risks and side effects may be discovered, the rate of known risks or side effects may increase, and risks previously viewed as less significant could be determined to be significant.

Previously unknown risks and adverse effects of JAKAFI may also be discovered in connection with unapproved, or off-label, uses of JAKAFI. We are prohibited by law from promoting or in any way supporting or encouraging the promotion of JAKAFI for off-label uses, but physicians are permitted to use products for off-label purposes. In addition, we are studying and expect to continue to study JAKAFI in diseases other than intermediate or high-risk myelofibrosis in controlled clinical settings, and independent investigators are doing so as well. In the event of any new risks or adverse effects discovered as new patients are treated for intermediate or high-risk myelofibrosis and as JAKAFI is studied in or used by patients for off-label indications, regulatory authorities may delay or revoke their approvals, we may be required to conduct additional clinical trials, make changes in labeling of JAKAFI, reformulate JAKAFI or make changes and obtain new approvals. We may also experience a significant drop in the potential sales of JAKAFI, experience harm to our reputation and the reputation of JAKAFI in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of JAKAFI or substantially increase the costs and expenses of commercializing and marketing JAKAFI.

Patients who have been enrolled in our clinical trials or who may use JAKAFI in the future often have severe and advanced stages of disease and known as well as unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to JAKAFI. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market JAKAFI, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to JAKAFI, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay the regulatory approval process for our collaborator Novartis in other countries, or impact and limit the type of regulatory approvals JAKAFI receives or maintains.

**If we market JAKAFI in a manner that violates various federal and state health care related laws and regulations, we may be subject to civil or criminal penalties.**

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally- or state-financed health care programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for off-label uses that the FDA has not approved that caused claims to be submitted to federally-financed health care programs for non-covered off-label uses; providing financial remuneration to health care providers to induce them to prescribe certain pharmaceutical products, claims for which are then submitted to federally-financed health care

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programs for reimbursement; and submitting inflated best price information to the Medicaid Rebate Program.

Although physicians are permitted, based on their medical judgment, to prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market JAKAFI for intermediate or high-risk myelofibrosis and provide promotional materials to physicians regarding the use of JAKAFI for this indication. Although we believe that our marketing materials for physicians do not constitute off-label promotion of JAKAFI, the FDA may disagree. If the FDA determines that our promotional materials or other activities constitute off-label promotion of JAKAFI, it could request that we modify our promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our position and have to divert significant management resources from other matters.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In recent years, several states and localities, including California, Connecticut, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Texas, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Additionally, as part of the Patient Protection and Affordable Care Act, the federal government has enacted the Physician Payment Sunshine provisions. Beginning in 2013, the Sunshine provisions require manufacturers to publicly report any gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity. See also " Other Risks Relating to our Business If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business" below.

## OTHER RISKS RELATING TO OUR BUSINESS

**We are building our drug discovery, development and commercialization operations and we may be unsuccessful in our efforts.**

Except for JAKAFI for the treatment of intermediate or high-risk myelofibrosis in the United States, none of our drug candidates has received regulatory approval. We are building our drug discovery, development and commercialization operations. Our ability to discover, develop and commercialize pharmaceutical products will depend on our ability to:

- hire and retain key scientific employees;
- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally or license drug candidates from others;

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identify and enroll suitable human subjects, either in the United States or abroad, for our clinical trials;

complete laboratory testing and clinical trials on humans;

obtain and maintain necessary intellectual property rights to our products;

obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;

enter into arrangements with third parties to provide services or to manufacture our products on our behalf;

deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions in compliance with all applicable laws;

obtain appropriate coverage and reimbursement levels for the cost of our products from governmental authorities, private health insurers and other third party payors;

lease facilities at reasonable rates to support our growth; and

enter into arrangements with third parties to license and commercialize our products.

We have limited experience with the activities listed above and may not be successful in discovering, developing, or commercializing drug products.

**We depend heavily on the success of our most advanced product candidates. We might not be able to commercialize any of our drug candidates successfully, and we may spend significant time and money attempting to do so.**

We have invested significant resources in the development of our most advanced product candidates. In addition to the recent commercial launch of JAKAFI for the treatment of intermediate or high-risk myelofibrosis, ruxolitinib is also in a Phase III clinical trial for the treatment of polycythemia vera. Further, we have a number of drug candidates in Phase I and Phase II clinical trials. Our ability to generate product revenues will depend on the successful development and eventual commercialization of our most advanced product candidates. We, or our collaborators or licensees, may decide to discontinue development of any or all of our drug candidates at any time for commercial, scientific or other reasons. For example, in March 2008, we announced that we would not advance our lead CCR5 antagonist into Phase IIb trials and, in September 2011, we announced that we had discontinued development of our lead sheddase inhibitor, INCB7839, for the treatment of breast cancer. If a product is developed, but is not marketed, we may have spent significant amounts of time and money on it, which could adversely affect our operating results and financial condition.

**Our efforts to discover and develop potential drug candidates may not lead to the discovery, development, commercialization or marketing of drug products.**

JAKAFI is our only drug candidate that has, to date, received regulatory approval for sale in the United States. Discovery and development of potential drug candidates are expensive and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. If our efforts do not lead to the discovery of a suitable drug candidate, we may be unable to grow our clinical pipeline or we may be unable to enter into agreements with collaborators who are willing to develop our drug candidates. Of the compounds that we identify as potential drug products or that we in-license from other companies, only a few, if any, are likely to lead to successful drug development programs. We have also licensed to other parties certain rights to our JAK1 and JAK2 inhibitor compounds and c-MET inhibitor compounds and our portfolio of CCR2 antagonist compounds. We have no or limited control over the further clinical development of these compounds.

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**The success of our drug discovery and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful in the development and commercialization of our compounds, our research, development and commercialization efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.**

An important element of our business strategy is to enter into collaborative or license arrangements with other parties, such as our collaborations with Novartis and Lilly for our JAK inhibitors, under which we license our drug candidates to those parties for development and commercialization. We are evaluating strategic relationships with respect to several of our other programs and may enter into an agreement with respect to one or more of these programs in the future. However, these arrangements and negotiations are complex and time consuming and there can be no assurance that we will reach agreement with a collaborator or licensee with respect to any of these programs.

Because collaboration and license arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. Also, we may not have drug compounds that are desirable to other parties, or we may be unwilling to license a drug compound because the party interested in it is a competitor. The terms of any such arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are not able to establish collaborative or license arrangements, we may not be able to develop and commercialize a drug product, which would adversely affect our business and our revenues.

In order for any of these collaboration or license arrangements to be successful, we must first identify potential collaborators or licensees whose capabilities complement and integrate well with ours. We may rely on these arrangements for not only financial resources, but also for expertise or economies of scale that we expect to need in the future relating to clinical trials, manufacturing, sales and marketing, and for licenses to technology rights. However, it is likely that we will not be able to control the amount and timing of resources that our collaborators or licensees devote to our programs or potential products. If our collaborators or licensees prove difficult to work with, are less skilled than we originally expected, do not devote adequate resources to the program, or do not agree with our approach to development or manufacturing of the potential product, the relationship could be unsuccessful. If a business combination involving a collaborator or licensees and a third party were to occur, the effect could be to diminish, terminate or cause delays in development of a potential product.

**Conflicts may arise between our collaborators and licensees and us, or our collaborators and licensees may choose to terminate their agreements with us, which may adversely affect our business.**

Conflicts may arise with our collaborators and licensees if they pursue alternative technologies or develop alternative products either on their own or in collaboration with others as a means for developing treatments for the diseases that we have targeted. Competing products and product opportunities may lead our collaborators and licensees to withdraw their support for our product candidates. Any failure of our collaborators and licensees to perform their obligations under our agreements with them could negatively impact the development of our compounds and product candidates, lead to our loss of potential revenues from product sales and milestones and delay our achievement, if any, of profitability. Additionally, conflicts may arise if there is a dispute about the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of a collaborative relationship.

Our existing collaborative and license agreements can be terminated by our collaborators and licensees for convenience, among other circumstances. If any of our collaborators or licensees terminates its agreement with us, or terminates its rights with respect to certain indications or compounds, we may not be able to find a new collaborator for them, and our business could be adversely affected. Should an agreement be terminated before we have realized the benefits of the collaboration or license, our reputation could be harmed, we may not obtain revenues that we anticipated receiving, and our business could be adversely affected.

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**Although we obtained a special protocol assessment agreement for ruxolitinib for polycythemia vera, a special protocol assessment agreement does not guarantee any particular outcome from regulatory review, including any regulatory approval.**

We have obtained a special protocol assessment, or SPA, agreement for the registration trial for ruxolitinib for the treatment of polycythemia vera in the United States. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of an NDA, and provides a product sponsor with an agreement confirming that the design and size of a trial will be appropriate to form the primary basis of an efficacy claim for an NDA if the trial is performed according to the SPA. Even if we believe that the data from a clinical trial are supportive, an SPA is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, a trial will be adequate to demonstrate safety and efficacy, or otherwise be sufficient to support regulatory approval. There can be no assurance that the terms of an SPA will ultimately be binding on the FDA, and the FDA is not obligated to approve an NDA, if any, even if the clinical outcome is positive. The FDA retains significant latitude and discretion in interpreting the terms of an SPA and the data and results from a clinical trial, and can require trial design changes or additional studies if issues arise essential to determining safety or efficacy. Data may subsequently become available that causes the FDA to reconsider the previously agreed upon scope of review and the FDA may have subsequent safety or efficacy concerns that override an SPA, and we can give no assurance that as clinical trials proceed or as part of an NDA review process, if any, the FDA will determine that a previously approved SPA is still valid.

Additionally, an SPA may be changed only with written agreement of the FDA and sponsor, and any further changes we may propose to the protocol will remain subject to the FDA's approval. The FDA may not agree to any such amendment and, even if they agree, they may request other amendments to the trial design that could require additional cost and time, as well as increase the degree of difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to support an efficacy claim and product approval.

**Even if a drug candidate that we develop receives regulatory approval, we may decide not to commercialize it if we determine that commercialization of that product would require more money and time than we are willing to invest.**

Even if any of our drug candidates receives regulatory approval, it would be subject to post-regulatory surveillance, and may have to be withdrawn from the market or subject to restrictions if previously unknown problems occur. Regulatory agencies may also require additional clinical trials or testing, and the drug product may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. As a result, we may not continue to commercialize a product even though it has obtained regulatory approval. Further, we may decide not to continue to commercialize a product if the market does not accept the product because it is too expensive or because third parties such as insurance companies or Medicare have not approved it for substantial reimbursement. In addition, we may decide not to continue to commercialize a product if another product comes on the market that is as effective but has fewer side effects. There is also a risk that competitors may develop similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

**We may not be able to successfully commercialize any drug candidates that obtain regulatory approval if we do not establish third-party relationships for the commercialization of those drug candidates, and any revenues we receive from any approved drugs could be dependent on those relationships.**

We have granted commercialization rights to other pharmaceutical companies with respect to certain of our drug candidates in specific geographic locations, and intend to seek other collaborative or licensing arrangements with respect to other of our drug candidates. To the extent that our collaborators have commercial rights to our drug candidates, any revenues we receive from any approved drugs will depend primarily on the sales and marketing efforts of others. We do not know whether we will be able to enter into additional third-party sales and marketing arrangements with respect to any of our other drug candidates on acceptable terms, if at all.

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**If we fail to enter into additional licensing agreements or if these arrangements are unsuccessful, our business and operations might be adversely affected.**

In addition to establishing collaborative or license arrangements under which other parties license our drug candidates for development and commercialization, we may explore opportunities to develop our clinical pipeline by in-licensing drug compounds that fit within our expertise and research and development capabilities. We may be unable to enter into any additional in-licensing agreements because suitable product candidates that are within our expertise may not be available to us on terms that are acceptable to us or because competitors with greater resources seek to in-license the same product candidates. Product candidates that we would like to develop may not be available to us because they are controlled by competitors who are unwilling to license the rights to the drug compound or candidate to us. In addition, we may enter into license agreements that are unsuccessful and our business and operations might be adversely affected by the termination of a drug candidate and termination and winding down of the related license agreement. We may also need to license drug delivery or other technology in order to continue to develop our drug candidate pipeline. If we are unable to enter into additional agreements to license drug candidates, drug delivery technology or other technology or if these arrangements are unsuccessful, our research and development efforts could be adversely affected.

**Any drug products that we bring to the market, even if they receive marketing approval, may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community.**

Even if we are successful in gaining regulatory approval of any of our product candidates in addition to JAKAFI for the treatment of intermediate or high-risk myelofibrosis in the United States, we may not generate significant product revenues and we may not become profitable if these drug products do not achieve an adequate level of acceptance. Physicians may not recommend our drug products until clinical data or other factors demonstrate the safety and efficacy of our drug products as compared to other alternative treatments. Even if the clinical safety and efficacy of our drug products is established, physicians may elect not to prescribe these drug products for a variety of reasons, including the reimbursement policies of government and other third-party payors and the effectiveness of our competitors in marketing their products.

Market acceptance of our drug products, if approved for commercial sale, will depend on a number of factors, including:

- the willingness and ability of patients and the healthcare community to use our products;
- the ability to manufacture our drug products in sufficient quantities with acceptable quality and to offer our drug products for sale at competitive prices;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of our drug products compared to those of competing products or therapies;
- the label and promotional claims allowed by the FDA;
- the pricing and reimbursement of our drug products relative to existing treatments; and
- marketing and distribution support for our drug products.

**We have limited expertise with and capacity to conduct preclinical testing and clinical trials, and our resulting dependence on other parties could result in delays in and additional costs for our drug development efforts.**

We have limited experience with clinical trials, formulation, manufacturing and commercialization of drug products. We also have limited internal resources and capacity to perform preclinical testing and clinical trials. As part of our development strategy, we intend to hire clinical research organizations, or

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CROs, to perform preclinical testing and clinical trials for drug candidates. If the CROs that we hire to perform our preclinical testing and clinical trials or our collaborators or licensees do not meet deadlines, do not follow proper procedures, or a conflict arises between us and our CROs, our preclinical testing and clinical trials may take longer than expected, may be delayed or may be terminated. If we were forced to find a replacement entity to perform any of our preclinical testing or clinical trials, we may not be able to find a suitable entity on favorable terms, or at all. Even if we were able to find another company to perform a preclinical test or clinical trial, the delay in the test or trial may result in significant additional expenditures. Events such as these may result in delays in our obtaining regulatory approval for our drug candidates or our ability to commercialize our products and could result in increased expenditures that would adversely affect our operating results.

In addition, for some of our drug candidates, we have contracted with collaborators to advance those candidates through later-stage, more expensive clinical trials, rather than invest our own resources to perform these clinical trials. Under the terms of our agreements with these collaborators, we have no or limited control over the conduct of these clinical trials, and in any event we are subject to the risks associated with depending on collaborators to develop these drug candidates.

**If we are unable to obtain regulatory approval to develop and market products in the United States and foreign jurisdictions, we will not be permitted to manufacture or commercialize products resulting from our research.**

In order to manufacture and commercialize drug products in the United States, our drug candidates will have to obtain regulatory approval from the FDA. Satisfaction of regulatory requirements typically takes many years. To obtain regulatory approval, we must first show that our drug products are safe and effective for target indications through preclinical testing (animal testing) and clinical trials (human testing). Preclinical testing and clinical development are long, expensive and uncertain processes, and we do not know whether the FDA will allow us to undertake clinical trials of any potential drug products in addition to our compounds currently in clinical trials.

Completion of clinical trials may take several years and failure may occur at any stage of testing. The length of time required varies substantially according to the type, complexity, novelty and intended use of the product candidate. Interim results of a preclinical test or clinical trial do not necessarily predict final results, and acceptable results in early clinical trials may not be repeated in later clinical trials. For example, a drug candidate that is successful at the preclinical level may cause harmful or dangerous side effects when tested at the clinical level. Our rate of commencement and completion of clinical trials may be delayed by many factors, including:

- the high degree of risk associated with drug development;
- our inability to formulate or manufacture sufficient quantities of materials for use in clinical trials;
- variability in the number and types of patients available for each study;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- poor or unanticipated effectiveness of drug candidates during the clinical trials; or
- government or regulatory delays.

Data obtained from clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier clinical trials. In addition, regulatory authorities may refuse or delay approval as a result of other factors, such as changes in regulatory policy during the period of product development

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and regulatory agency review. For example, the FDA has in the past required and could in the future require that we conduct additional trials of any of our product candidates, which would result in delays.

Although we received regulatory approval to market JAKAFI for the treatment of intermediate or high-risk myelofibrosis in the United States, we cannot predict whether or when regulatory approval will be obtained for any other drug product we develop. We have licensed to Novartis rights to ruxolitinib in certain indications outside of the United States and worldwide rights to c-MET and licensed to Lilly worldwide rights to LY3009104. We have also licensed to Pfizer our portfolio of CCR2 antagonist compounds. We have no or limited control over the further clinical development of any compounds we licensed to these collaborators. Compounds developed by us, alone or with other parties, may not prove to be safe and effective in clinical trials and may not meet all of the applicable regulatory requirements needed to receive marketing approval. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective. Failure to obtain regulatory approval would delay or prevent us from commercializing products.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks associated with the FDA approval process described above and may also include additional risks. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require us to perform additional testing and expend additional resources. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA.

**We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.**

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our drug discovery and development efforts may target diseases and conditions that are already subject to existing therapies or that are being developed by our competitors, many of which have substantially greater resources, larger research and development staffs and facilities, more experience in completing preclinical testing and clinical trials, and formulation, marketing and manufacturing capabilities. As a result of these resources, our competitors may develop drug products that render our products obsolete or noncompetitive by developing more effective drugs or by developing their products more efficiently. Our ability to develop competitive products would be limited if our competitors succeeded in obtaining regulatory approvals for drug candidates more rapidly than we were able to or in obtaining patent protection or other intellectual property rights that limited our drug development efforts. Any drugs resulting from our research and development efforts, or from our joint efforts with collaborators or licensees, might not be able to compete successfully with our competitors' existing and future products, or obtain regulatory approval in the United States or elsewhere.

**Our reliance on other parties to manufacture our drug candidates could result in a short supply of the drugs, delays in clinical trials or drug development, increased costs, and withdrawal or denial of a regulatory authority's approval.**

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates. We currently rely on third parties for the manufacture of the raw materials, the API and finished drug product of JAKAFI and our other drug candidates for clinical trials. In addition, we expect to continue to rely on third parties for the manufacture of commercial supplies of raw materials, API and finished drug product for any drugs that we successfully develop. For JAKAFI and most of our drug candidates, we rely on third parties to manufacture the raw materials, another third party to manufacture the API and another to make the finished drug product and to package and label the finished product. The

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FDA requires that the raw materials, API and finished product for each of our drug products be manufactured according to its current Good Manufacturing Practices regulations and regulatory authorities in other countries have similar requirements. There are only a limited number of manufacturers that comply with these requirements. If the third parties that manufacture our drug candidates are not compliant with the applicable regulatory requirements, the FDA or a foreign regulatory authority may require us to halt ongoing clinical trials or not approve our application to market our drug products. Failure to comply with current Good Manufacturing Practices and the applicable regulatory requirements of other countries in the manufacture of our products could result in the FDA or foreign regulatory authority halting our clinical trials, withdrawing or denying regulatory approval of our drug product, enforcing product recalls or other enforcement actions, which could have a material adverse effect on our business.

We may not be able to obtain sufficient quantities of our drug candidates or any drug products we may develop if our designated manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. In addition, we may not be able to arrange for our drug candidates or any drug products that we may develop to be manufactured by one of these parties on reasonable terms, if at all. Also, raw materials that may be required to manufacture any products we develop may only be available from a limited number of suppliers and, in the case of JAKAFI, are currently supplied by a single source. As noted above, generally, we have only single sources that are qualified to supply each of the API and finished product of JAKAFI and our other drug candidates. If any of these single source suppliers were to become unable or unwilling to supply us with raw materials, API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply that could have a material adverse effect on our business. We are currently seeking to qualify a second source of supply for the API for JAKAFI, however, there is no assurance that we will be able to identify and qualify a second source of supply for JAKAFI. If we have promised delivery of a drug candidate or drug product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs could be delayed, we may have to expend additional sums in order to ensure that manufacturing capacity is available when we need it even if we do not use all of the manufacturing capacity, and our business and operating results could be harmed.

Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations.

In order to obtain approval of our products, by the FDA and foreign regulatory agencies, we need to complete testing on both the API and on the finished product in the packaging we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, we will be required to consistently produce the API in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation.

We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. Foreign manufacturing approval processes typically include all of the risks associated with the FDA approval process for manufacturing and may also include additional risks.

**If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business.**

Our activities, and the activities of our collaborators, partners and third party providers, are subject to extensive government regulation and oversight both in the United States and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business

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activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. States increasingly have been placing greater restrictions on the marketing practices of healthcare companies. In addition, pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state healthcare business, submission of false claims for government reimbursement, antitrust violations, or violations related to environmental matters. Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

**Health care reform measures could impact the pricing and profitability of pharmaceuticals, and adversely affect the commercial viability of our drug candidates. Our ability to generate revenues will be diminished if we are unable to obtain an adequate level of reimbursement from private insurers, government insurance programs or other third-party payors of health care costs, which could be affected by recent healthcare reform legislation.**

Our ability to commercialize our drug candidates successfully will depend in part on the extent to which adequate reimbursement levels for the cost of our products and related treatment are obtained from third-party payors, such as private insurers, government insurance programs, including Medicare and Medicaid, health maintenance organizations (HMOs) and other health care related organizations. The continuing efforts of these third-party payors to contain or reduce the costs of health care by challenging the prices charged for medical products and services may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers, collaborators and licensees and the availability of capital.

In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. These reforms could significantly reduce payments from Medicare and Medicaid. Reforms or other changes to these payment systems, may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payors for our drug candidates. Some of these changes and proposed changes could result in reduced reimbursement rates, which could reduce the price that we or any of our collaborators or licensees receive for any products, if commercialized, in the future, and which would adversely affect our business strategy, operations and financial results. Further federal and state proposals and health care reforms are possible, which could limit the prices that can be charged for any of our drug candidates and may further limit the commercial viability of our drug candidates. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. If reimbursement for our products, if commercialized, is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. There may be future changes that result in reductions in current coverage and reimbursement levels for our drug candidates, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care

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services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. Adoption of our drug candidates by the medical community may be limited without adequate reimbursement for our products. Cost control initiatives may decrease coverage and payment levels for our drug candidates and, in turn, the price that we will be able to charge for any product, if commercialized. Our drug candidates may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors to our drug candidates.

The cost containment measures that health care payors and providers are instituting and any denial of private or government payor coverage or inadequate reimbursement for our drug candidates could materially and adversely affect our business strategy, operations and financial results.

**As our drug discovery and development operations are conducted at our headquarters in Wilmington, Delaware, the loss of access to this facility would negatively impact our business.**

Our facility in Wilmington, Delaware is our headquarters and is also where we conduct all of our drug discovery operations and research and development activities. Our lease contains provisions that provide for its early termination upon the occurrence of certain events of default or upon a change of control. Further, our headquarters facility is located in a large research and development complex that may be temporarily or permanently shut down if certain environmental or other hazardous conditions were to occur within the complex. In addition, actions of activists opposed to aspects of pharmaceutical research may disrupt our experiments or our ability to access or use our facilities. The loss of access to or use of our Wilmington, Delaware, facility, either on a temporary or permanent basis, or early termination of our lease would result in an interruption of our business and, consequently, would adversely affect the advancement of our drug discovery and development programs and our overall business.

**We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees or our inability to attract and retain additional personnel would affect our ability to expand our drug discovery and development programs and achieve our objectives.**

We are highly dependent on the principal members of our management, operations and scientific staff. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials, for the establishment of collaborations with other companies and for our marketing, medical, and operational infrastructure to support commercialization marketing efforts. If we lose the services of any of these people or if we are unable to recruit sufficient qualified personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed. We do not maintain "key person" insurance on any of our employees.

**If we fail to manage our growth effectively, our ability to develop and commercialize products could suffer.**

We expect that if our clinical drug candidates continue to progress in development, we continue to build our development, medical and marketing organizations and our drug discovery efforts continue to generate drug candidates, we will require significant additional investment in personnel, management and resources. Our ability to commercialize our drug candidates and to achieve our research and development objectives depends on our ability to respond effectively to these demands and expand our internal organization, systems and controls to accommodate additional anticipated growth. If we are unable to manage our growth effectively, our business could be harmed and our ability to execute our business strategy could suffer.

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**If product liability lawsuits are brought against us, we could face substantial liabilities and may be required to limit commercialization of our products and our results of operations could be harmed.**

The clinical trials and marketing of medical products that are intended for human use entails an inherent risk of product liability. If any product that we or any of our collaborators or licensees develops causes or is alleged to cause injury or is found to be unsuitable during clinical trials, manufacturing or sale, we may be held liable. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities, including substantial damages to be paid to the plaintiffs and legal costs, or we may be required to limit commercialization of our products. Our product liability insurance policy that provides coverage for liabilities arising from our clinical trials may not fully cover our potential liabilities. In addition, we may determine that we should increase our coverage upon the undertaking of new clinical trials, and this insurance may be prohibitively expensive to us or our collaborators or licensees and may not fully cover our potential liabilities. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with our collaborators. Additionally, any product liability lawsuit could cause injury to our reputation, recall of products, participants to withdraw from clinical trials, and potential collaborators or licensees to seek other partners, any of which could impact our results of operations.

**Because our activities involve the use of hazardous materials, we may be subject to claims relating to improper handling, storage or disposal of these materials that could be time consuming and costly.**

We are subject to various environmental, health and safety laws and regulations governing, among other things, the use, handling, storage and disposal of regulated substances and the health and safety of our employees. Our research and development processes involve the controlled use of hazardous and radioactive materials and biological waste resulting in the production of hazardous waste products. We cannot completely eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. If any injury or contamination results from our use or the use by our collaborators or licensees of these materials, we may be sued and our liability may exceed our insurance coverage and our total assets. Further, we may be required to indemnify our collaborators or licensees against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations or licenses. Compliance with the applicable environmental and workplace laws and regulations is expensive. Future changes to environmental, health, workplace and safety laws could cause us to incur additional expense or may restrict our operations or impair our research, development and production efforts.

## RISKS RELATING TO OUR FINANCIAL RESULTS

**We expect to incur losses in the future and we may not achieve or maintain profitability in the future.**

We had net losses from inception in 1991 through 1996 and in 1999 through 2011. Because of those losses, we had an accumulated deficit of $1.6 billion as of December 31, 2011. We intend to continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we could continue to incur losses in 2012 and in future periods as well.

We anticipate that our drug discovery and development efforts and related expenditures will increase as we focus on the studies, including preclinical tests and clinical trials prior to seeking regulatory approval, that are required before we can sell a drug product.

The development of drug products will require us to spend significant funds on research, development, testing, obtaining regulatory approvals, manufacturing and marketing. To date, we do not have any drug products that have generated significant revenues and we cannot assure you that we will generate significant revenues from the drug candidates that we license or develop, including JAKAFI, for several years, if ever.

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We cannot be certain whether or when we will achieve profitability because of the significant uncertainties relating to our ability to generate commercially successful drug products. Even if we were successful in obtaining regulatory approvals for manufacturing and commercializing a drug candidate, we expect that we will continue to incur losses if our drug products do not generate significant revenues. If we achieve profitability, we may not be able to sustain or increase profitability.

**We will need additional capital in the future. If we are unable to generate sufficient funds from operations, the capital markets may not permit us to raise additional capital at the time that we require it, which could result in limitations on our research and development or commercialization efforts or the loss of certain of our rights in our technologies or drug candidates.**

Our future funding requirements will depend on many factors and we anticipate that we may need to raise additional capital to fund our business plan and research and development efforts going-forward and to repay our indebtedness.

Additional factors that may affect our future funding requirements include:

- the amount of revenues generated from our business activities;
- any changes in the breadth of our research and development programs;
- the results of research and development, preclinical testing and clinical trials conducted by us or our future collaborators or licensees, if any;
- our exercise of any co-development options with collaborators that may require us to fund future development;
- the acquisition of technologies, if any;
- our ability to maintain and establish new corporate relationships and research collaborations;
- competing technological and market developments;
- the time and costs involved in filing, prosecuting, defending and enforcing patent and intellectual property claims;
- the receipt of contingent licensing or milestone fees or royalties on product sales from our current or future collaborative and license arrangements, if established; and
- the timing of regulatory approvals, if any.

If we require additional capital at a time when investment in companies such as ours, or in the marketplace generally, is limited due to the then prevailing market or other conditions, we may have to scale back our operations, eliminate one or more of our research or development programs, or attempt to obtain funds by entering into an agreement with a collaborator or licensee that would result in terms that are not favorable to us or relinquishing our rights in certain of our proprietary technologies or drug candidates. If we are unable to raise funds at the time that we desire or at any time thereafter on acceptable terms, we may not be able to continue to develop our potential drug products. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders, and debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness.

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**We have a large amount of debt and our debt service obligations may prevent us from taking actions that we would otherwise consider to be in our best interests.**

As of December 31, 2011, the aggregate principal amount of our total consolidated debt was $420.0 million and our stockholders' deficit was $227.1 million. Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing for working capital, capital and research and development expenditures, and general corporate purposes;
- requiring the dedication of a substantial portion of our expected cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes, including working capital, capital expenditures and research and development expenditures;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or
- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources.

We may not generate sufficient cash flow from our operations in the future to enable us to meet our anticipated fixed charges, including our obligations with respect to our outstanding convertible senior notes. As of December 31, 2011, $20.0 million aggregate principal amount of the non-interest bearing convertible subordinated notes held by Pfizer was outstanding, of which $10.0 million is due in 2013 and $10.0 million is due in 2014. As of December 31, 2011, $400.0 million aggregate principal amount of our 4.75% convertible senior notes due 2015 was outstanding and due in October 2015. Annual interest payments for our 4.75% convertible senior notes through 2015, assuming that none of these notes are converted, repurchased or exchanged, are $19.0 million. Funds sufficient to pay interest payments through October 2012 on our 4.75% convertible senior notes are held in an escrow account as security for these interest payments. If we are unable to generate cash from our operations or raise additional cash through financings sufficient to meet the remaining obligations under our 4.75% convertible senior notes or under our notes held by Pfizer, we will need to use existing cash or liquidate marketable securities in order to fund these obligations, which may delay or curtail our research, development and commercialization programs.

The indenture governing our 4.75% convertible senior notes includes limitations on our ability to incur additional indebtedness, issue certain preferred stock, and incur liens on our assets, including on intellectual property concerning our JAK inhibitor program. These limitations could interfere with our ability to raise additional capital in the future or engage in activities that may be in our long-term best interest.

**Our marketable securities are subject to certain risks that could adversely affect our overall financial position.**

We invest our cash in accordance with an established internal policy and customarily in instruments and money market funds which historically have been highly liquid and carried relatively low risk. Recently similar types of investments and money market funds have experienced losses in value or liquidity issues which differ from their historical pattern.

Should a portion of our cash or marketable securities lose value or have their liquidity impaired, it could adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing, if available, may not be available on commercially attractive terms.

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**Our current revenues are derived from JAKAFI product sales, collaborations and from licensing our intellectual property. If we are unable to achieve milestones, develop products or renew or enter into new collaborations, our revenues may decrease, and future milestone and royalty payments may not contribute significantly to revenues for several years, and may never result in revenues.**

We derived all of our revenues for the year ended December 31, 2011 from JAKAFI product sales, our collaborations and licensing our intellectual property to others. Future revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from our research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the future revenues contemplated under our collaborative agreements.

## RISKS RELATING TO INTELLECTUAL PROPERTY AND LEGAL MATTERS

**If we are subject to arbitration, litigation and infringement claims, they could be costly and disrupt our drug discovery and development efforts.**

The technology that we use to make and develop our drug products, the technology that we incorporate in our products, and the products we are developing may be subject to claims that they infringe the patents or proprietary rights of others. The success of our drug discovery and development efforts will also depend on our ability to develop new compounds, drugs and technologies without infringing or misappropriating the proprietary rights of others. We are aware of patents and patent applications filed in certain countries claiming intellectual property relating to some of our drug discovery targets and product candidates. While the validity of issued patents, patentability of pending patent applications and applicability of any of them to our programs are uncertain, if any of these patents are asserted against us or if we choose to license any of these patents, our ability to commercialize our products could be harmed or the potential return to us from any product that may be successfully commercialized could be diminished.

From time to time we have received, and we may in the future receive, notices from third parties offering licenses to technology or alleging patent, trademark, or copyright infringement, claims regarding trade secrets or other contract claims. Receipt of these notices could result in significant costs as a result of the diversion of the attention of management from our drug discovery and development efforts. Parties sending these notices may have brought and in the future may bring litigation against us or seek arbitration relating to contract claims.

We may be involved in future lawsuits or other legal proceedings alleging patent infringement or other intellectual property rights or contract violations. In addition, litigation or other legal proceedings may be necessary to:

assert claims of infringement;

enforce our patents or trademarks;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

We may be unsuccessful in defending or pursuing these lawsuits, claims or other legal proceedings. Regardless of the outcome, litigation or other legal proceedings can be very costly and can divert management's efforts. For example, we settled patent litigation with Invitrogen Corporation in 2006. We incurred significant expenses related to this litigation and, as part of the settlement, paid Invitrogen $3.4 million. An adverse determination may subject us to significant liabilities or require us or our collaborators or licensees to seek licenses to other parties' patents or proprietary rights. We or our collaborators or licensees may also be restricted or prevented from manufacturing or selling a drug or other product that we or they develop. Further, we or our future collaborators or licensees may not be able

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to obtain any necessary licenses on acceptable terms, if at all. If we are unable to develop non-infringing technology or license technology on a timely basis or on reasonable terms, our business could be harmed.

**We may be unable to adequately protect or enforce our proprietary information, which may result in its unauthorized use, a loss of revenue under a collaboration agreement or loss of sales to generic versions of our products or otherwise reduce our ability to compete in developing and commercializing products.**

Our business and competitive position depends in significant part upon our ability to protect our proprietary technology, including any drug products that we create. Despite our efforts to protect this information, unauthorized parties may attempt to obtain and use information that we regard as proprietary. For example, one of our collaborators may disclose proprietary information pertaining to our drug discovery efforts. In addition, while we have filed numerous patent applications with respect to our product candidates in the United States and in foreign countries, our patent applications may fail to result in issued patents. In addition, because patent applications can take several years to issue as patents, there may be pending patent applications of others that may later issue as patents that cover some aspect of our drug candidates. Our existing patents and any future patents we may obtain may not be broad enough to protect our products or all of the potential uses of our products, or otherwise prevent others from developing competing products or technologies. In addition, our patents may be challenged and invalidated or may fail to provide us with any competitive advantages if, for example, others were first to invent or first to file a patent application for the technologies and products covered by our patents.

Additionally, when we do not control the prosecution, maintenance and enforcement of certain important intellectual property, such as a drug compound in-licensed to us or subject to a collaboration with a third party, the protection of the intellectual property rights may not be in our hands. If we do not control the intellectual property rights in-licensed to us with respect to a compound and the entity that controls the intellectual property rights does not adequately protect those rights, our rights may be impaired, which may impact our ability to develop, market and commercialize the in-licensed compound.

Our means of protecting our proprietary rights may not be adequate, and our competitors may:

independently develop substantially equivalent proprietary information, products and techniques;

otherwise gain access to our proprietary information; or

design around patents issued to us or our other intellectual property.

We pursue a policy of having our employees, consultants and advisors execute proprietary information and invention agreements when they begin working for us. However, these agreements may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we fail to maintain trade secret and patent protection, our potential, future revenues may be decreased.

**If the effective term of our patents is decreased due to changes in the United States patent laws or if we need to refile some of our patent applications, the value of our patent portfolio and the revenues we derive from it may be decreased.**

The value of our patents depends in part on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that we obtain and may decrease the revenues we derive from our patents. The United States patent laws were amended in 1995 to change the term of patent protection from 17 years from patent issuance to 20 years from the earliest effective filing date of the application. Because the time from filing to issuance of biotechnology applications may be more than three years depending on the subject matter, a 20-year patent term from the filing date may result in substantially shorter patent protection.

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Additionally, United States patent laws were amended in 2011 with the enactment of the America Invents Act and, effective September 16, 2012, third parties will be able to challenge the validity of issued U.S. patents through various review proceedings; thus rendering the validity of U.S. patents more uncertain. We may be obligated to participate in review proceedings to determine the validity of our U.S. patents. We cannot predict the ultimate outcome of these proceedings, the conduct of which could result in substantial costs and diversion of our efforts and resources. If we are unsuccessful in these proceedings some or all of our claims in the patents may be narrowed or invalidated and the patent protection for our drugs and drug candidates in the United States could be substantially shortened. Further, if all of the patents covering one of our products are invalidated, the FDA could approve requests to manufacture a generic version of that product prior to the expiration date of those patents.

**International patent protection is particularly uncertain and costly, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.**

Biotechnology and pharmaceutical patent law outside the United States is even more uncertain and costly than in the United States and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as United States laws. For example, certain countries do not grant patent claims that are directed to the treatment of humans. We may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

**Item 1B.** ***Unresolved Staff Comments.***

None.

**Item 2.** ***Properties***

Our corporate headquarters is in Wilmington, Delaware, which is where our drug discovery and development operations are also located. As of December 31, 2011, we had a lease agreement covering approximately 110,000 square feet that expires in June 2013. We believe that these facilities are adequate to meet our business requirements for the near-term and that additional space will be available on commercially reasonable terms, if required.

**Item 3.** ***Legal Proceedings***

We are not currently a party to any material legal proceedings. We may from time to time become involved in various legal proceedings arising in the ordinary course of business.

**Item 4.** ***Mine Safety Disclosures***

Not applicable.

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**Executive Officers of the Registrant**

Our executive officers are as follows:

*Paul A. Friedman,* M.D., age 69, joined Incyte as the Chief Executive Officer and a Director in November 2001. Dr. Friedman also serves as our President. From 1998 until October 2001, Dr. Friedman served as President of DuPont Pharmaceuticals Research Laboratories, a wholly owned subsidiary of DuPont Pharmaceuticals Company (formerly The DuPont Merck Pharmaceutical Company), from 1994 to 1998 he served as President of Research and Development of The DuPont Merck Pharmaceutical Company, and from 1991 to 1994 he served as Senior Vice President at Merck Research Laboratories. Prior to his work at Merck and DuPont, Dr. Friedman was an Associate Professor of Medicine and Pharmacology at Harvard Medical School. Dr. Friedman is a Diplomate of the American Board of Internal Medicine and a Member of the American Society of Clinical Investigation. He received his A.B. in Biology from Princeton University and his M.D. from Harvard Medical School. Dr. Friedman is also a director of Auxilium Pharmaceuticals, Inc.

*Patricia S. Andrews,* age 53, joined Incyte as Executive Vice President and Chief Commercial Officer in October 2008. From 1991 to October 2008, Ms. Andrews was employed by Pfizer in various roles of increasing responsibility in Corporate Strategic Planning and Worldwide Pharmaceutical Operations. Ms. Andrews was most recently Vice President, General Manager of the U.S. Oncology business unit and Vice President, Specialty Markets, responsible for U.S. marketing of oncology, ophthalmology, endocrinology, anti-infectives, HIV and all products still sold but no longer actively marketed in the United States. Prior to joining Pfizer, from 1985 to 1990, Ms. Andrews held various positions at Marine Midland Bank, including Vice President, Capital Finance. Ms. Andrews received her B.A. in history and political science from Brown University and her M.B.A. from the University of Michigan.

*David C. Hastings,* age 50, has served as Executive Vice President and Chief Financial Officer since October 2003. From February 2000 to September 2003, Mr. Hastings served as Vice President, Chief Financial Officer, and Treasurer of ArQule, Inc. Prior to his employment with ArQule, Mr. Hastings was Vice President and Corporate Controller at Genzyme, Inc., where he was responsible for the management of the finance department. Prior to his employment with Genzyme, Mr. Hastings was the Director of Finance at Sepracor, Inc., where he was primarily responsible for Sepracor's internal and external reporting. Mr. Hastings is a Certified Public Accountant and received his B.A. in Economics at the University of Vermont.

*Richard S. Levy,* M.D., age 54, has served as Executive Vice President and Chief Drug Development and Medical Officer since January 2009 and joined the company as Senior Vice President of Drug Development in August 2003. Prior to joining Incyte, Dr. Levy held positions of increasing responsibilities in drug development, clinical research and regulatory affairs at Celgene, from 2002 to 2003, DuPont Pharmaceuticals Company, from 1997 to 2002, and Sandoz (now part of Novartis), from 1991 to 1997. Prior to joining the pharmaceutical industry, Dr. Levy was Assistant Professor of Medicine at the UCLA School of Medicine. Dr. Levy is Board Certified in Internal Medicine and Gastroenterology and received his A.B. in Biology from Brown University and his M.D. from the University of Pennsylvania.

*Eric H. Siegel*, age 47, joined Incyte as our Chief Compliance Officer in October 2010 and became Executive Vice President and General Counsel in August 2011. Prior to joining Incyte, from April 2009 to October 2011, he was Chief Compliance Officer at EMD Serono, a privately-held biotechnology company. From 2007 to 2009 he served as General Counsel for Solstice Neurosciences, also a privately-held biotechnology company. He was Vice President, Deputy General Counsel and Chief Compliance Officer at Cephalon from 2004 to 2007. Mr. Siegel holds a B.A. from Franklin and Marshall College, his M.B.A from Temple University and his J.D. from the University of Pennsylvania.

*Paula J. Swain,* age 54, has served as Executive Vice President, Human Resources, of Incyte since August 2002 and joined the company as Senior Vice President of Human Resources in January 2002.

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Ms. Swain served as Senior Vice President of Human Resources at Bristol Meyers Squibb from October 2001 to January 2002, after they acquired DuPont Pharmaceuticals Company. From July 1998 to October 2001, Ms. Swain was Senior Vice President of Human Resources at DuPont Pharmaceuticals. From October 1992 to July 1998, Ms. Swain held a variety of human resources positions of increasing responsibility at DuPont Pharmaceuticals. Ms. Swain received her B.A. in Psychology and Industrial Relations from Rockhurst University.

## PART II

### Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

Our common stock, $.001 par value per share, is traded on The NASDAQ Global Market (Nasdaq) under the symbol "INCY." The following table sets forth, for the periods indicated, the range of high and low sales prices for our common stock on Nasdaq as reported in its consolidated transaction reporting system.

| | High | Low |
|---|---|---|
| **2010** | | |
| First Quarter | $ 14.49 | $ 9.16 |
| Second Quarter | 14.98 | 8.50 |
| Third Quarter | 16.05 | 10.21 |
| Fourth Quarter | 17.48 | 14.51 |
| **2011** | | |
| First Quarter | $ 16.72 | $ 13.16 |
| Second Quarter | 21.15 | 15.63 |
| Third Quarter | 20.36 | 12.58 |
| Fourth Quarter | 16.46 | 11.76 |

As of December 31, 2011, our common stock was held by 247 stockholders of record. We have never declared or paid dividends on our capital stock and do not anticipate paying any dividends in the foreseeable future.

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**Item 6.** ***Selected Financial Data***

**Selected Consolidated Financial Data**
**(in thousands, except per share data)**

The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 and the Consolidated Financial Statements and related Notes included in Item 8 of this Report.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | **2011** | **2010** | **2009** | **2008** | **2007** |
| **Consolidated Statement of Operations Data:** | | | | | |
| Revenues: | | | | | |
| Product revenues(1), net | $ 2,012 | $ | $ | $ | $ |
| Contract revenues(2) | 91,948 | 168,948 | 5,755 | 659 | 29,852 |
| License and royalty revenues | 495 | 930 | 3,510 | 3,260 | 4,588 |
| Total revenues | 94,455 | 169,878 | 9,265 | 3,919 | 34,440 |
| Costs and expenses: | | | | | |
| Research and development | 178,707 | 123,880 | 119,442 | 146,362 | 104,889 |
| Selling, general and administrative | 58,219 | 32,328 | 27,580 | 17,073 | 15,238 |
| Other expenses(3) | 712 | (379) | 2,011 | (227) | (407) |
| Total costs and expenses | 237,638 | 155,829 | 149,033 | 163,208 | 119,720 |
| Income (loss) from operations | (143,183) | 14,049 | (139,768) | (159,289) | (85,280) |
| Interest and other income, net | 462 | 1,416 | 50 | 5,306 | 22,431 |
| Interest expense | (43,819) | (43,323) | (32,125) | (24,937) | (24,032) |
| Loss on embedded derivative liability | | | (34,300) | | |
| Loss on redemption/repurchase of convertible senior and subordinated notes | | (3,988) | (5,727) | | |
| Net loss | $ (186,540) | $ (31,846) | $ (211,870) | $ (178,920) | $ (86,881) |
| Basic and diluted net loss per share | $ (1.49) | $ (0.26) | $ (2.06) | $ (1.99) | $ (1.03) |
| Number of shares used in computation of basic and diluted net loss per share | 125,362 | 121,628 | 102,943 | 89,785 | 84,185 |

(1) 2011 product revenues, net relates to our product sales of JAKAFI.

(2)

2011, 2010 and 2009 contract revenues relates to our collaborative research and license agreements with Novartis and Lilly. 2008 and 2007 contract revenues relate to our collaborative research and license agreement with Pfizer Inc.

(3)

2011 primarily relates to a settlement agreement. 2010, 2009, 2008 and 2007 relate to restructuring activity.

| | December 31, | | | | |
|---|---|---|---|---|---|
| | **2011** | **2010** | **2009** | **2008** | **2007** |
| **Consolidated Balance Sheet Data:** | | | | | |
| Cash, cash equivalents, and short-term and long-term marketable securities | $ 277,594 | $ 424,168 | $ 473,931 | $ 217,783 | $ 257,327 |
| Working capital | 175,164 | 341,881 | 523,229 | 155,157 | 227,817 |
| Total assets | 328,962 | 489,581 | 712,390 | 232,388 | 275,695 |
| Convertible senior notes | 298,193 | 276,445 | 308,059 | 130,969 | 122,180 |
| Convertible subordinated notes | 17,960 | 16,987 | 135,079 | 265,198 | 264,376 |
| Stockholders' deficit | (227,077) | (88,644) | (102,384) | (220,750) | (159,517) |

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**Item 7.** ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Consolidated Financial Data" and the Consolidated Financial Statements and related Notes included elsewhere in this Report.

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.

The therapeutic and commercial value of new medicines is difficult to predict, and conducting clinical trials for our drug candidates in development is a lengthy, time-consuming and expensive process. Therefore, if we are unable to successfully commercialize JAKAFI or develop and market some of our other pharmaceutical products over the next several years, our business, financial condition and results of operations would be adversely impacted. To date, we have not, and we may never, achieve sustained revenues sufficient to offset expenses. We may incur net losses in future periods, and we may never achieve or maintain profitability. We also expect that our operating results may fluctuate from period to period and that those fluctuations may be substantial.

**License Agreements**

***Novartis***

In November 2009, we entered into a Collaboration and License Agreement with Novartis International Pharmaceutical Ltd. 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

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tumors and myeloproliferative diseases. We retained exclusive development and commercialization rights to 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 $210.0 million and were initially eligible to receive additional payments of up to approximately $1.1 billion if defined development and commercialization milestones are achieved. In 2011, we received $25.0 million in milestone payments under this agreement and in 2010 we received a $50.0 million milestone payment. 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 Eli Lilly and Company. 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 $90.0 million, and were initially eligible to receive additional payments of up to $665.0 million based on the achievement of defined development, regulatory and commercialization milestones. In 2010, we received $49.0 million in milestone payments from Lilly. 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 Phase IIb trial through regulatory approval. 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

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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 milestone payments. We received a $3.0 million milestone payment from Pfizer in 2010.

**Critical Accounting Policies and Significant Estimates**

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our condensed consolidated financial statements:

Revenue recognition;

Research and development costs;

Stock compensation;

Investments;

Inventory; and

Convertible debt and derivative accounting.

***Revenue Recognition.*** Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed and determinable and (4) collectability is reasonably assured. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

*Product Revenues*

Our product revenues consist of U.S. sales of JAKAFI and are recognized once we meet all four revenue recognition criteria described above. Upon receipt of product by the specialty pharmacy, we meet three of the four revenue recognition criteria in that persuasive evidence of an arrangement exists, delivery has occurred and collectability is reasonably assured. However, at the time of receipt of product by the specialty pharmacy, we presently do not have the ability to estimate product that will ultimately be returned due to our lack of history with product revenues at this time. Accordingly, the price is not deemed fixed and determinable at this time since JAKAFI is a new and novel product, JAKAFI is the first approved treatment for intermediate or high-risk myelofibrosis, and JAKAFI is the first ever commercial drug product for Incyte.

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Therefore, we recognize revenue once the specialty pharmacy has filled the patient's prescription for JAKAFI. This approach is frequently referred to as the "sell-through" revenue recognition model. Under the sell-through approach, revenue is recognized when the specialty pharmacy provides product to a patient based on the fulfillment of a prescription. Once the prescription has been filled and it is no longer in the specialty pharmacy's inventory, it may no longer be returned to Incyte by the specialty pharmacy.

We recognize revenues for prescriptions filled net of allowances for customer credits, including estimated rebates, discounts, returns, distribution service fees, patients assistance programs, and Medicare part D coverage gap reimbursements. Product shipping and handling costs are included in cost of sales.

*Customer Credits:* The specialty pharmacies are offered various forms of consideration including allowances, service fees and prompt payment discounts. We expect the specialty pharmacies will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from product sales as they are earned.

*Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts are based upon contractual agreements or legal requirements with public sector (e.g., Medicaid) benefit providers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimates for the expected utilization of rebates are based in part on third party market research data, and data received from the specialty pharmacies. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter's unpaid rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Chargebacks:* Chargebacks are discounts that occur when contracted customers purchase directly from a specialty pharmacy, or an intermediary distributor. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or distributor, in turn, charges back to us the difference between the price initially paid by the specialty pharmacy or distributor and the discounted price paid to the specialty pharmacy or distributor by the customer. The allowance for chargebacks is based on known sales to contracted customers.

*Medicare Part D Coverage Gap:* Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for expected Medicare Part D coverage gap are based in part on third party market research data, and data received from the specialty pharmacies. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Co-payment assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

*Contract, License and Royalty Revenues*

Under agreements involving multiple deliverables, services and/or rights to use assets that we entered into prior to January 1, 2011, the multiple elements are divided into separate units of accounting when

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certain criteria are met, including whether the delivered items have stand- alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. When separate units of accounting exist, consideration is allocated among the separate elements based on their respective fair values. The determination of fair value of each element is based on objective evidence from historical sales of the individual elements by us to other customers. If such evidence of fair value for each undelivered element of the arrangement does not exist, all revenue from the arrangement is deferred until such time that evidence of fair value for each undelivered element does exist or until all elements of the arrangement are delivered. When elements are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligation tied to the element is completed. When revenues for an element are not specifically tied to a separate earnings process, they are recognized ratably over the term of the agreement. We assess whether a substantive milestone exists at the inception of our agreements. For all milestones within our arrangements that are considered substantive, we recognize revenue upon the achievement of the associated milestone. If a milestone is not considered substantive, we would recognize the applicable milestone payment over the remaining period of performance under the arrangement. As of December 31, 2011, all remaining potential milestones under our collaborative arrangements are considered substantive.

On January 1, 2011, updated guidance on the recognition of revenues for agreements with multiple deliverables became effective and applies to any agreements we may enter into on or after January 1, 2011. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method. During the year ended December 31, 2011, we did not enter into any agreements that are subject to this updated guidance. If we enter into an agreement with multiple deliverables after January 1, 2011, this updated guidance could have a material effect on our financial statements.

Our collaborations often include contractual milestones, which typically relate to the achievement of pre-specified development, regulatory and commercialization events. These three categories of milestone events reflect the three stages of the life-cycle of our drugs, which we describe in more detail in the following paragraph.

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing approval by the U.S. Food and Drug Administration (FDA) requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate's safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application (IND), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include preclinical laboratory tests, animal studies and formulation studies, submission to the FDA of an IND for human clinical testing, performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication, submission of a new drug application (NDA) to the FDA for review and FDA approval of the NDA.

Similar requirements exist within foreign regulatory agencies as well. The time required to satisfy the FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity, which includes animal studies, to assess potential safety and efficacy as well as product chemistry,

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stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The FDA may raise concerns or questions about safety issues such as the conduct of the clinical trials as outlined in the IND, and any of these concerns or questions must be resolved before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence. Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the institutional review board for a trial, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Generally, the milestone events contained in our collaboration agreements coincide with the progression of our drugs from development, to regulatory approval and then to commercialization. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve. Therefore, as a drug candidate progresses through the stages of its life-cycle, the value of the drug candidate generally increases.

Revenues from licenses to our intellectual property are recognized when earned under the terms of the related agreements. Royalty revenues are recognized upon the sale of products or services to third parties by the licensee or other agreed upon terms. We estimate royalty revenues based on previous period royalties received and information provided by the third party licensee. We exercise judgment in determining whether the information provided by licensees is sufficiently reliable for us to base our royalty revenue recognition thereon.

***Research and Development Costs.*** Our policy is to expense research and development costs as incurred. We often contract with clinical research organizations (CROs) to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most professional fees, including project and clinical management, data management, monitoring, and medical writing fees are incurred throughout the contract period. These professional fees are expensed based on their percentage of completion at a particular date. Our CRO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We expense the costs of pass through fees under our CRO contracts as they are incurred, based on the best information available to us at the time. The estimates of the pass through fees incurred are based on the amount of work completed for the clinical trial and are monitored through correspondence with the CROs, internal reviews and a review of contractual terms. The factors utilized to derive the estimates include the number of patients enrolled,

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duration of the clinical trial, estimated patient attrition, screening rate and length of the dosing regimen. CRO fees incurred to set up the clinical trial are expensed during the setup period. Reimbursable costs incurred in connection with collaborative license agreements are recorded as a reduction of research and development expenses.

***Stock Compensation.*** Accounting guidance for stock compensation requires all share-based payment transactions with employees, including grants of employee stock options, to be recognized as compensation expense over the requisite service period based on their fair values. The accounting guidance also requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value equity-based compensation and requires the recognition of the fair value of stock compensation in the statement of operations. We recorded $29.0 million, $14.9 million and $10.0 million of stock compensation expense for the years ended December 31, 2011, 2010 and 2009, respectively.

***Investments.*** We carry our investments at their respective fair values. We periodically evaluate the fair values of our investments to determine whether any declines in the fair value of investments represent an other-than-temporary impairment. This evaluation consists of a review of several factors, including the length of time and extent that a security has been in an unrealized loss position, the existence of an event that would impair the issuer's future repayment potential, the near term prospects for recovery of the market value of a security and if we intend to sell or if it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If management determines that such an impairment exists, we would recognize an impairment charge. Because we may determine that market or business conditions may lead us to sell a short-term investment or marketable security prior to maturity, we classify our short-term investments and marketable securities as "available-for-sale." Investments in securities that are classified as available-for-sale and have readily determinable fair values are measured at fair market value in the balance sheets, and unrealized holding gains and losses for these investments are reported as a separate component of stockholders' equity until realized. We classify those marketable securities that may be used in operations within one year as short-term investments. Those marketable securities in which we have both the ability to hold until maturity and have a maturity date beyond one year from our most recent condensed consolidated balance sheet date are classified as long-term marketable securities.

***Inventory.*** Inventories are determined at the lower of cost or market value with cost determined under the specific identification method. Inventories consisted of raw materials at December 31, 2011 but we may also have work in process and finished goods at any given time. We began capitalizing inventory in mid-November 2011 once the FDA approved JAKAFI as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to approval of JAKAFI have been recorded as research and development expense in our statement of operations. As a result, inventory balances and cost of revenue for the next several quarters will reflect a lower average per unit cost of materials.

***Convertible Debt and Derivative Accounting.*** We perform an assessment of all embedded features of a debt instrument to determine if (1) such features should be bifurcated and separately accounted for, and (2) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liabilities. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the condensed consolidated balance sheet, and remeasured each reporting period. Any changes in fair value are recorded in the condensed consolidated statement of operations. We monitor, on an ongoing basis, whether events or circumstances could give rise to a change in our classification of embedded features.

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**Results of Operations**

***Years Ended December 31, 2011 and 2010***

We recorded net losses for the years ended December 31, 2011 and 2010 of $186.5 million and $31.8 million, respectively. On a basic and diluted per share basis, net loss was $1.49 and $0.26 for the years ended December 31, 2011 and 2010, respectively.

***Revenues***

| | For the Years Ended, December 31, | |
|---|---|---|
| | 2011 | 2010 |
| | (in millions) | |
| Product revenues, net | $ 2.0 | $ |
| Contract revenues | 91.9 | 169.0 |
| License and royalty revenues | 0.5 | 0.9 |
| Total revenues | $ 94.4 | $ 169.9 |

Our product revenues, net of $2.0 million in 2011 resulted from commercial sale of JAKAFI following FDA approval on November 16, 2011 and excludes approximately $2.3 million of deferred product revenue for JAKAFI shipped to specialty pharmacies but not yet delivered to patients. As we currently have no historical data on returns, we currently use the sell-through method for revenue recognition under which we defer revenue until the patient receives JAKAFI. We plan to transition to the sell-in method of recognizing revenue when JAKAFI is received by the specialty pharmacy once a sufficient period of time has elapsed to enable us to estimate product returns.

Our contract revenues were $91.9 million and $169.0 million in 2011 and 2010, respectively. For the year ended December 31, 2011 and 2010, contract revenues were derived from the straight line recognition of revenue associated with the Novartis and Lilly upfront fees over the estimated performance periods. The upfront fees related to the Novartis agreement included a $150.0 million upfront payment received in 2009, a $60.0 million immediate milestone payment received in 2010 and $10.9 million of reimbursable costs incurred prior to the effective date of the agreement. The upfront fees related to the Lilly agreement consisted of a $90.0 million upfront payment received in 2010. The decrease from 2010 to 2011 primarily relates to recognition of $102.0 million in milestone payments from Novartis, Lilly and Pfizer in 2010 compared to the recognition of $25.0 million in milestone payments from Novartis in 2011.

***Cost of Revenues***

We began capitalizing inventory in mid-November 2011 once the FDA approved JAKAFI as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to FDA approval have been recorded as research and development expenses in our statement of operations. As a result, cost of revenues for the next several quarters will reflect a lower average per unit cost of materials. Cost of revenues was $0.0 million for the year ended December 31, 2011.

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***Operating Expenses***

*Research and development expenses*

| | For the Years Ended, December 31, | |
|---|---|---|
| | 2011 | 2010 |
| | (in millions) | |
| Salary and benefits related | $ 55.4 | $ 43.3 |
| Stock compensation | 18.6 | 10.0 |
| Clinical research and outside services | 83.0 | 53.4 |
| Occupancy and all other costs | 21.7 | 17.2 |
| Total research and development expenses | $ 178.7 | $ 123.9 |

We currently track research and development costs by natural expense line and not costs by project. Salary and benefits related expense increased from 2010 to 2011 due to increased development headcount to sustain our development pipeline. Stock compensation expense may fluctuate from period to period based on the number of options granted, stock price volatility and expected option lives, as well as expected option forfeiture rates which are used to value equity-based compensation. The increase in clinical research and outside services expense from 2010 to 2011 was primarily the result of increased development costs. Research and development expenses for the year ended December 31, 2011 and 2010 were net of $3.8 million and $9.9 million, respectively, of costs reimbursed by our collaborative partners. The increase in occupancy and all other costs from 2010 to 2011 was primarily the result of increased laboratory expenses. Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial related activities. Many factors can affect the cost and timing of our clinical trials, including requests by regulatory agencies for more information, inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects among patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of our investigational drugs in our clinical trials. In addition, the development of all of our products will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our products.

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 Phase IIb trial through regulatory approval. We have retained certain mechanisms to give us cost protection as LY3009104 advances in clinical development. We can defer our portion of co-development study costs by indication if they exceed a predetermined level. This deferment would be credited against future milestones or royalties and we would still be eligible for the full incremental royalties related to the co-development option. In addition, even if we have started co-development funding for any indication, we can at any time opt out for that indication and stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental pro-rated royalty commensurate with our contribution to the total co-development cost for those indications for which we contributed funding.

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*Selling, general and administrative expenses*

| | For the Years Ended, December 31, | |
|---|---|---|
| | 2011 | 2010 |
| | ($ in millions) | |
| Salary and benefits related | $ 19.6 | $ 10.4 |
| Stock compensation | 10.4 | 4.9 |
| Other contract services and outside costs | 28.2 | 17.0 |
| Total selling, general and administrative expenses | $ 58.2 | $ 32.3 |

Salary and benefits related expense increased from 2010 to 2011 due to increased headcount. This increased headcount was due to preparation for the commercialization of JAKAFI for intermediate or high-risk myelofibrosis. Stock compensation expense may fluctuate from period to period based on the number of options granted, stock price volatility and expected option lives, as well as expected option forfeiture rates which are used to value equity-based compensation. The increase in other contract services and outside costs was primarily the result of initial marketing preparations for the commercialization of JAKAFI for intermediate or high-risk myelofibrosis.

***Other income (expense)***

*Interest and other income, net.* Interest and other income, net, for the years ended December 31, 2011 and 2010 was $0.5 million and $1.4 million, respectively. The decrease in 2010 from 2011 is primarily due to the Qualifying Therapeutic Discovery Project grants received in October 2010, for which we were awarded $0.7 million in connection with our development programs.

*Interest expense.* Interest expense for the years ended December 31, 2011 and 2010 was $43.8 million and $43.3 million, respectively. The increase in 2011 from 2010 is primarily attributable to accretion of the discount related to our 4.75% convertible senior notes due 2015 issued in September 2009.

*Loss on repurchase of convertible senior and subordinated notes.* During the year ended December 31, 2010, we redeemed the remaining $55.6 million principal amount of our 3 1/2% convertible senior notes due 2011 and $119.0 million principal amount of our 3 1/2% convertible subordinated notes due 2011. These redemptions resulted in a loss of $4.0 million primarily related to the unamortized debt discount from the 3 1/2% convertible senior notes we redeemed.

***Years Ended December 31, 2010 and 2009***

We recorded net losses for the years ended December 31, 2010 and 2009 of $31.8 million and $211.9 million, respectively. On a basic and diluted per share basis, net loss was $0.26 and $2.06 for the years ended December 31, 2010 and 2009, respectively.

***Revenues***

| | For the Years Ended, December 31, | |
|---|---|---|
| | 2010 | 2009 |
| | (in millions) | |
| Contract revenues | $ 169.0 | $ 5.8 |
| License and royalty revenues | 0.9 | 3.5 |
| Total revenues | $ 169.9 | $ 9.3 |

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Our contract revenues were $169.0 million and $5.8 million in 2010 and 2009, respectively. For the year ended December 31, 2010 and 2009, contract revenues were derived from the straight line recognition of revenue associated with the Novartis and Lilly upfront fees over the estimated performance periods. The upfront fees related to the Novartis agreement included a $150.0 million upfront payment received in 2009, a $60.0 million immediate milestone payment received in 2010 and $10.9 million of reimbursable costs incurred prior to the effective date of the agreement. The upfront fees related to the Lilly agreement consisted of a $90.0 million upfront payment received in 2010. The increase from 2009 to 2010 primarily relates to 2010 amortization of the upfront fee received from Novartis and Lilly under our collaboration and license agreements. In addition, in 2010 we received and recognized a total of $102.0 million in milestone payments from Novartis, Lilly and Pfizer.

***Operating Expenses***

*Research and development expenses*

| | For the Years Ended, December 31, | |
|---|---|---|
| | **2010** | **2009** |
| | **(in millions)** | |
| Salary and benefits related | $ 43.3 | $ 38.8 |
| Stock compensation | 10.0 | 7.1 |
| Clinical research and outside services | 53.4 | 57.8 |
| Occupancy and all other costs | 17.2 | 15.7 |
| Total research and development expenses | $ 123.9 | $ 119.4 |

Salary and benefits related expense increased from 2009 to 2010 due to increased development headcount to sustain our development pipeline. Stock compensation expense may fluctuate from period to period based on the number of options granted, stock price volatility and expected option lives, as well as expected option forfeiture rates which are used to value equity-based compensation. The decrease in clinical research and outside services expense from 2009 to 2010 was primarily the result of decreased development costs due to our shared costs arrangements with our collaborators. Research and development expenses for the year ended December 31, 2010 and 2009 were net of $9.9 million and $1.5 million, respectively, of costs reimbursed by our collaborative partners. The increase in occupancy and all other costs from 2009 to 2010 was primarily the result of increased laboratory expenses.

*Selling, general and administrative expenses*

| | For the Years Ended, December 31, | |
|---|---|---|
| | **2010** | **2009** |
| | **($ in millions)** | |
| Salary and benefits related | $ 10.4 | $ 8.4 |
| Stock compensation | 4.9 | 2.9 |
| Other contract services and outside costs | 17.0 | 16.3 |
| Total selling, general and administrative expenses | $ 32.3 | $ 27.6 |

Salary and benefits related expense increased from 2009 to 2010 due to increased headcount. This increased headcount was due to preparation for the potential commercialization of JAKAFI for intermediate or high-risk myelofibrosis. Stock compensation expense may fluctuate from period to period based on the number of options granted, stock price volatility and expected option lives, as well as expected option forfeiture rates which are used to value equity-based compensation. The increase in other

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contract services and outside costs was primarily the result of initial marketing preparations for the commercialization of JAKAFI for intermediate or high-risk myelofibrosis.

*Other expenses.* Other expenses for the years ended December 31, 2010 and 2009 were $(0.4) million and $2.0 million, respectively. In 2010, we recorded $0.2 million of expense in connection with our 2004 restructuring program and $(0.6) million of expense (benefit) in connection with our 2002 restructuring program. In 2009, we recorded $0.4 million of expense in connection with our 2004 restructuring program and $1.6 million of expense in connection with our 2002 restructuring program.

***Other income (expense)***

*Interest and other income, net.* Interest and other income, net, for the years ended December 31, 2010 and 2009 was $1.4 million and $0.1 million, respectively. The increase in 2010 from 2009 is primarily due to the Qualifying Therapeutic Discovery Project grants received in October 2010, for which we were awarded $0.7 million in connection with our development programs.

*Interest expense.* Interest expense for the years ended December 31, 2010 and 2009 was $43.3 million and $32.1 million, respectively. The increase in 2010 from 2009 is primarily attributable to the increase in coupon interest and accretion of the discount related to our 4.75% convertible senior notes due 2015 issued in September 2009.

*Loss on embedded derivative liability.* The loss on embedded derivative liability related to the conversion feature on our 4.75% convertible senior notes due 2015 which was originally valued on September 30, 2009 at $148.1 million. On November 24, 2009, we increased the number of shares of our common stock authorized for issuance in an amount sufficient to satisfy conversion of our 4.75% convertible senior notes, and we recorded a mark-to-market adjustment in the value of the embedded derivative liability to $182.4 million as, among other factors, our stock price increased from September 30, 2009, which resulted in a $34.3 million non-cash charge. As a result of the increase in our common stock authorized for issuance, classification of this embedded derivative as a liability is no longer required, and we have reclassified it to additional-paid-in-capital.

*Loss on repurchase of convertible senior and subordinated notes.* During the year ended December 31, 2010, we redeemed the remaining $55.6 million principal amount of our 3 1/2% convertible senior notes due 2011 and $119.0 million principal amount of our 3 1/2% convertible subordinated notes due 2011. These redemptions resulted in a loss of $4.0 million primarily related to the unamortized debt discount from the 3 1/2% convertible senior notes we redeemed. During the year ended December 31, 2009, we repurchased $96.2 million of our 3 1/2% convertible senior notes due 2011 and $131.0 million of our 3 1/2% convertible subordinated notes due 2011. These repurchases resulted in a loss of $5.7 million primarily related to the pro rata share of the unamortized debt discount from the 3 1/2% convertible senior notes we repurchased during the year ended December 31, 2009.

**Recent Accounting Pronouncements**

In April 2010, the Financial Accounting Standards Board issued guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The guidance provides criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. We adopted this guidance on January 1, 2011, which had no impact on our consolidated financial statements.

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**Liquidity and Capital Resources**

| | 2011 | 2010 | 2009 |
|---|---|---|---|
| | (in millions) | | |
| **December 31:** | | | |
| Cash, cash equivalents, and short-term and long-term marketable securities | $ 277.6 | $ 424.2 | $ 473.9 |
| Working capital | $ 175.2 | $ 341.9 | $ 523.2 |
| **Year ended December 31:** | | | |
| Cash provided by (used in): | | | |
| Operating activities | $ (161.7) | $ 97.9 | $ 12.4 |
| Investing activities | $ (2.5) | $ 15.2 | $ 16.5 |
| Financing activities | $ 19.5 | $ (145.1) | $ 242.3 |
| Capital expenditures (included in investing activities above) | $ 3.8 | $ 4.1 | $ 0.4 |

*Sources and Uses of Cash.* We had net losses from inception in 1991 through 1996 and in 1999 through 2011. Because of those losses, we had an accumulated deficit of $1.6 billion as of December 31, 2011. We have funded our research and development operations through sales of equity securities, the issuance of convertible notes, cash received from customers, and collaborative arrangements. At December 31, 2011, we had available cash, cash equivalents, and marketable securities of $277.6 million, excluding a funded restricted cash and investment escrow account of $19.0 million reserved for interest payments through October 2012 on our 4.75% convertible senior notes due 2015. Our cash and marketable securities balances are held in a variety of interest-bearing instruments, including money market accounts and U.S. government agency and non-agency mortgage-backed securities. Available cash is invested in accordance with our investment policy's primary objectives of liquidity, safety of principal and diversity of investments.

*Cash provided by (used in) Operating Activities.* The $259.6 million decrease in cash provided by operating activities from 2010 to 2011 was due primarily to remaining upfront payments of $150.0 million and milestone payments of $102.0 million received from our collaborators during 2010. The $85.5 million increase in cash provided by operating activities from 2009 to 2010 was due primarily to remaining upfront payments of $150.0 million and milestone payments of $102.0 million received from our collaborators during 2010.

*Cash provided by Investing Activities.* Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures and sales and purchases of long-term investments. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of strategic equity investments, acquisitions, including possible earn-out payments to former stockholders of Maxia Pharmaceuticals, Inc., capital expenditures and maturities/sales and purchases of marketable securities.

*Cash provided by (used in) Financing Activities.* During 2011, net cash provided by financing activities was $19.5 million proceeds from issuance of common stock under our stock plans and employee stock purchase plan. During 2010, net cash used in financing activities was $145.1 million, which represented primarily $158.6 million used to redeem the remaining 3½% convertible senior notes due 2011 and 3½% convertible subordinated notes due 2011, offset by proceeds of $13.6 million from the issuance of common stock under our stock plans and employee stock purchase plan. During 2009, we received net proceeds of $132.3 million from the issuance of common stock in a public offering and net proceeds of $387.4 million from the issuance of our 4.75% convertible senior notes due 2015 in a private placement. We also used $223.3 million to repurchase $227.2 million aggregate principal amount of our 3½% convertible senior notes due 2011 and 3½% convertible subordinated notes due 2011. In 2009, we also funded an escrow account of $56.2 million for the first six semi-annual interest payments on our 4.75% convertible senior

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notes. In addition, in 2009 we received $2.1 million of proceeds from issuance of common stock under our stock plans and employee stock purchase plan.

The following summarizes our significant contractual obligations as of December 31, 2011 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in millions):

| | Total | Less Than 1 Year | Years 1 - 3 | Years 4 - 5 | Over 5 Years |
|---|---|---|---|---|---|
| **Contractual Obligations:** | | | | | |
| Principal on convertible subordinated debt | $ 20.0 | $ | 20.0 | $ | $ |
| Principal on convertible senior debt | 400.0 | | | 400.0 | |
| Interest on convertible senior debt | 76.0 | 19.0 | 38.0 | 19.0 | |
| Non-cancelable operating lease obligations: | | | | | |
| Related to corporate headquarters | 9.3 | 6.2 | 3.1 | | |
| Total contractual obligations | $ 505.3 | $ 25.2 | $ 61.1 | $ 419.0 | $ |

We have funded an escrow account of $19.0 million as of December 31, 2011 for interest payments through October 2012 on our 4.75% convertible senior notes.

The table above excludes certain commitments that are contingent upon future events. The most significant of these contractual commitments that we consider to be contingent obligations are summarized below.

Commitments related to Maxia Pharmaceuticals, Inc. are considered contingent commitments as future events must occur to cause these commitments to be enforceable. In February 2003, we completed our acquisition of Maxia. Under the merger agreement, former Maxia stockholders have the right to receive certain earn out amounts of up to a potential aggregate amount of $14.0 million upon the occurrence of certain research and development milestones set forth in the merger agreement. Twenty percent of each earn out payment, if earned, will be paid in cash and the remaining eighty percent will be paid in shares of our common stock. None of these milestones has been achieved as of December 31, 2011.

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

We believe that our cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs for at least the next twelve months. Our cash requirements depend on numerous factors, including our expenditures in connection with our drug discovery and development programs and commercialization operations; expenditures in connection with litigation or other legal proceedings; competing technological and market developments; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; our receipt of any milestone or other payments under any collaborative agreements we may enter into, including the agreements with Novartis, Lilly and Pfizer, the extent to which commercialization of JAKAFI is successful; and expenditures in connection with strategic relationships and license agreements. Changes in our research and development or commercialization plans or other changes affecting our operating expenses may result in changes in the timing and amount of expenditures of our capital resources.

Until we can generate a sufficient amount of product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders, and may provide for rights, preferences or privileges senior to those of our holders of common stock. Debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our

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ability to incur further indebtedness. The indenture under which our 4.75% convertible senior notes due 2015 are issued contains a covenant that, among other things, limits our ability and the ability of any of our subsidiaries to incur additional indebtedness, create liens, or sell, lease, license, transfer or otherwise dispose of certain of our or their assets. We do not know whether additional funding will be available on acceptable terms, if at all. If we are not able to secure additional funding when needed, we may have to scale back our operations, delay or eliminate one or more of our research or development programs, or attempt to obtain funds by entering into an agreement with a collaborator or licensee that would result in terms that are not favorable to us or relinquishing our rights in certain of our proprietary technologies or drug candidates.

**Off Balance Sheet Arrangements**

We have no off-balance sheet arrangements other than those that are discussed above.

**Item 7A.** ***Quantitative and Qualitative Disclosures About Market Risk***

Our investments in marketable securities, which are composed primarily of U.S. government agency and non-agency mortgage-backed securities and money market funds, are subject to default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market rate interest rates increase. As of December 31, 2011, cash, cash equivalents and marketable securities were $277.6 million, excluding a funded restricted cash and investment escrow account of $19.0 million reserved for interest payments through October 2012 on our 4.75% convertible senior notes due 2015. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of December 31, 2011, the decline in fair value would not be material.

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**Item 8.** ***Financial Statements and Supplementary Data***

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Incyte Corporation

We have audited the accompanying consolidated balance sheets of Incyte Corporation as of December 31, 2011 and 2010, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Incyte Corporation, at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Incyte Corporation's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control  Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 22, 2012 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Philadelphia, Pennsylvania
February 22, 2012

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**INCYTE CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

**(in thousands, except number of shares and par value)**

| | December 31, 2011 | December 31, 2010 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 273,164 | $ 417,912 |
| Marketable securities available-for-sale | 4,430 | 6,256 |
| Restricted cash and investments | 19,294 | 18,985 |
| Accounts receivable | 6,415 | 5,701 |
| Prepaid expenses and other current assets | 7,475 | 6,600 |
| Total current assets | 310,778 | 455,454 |
| Restricted cash and investments | | 18,891 |
| Inventory | 3,536 | |
| Property and equipment, net | 6,431 | 4,804 |
| Intangible and other assets, net | 8,217 | 10,432 |
| Total assets | $ 328,962 | $ 489,581 |
| **LIABILITIES AND STOCKHOLDERS' DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable | $ 14,939 | $ 10,773 |
| Accrued compensation | 21,856 | 14,678 |
| Interest payable | 4,750 | 4,750 |
| Accrued and other current liabilities | 24,766 | 15,703 |
| Accrued restructuring | | 696 |
| Deferred revenue Product revenues | 2,332 | |
| Deferred revenue Collaborative agreements | 66,971 | 66,973 |
| Total current liabilities | 135,614 | 113,573 |
| Convertible senior notes | 298,193 | 276,445 |
| Convertible subordinated notes | 17,960 | 16,987 |
| Deferred revenue Collaborative agreements | 104,272 | 171,220 |
| Total liabilities | 556,039 | 578,225 |
| Stockholders' deficit: | | |
| Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of December 31, 2011 and December 31, 2010 | | |
| Common stock, $0.001 par value; 400,000,000 shares authorized; 126,471,999 and 123,280,474 shares issued and outstanding as of December 31, 2011 and December 31, 2010, respectively | 126 | 123 |
| Additional paid-in capital | 1,380,725 | 1,332,277 |
| Accumulated other comprehensive gain | 1,642 | 1,986 |
| Accumulated deficit | (1,609,570) | (1,423,030) |
| Total stockholders' deficit | (227,077) | (88,644) |

| | | | | |
|---|---|---|---|---|
| Total liabilities and stockholders' deficit | $ | 328,962 | $ | 489,581 |

See accompanying notes.

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**INCYTE CORPORATION**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**(in thousands, except per share amounts)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2011** | **2010** | **2009** |
| Revenues: | | | |
| Product revenues, net | $ 2,012 | $ | $ |
| Contract revenues | 91,948 | 168,948 | 5,755 |
| License and royalty revenues | 495 | 930 | 3,510 |
| Total revenues | 94,455 | 169,878 | 9,265 |
| Costs and expenses: | | | |
| Research and development | 178,707 | 123,880 | 119,442 |
| Selling, general and administrative | 58,219 | 32,328 | 27,580 |
| Other expenses | 712 | (379) | 2,011 |
| Total costs and expenses | 237,638 | 155,829 | 149,033 |
| Income (loss) from operations | (143,183) | 14,049 | (139,768) |
| Interest and other income, net | 462 | 1,416 | 50 |
| Interest expense | (43,819) | (43,323) | (32,125) |
| Loss on embedded derivative liability | | | (34,300) |
| Loss on repurchase of convertible senior and subordinated notes | | (3,988) | (5,727) |
| Net loss | $ (186,540) | $ (31,846) | $ (211,870) |
| Basic and diluted net loss per share | $ (1.49) | $ (0.26) | $ (2.06) |
| Shares used in computing basic and diluted net loss per share | 125,362 | 121,628 | 102,943 |

See accompanying notes.

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**INCYTE CORPORATION**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(in thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2011** | **2010** | **2009** |
| Net loss | $ (186,540) | $ (31,846) | $ (211,870) |
| Other comprehensive (loss) income: | | | |
| Unrealized (losses) gains on marketable securities | (159) | 1,462 | 2,200 |
| Reclassification adjustment for realized (gains) losses on marketable securities | (185) | (183) | 1,254 |
| Other comprehensive (loss) income | (344) | 1,279 | 3,454 |
| Comprehensive loss | $ (186,884) | $ (30,567) | $ (208,416) |

See accompanying notes.

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**INCYTE CORPORATION**

**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)**

**(in thousands, except number of shares)**

| | Common Stock | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|
| Balances at December 31, 2008 | $ 97 | $ 961,214 | $ (2,747) | $ (1,179,314) | $ (220,750) |
| Issuance of 104,919 shares of Common Stock upon exercise of stock options and 748,558 shares of Common Stock under the ESPP | 1 | 2,060 | | | 2,061 |
| Issuance of 20,700,000 shares of Common Stock | 21 | 132,315 | | | 132,336 |
| Stock compensation expense | | 9,980 | | | 9,980 |
| Other comprehensive income | | | 3,454 | | 3,454 |
| Reclassification of embedded derivative liability | | 182,405 | | | 182,405 |
| Net loss | | | | (211,870) | (211,870) |
| Balances at December 31, 2009 | $ 119 | $ 1,287,974 | $ 707 | $ (1,391,184) | $ (102,384) |
| Issuance of 1,701,368 shares of Common Stock upon exercise of stock options and 1,182,929 shares of Common Stock under the ESPP | 3 | 13,586 | | | 13,589 |
| Issuance of 1,502,851 shares of Common Stock upon conversion of convertible senior and subordinated notes | 1 | 15,861 | | | 15,862 |
| Stock compensation expense | | 14,856 | | | 14,856 |
| Other comprehensive income | | | 1,279 | | 1,279 |
| Net loss | | | | (31,846) | (31,846) |
| Balances at December 31, 2010 | $ 123 | $ 1,332,277 | $ 1,986 | $ (1,423,030) | $ (88,644) |
| Issuance of 2,294,586 shares of Common Stock upon exercise of stock options and 896,939 shares of Common Stock under the ESPP | 3 | 19,465 | | | 19,468 |
| Stock compensation expense | | 28,983 | | | 28,983 |
| Other comprehensive loss | | | (344) | | (344) |
| Net loss | | | | (186,540) | (186,540) |
| Balances at December 31, 2011 | $ 126 | $ 1,380,725 | $ 1,642 | $ (1,609,570) | $ (227,077) |

See accompanying notes.

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**INCYTE CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(in thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2011** | **2010** | **2009** |
| **Cash flows from operating activities**: | | | |
| Net loss | $ (186,540) | $ (31,846) | $ (211,870) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | |
| Non-cash restructuring charges (benefit) | (88) | (379) | 2,011 |
| Depreciation and amortization of debt discounts | 26,990 | 24,485 | 16,690 |
| Stock-based compensation | 28,983 | 14,856 | 9,980 |
| Loss on embedded derivative liability | | | 34,300 |
| Loss on repurchase of convertible senior and subordinated notes | | 3,988 | 5,727 |
| Impairment of long-term investments and marketable securities | | | 1,254 |
| Realized gain (loss) on long-term investments and marketable securities, net | 185 | (183) | 85 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (714) | 157,960 | (162,611) |
| Prepaid expenses and other assets | 17,824 | 15,521 | 3,954 |
| Inventory | (3,536) | | |
| Accounts payable | 4,166 | (10,191) | 5,285 |
| Accrued and other liabilities | 15,633 | (9,267) | 2,416 |
| Deferred revenue Product revenues | 2,332 | | |
| Deferred revenue Collaborative agreements | (66,950) | (67,006) | 305,137 |
| Net cash (used in) provided by operating activities | (161,715) | 97,938 | 12,358 |
| **Cash flows from investing activities**: | | | |
| Capital expenditures | (3,799) | (4,109) | (387) |
| Sales of marketable securities | | 431 | 1,212 |
| Maturities of marketable securities | 1,298 | 18,882 | 15,627 |
| Net cash (used in) provided by investing activities | (2,501) | 15,204 | 16,452 |
| **Cash flows from financing activities**: | | | |
| Proceeds from issuance of common stock under stock plans | 19,468 | 13,590 | 2,061 |
| Net proceeds from issuance of common stock | | | 132,336 |
| Changes in restricted cash | | | (56,223) |
| Repurchase of convertible senior and subordinated notes | | (158,644) | (223,289) |
| Net proceeds from issuance of convertible senior and subordinated notes | | | 387,369 |
| Net cash provided by (used in) financing activities | 19,468 | (145,054) | 242,254 |
| Change in currency translation adjustment | | | (7) |
| Net (decrease) increase in cash and cash equivalents | (144,748) | (31,912) | 271,057 |
| Cash and cash equivalents at beginning of year | 417,912 | 449,824 | 178,767 |
| Cash and cash equivalents at end of year | $ 273,164 | $ 417,912 | $ 449,824 |

| | | | |
|---|---|---|---|
| **Supplemental Schedule of Cash Flow Information** | | | |
| Interest paid | $ 19,000 | $ 22,175 | $ 15,141 |
| Taxes paid | $ | $ | $ |

See accompanying notes.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Organization and Summary of Significant Accounting Policies**

*Organization and Business.* Incyte Corporation ("Incyte," "we," "us," or "our") is a biopharmaceutical company focused on developing and commercializing proprietary small molecule drugs for oncology and inflammation. Our pipeline includes compounds in various stages, ranging from preclinical to commercialized product.

*Principles of Consolidation.* The consolidated financial statements include the accounts of Incyte Corporation and our wholly owned subsidiaries. All material inter-company accounts, transactions, and profits have been eliminated in consolidation.

*Use of Estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Concentrations of Credit Risk.* Cash, cash equivalents, marketable securities and trade receivables are financial instruments which potentially subject us to concentrations of credit risk. The estimated fair value of financial instruments approximates the carrying value based on available market information. We primarily invest our excess available funds in notes and bills issued by the U.S. government and its agencies and corporate debt securities and, by policy, limit the amount of credit exposure to any one issuer and to any one type of investment, other than securities issued or guaranteed by the U.S. government. Our receivables mainly relate to our product sales of JAKAFI and collaborative agreements with pharmaceutical companies. We have not experienced any significant credit losses on cash, cash equivalents, marketable securities or trade receivables to date and do not require collateral on receivables.

*Cash and Cash Equivalents.* Cash and cash equivalents are held in U.S. banks or in custodial accounts with U.S. banks. Cash equivalents are defined as all liquid investments and money market funds with maturity from date of purchase of 90 days or less that are readily convertible into cash.

*Marketable Securities Available-for-Sale.* All marketable securities are classified as available-for-sale. Available-for-sale securities are carried at fair value, based on quoted market prices and observable inputs, with unrealized gains and losses, net of tax, reported as a separate component of stockholders' equity (deficit). We classify marketable securities available to fund current operations as current assets on the consolidated balance sheets. Marketable securities are classified as long-term assets on the consolidated balance sheets if (i) they have been in an unrealized loss position for longer than six months and (ii) we have the ability to hold them until the carrying value is recovered and such holding period may be longer than one year. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretions of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in value judged to be other than temporary for available-for-sale securities are included in "Interest and other income, net." The cost of securities sold is based on the specific identification method.

*Accounts Receivable.* As of December 31, 2011 and 2010 we had no allowance for doubtful accounts. We provide an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are carried at fair value and charged off against the allowance for doubtful accounts when we determine that recovery is unlikely and we cease collection efforts.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 1. Organization and Summary of Significant Accounting Policies (Continued)**

*Inventory.* Inventories are determined at the lower of cost or market value with cost determined under the specific identification method. Inventories consisted of raw materials and work in process at December 31, 2011 but we may also have finished goods at any given time. We began capitalizing inventory in mid-November 2011 once the U.S. Food and Drug Administration ("FDA") approved JAKAFI as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to approval of JAKAFI have been recorded as research and development expense in our statement of operations. As a result, inventory balances and cost of revenue for the next several quarters will reflect a lower average per unit cost of materials.

*Property and Equipment.* Property and equipment is stated at cost, less accumulated depreciation and amortization. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets (generally three to five years). Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or lease term.

Management continually reviews the estimated useful lives of technologically sensitive equipment and believes that those estimates appropriately reflect the current useful life of our assets. In the event that a currently unknown significantly advanced technology became commercially available, we would re-evaluate the value and estimated useful lives of our existing equipment, possibly having a material impact on the financial statements.

*Intangible and Other Assets.* Patent application costs relating to ongoing drug discovery and development are charged to expense as incurred.

*Income Taxes.* We account for income taxes using an asset and liability approach which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and amounts reportable for income tax purposes. On January 1, 2007, we adopted the guidance related to accounting for uncertainty in income taxes. This guidance creates a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before it is recognized in the financial statements.

*Financing Costs Related to Long-term Debt.* Costs associated with obtaining long-term debt are deferred and amortized over the term of the related debt using the effective interest method. Such costs are included in intangibles and other assets, net on the consolidated balance sheet.

*Net Income (Loss) Per Share.* Our basic and diluted losses per share are calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during all periods presented. Options to purchase stock and convertible debt are included in diluted earnings per share calculations, unless the effects are anti-dilutive.

*Accumulated Other Comprehensive Income (Loss).* Accumulated other comprehensive income (loss) consists of unrealized gains or losses on marketable securities.

*Revenue Recognition.* Revenues are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed and determinable and (iv) collectability is reasonably assured. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectability is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 1. Organization and Summary of Significant Accounting Policies (Continued)**

or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and on the creditworthiness of the customer.

*Product Revenues*

Our product revenues consist of U.S. sales of JAKAFI and are recognized once we meet all four revenue recognition criteria described above. Upon receipt of product by the specialty pharmacy, we meet three of the four revenue recognition criteria in that persuasive evidence of an arrangement exists, delivery has occurred and collectability is reasonably assured. However, at the time of receipt of product by the specialty pharmacy, we presently do not have the ability to estimate product that will ultimately be returned due to our lack of history with product revenues at this time. Accordingly, the price is not deemed fixed and determinable at this time since JAKAFI is a new and novel product, JAKAFI is the first approved treatment for myelofibrosis, and JAKAFI is the first ever commercial product for Incyte.

Therefore, we recognize revenue once the specialty pharmacy has filled the patient's prescription for JAKAFI. This approach is frequently referred to as the "sell-through" revenue recognition model. Under the sell-through approach, revenue is recognized when the specialty pharmacy provides product to a patient based on the fulfillment of a prescription. Once the prescription has been filled and it is no longer in the specialty pharmacy's inventory, it may no longer be returned to Incyte by the specialty pharmacy.

We recognize revenues for prescriptions filled net of allowances for customer credits, including estimated rebates, discounts, returns, distribution service fees, patients assistance programs, and Medicare part D coverage gap reimbursements. Product shipping and handling costs are included in cost of sales.

*Customer Credits:* The specialty pharmacies are offered various forms of consideration including allowances, service fees and prompt payment discounts. We expect the specialty pharmacies will earn prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from product sales as they are earned.

*Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts are based upon contractual agreements or legal requirements with public sector (e.g. Medicaid) benefit providers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimates for expected utilization of rebates are based in part of third party market research data, and data received from the specialty pharmacies. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter's unpaid rebates. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Chargebacks:* Chargebacks are discounts that occur when contracted customers purchase directly from a specialty pharmacy, or an intermediary distributor. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or distributor, in turn, charges back to us the difference between the price initially paid by the specialty pharmacy or distributor and the discounted price paid to the specialty pharmacy or

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 1. Organization and Summary of Significant Accounting Policies (Continued)**

distributor by the customer. The allowance for chargebacks is based on known sales to contracted customers.

*Medicare Part D Coverage Gap:* Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the expected Medicare Part D coverage gap are based in part on third party market research data, and data received from the specialty pharmacies. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Co-payment assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

*Contract, License and Royalty Revenues*

Under agreements involving multiple deliverables, services and/or rights to use assets that we entered into prior to January 1, 2011, the multiple elements are divided into separate units of accounting when certain criteria are met, including whether the delivered items have stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. When separate units of accounting exist, consideration is allocated among the separate elements based on their respective fair values. The determination of fair value of each element is based on objective evidence from historical sales of the individual elements by us to other customers. If such evidence of fair value for each undelivered element of the arrangement does not exist, all revenue from the arrangement is deferred until such time that evidence of fair value for each undelivered element does exist or until all elements of the arrangement are delivered. When elements are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligation tied to the element is completed. When revenues for an element are not specifically tied to a separate earnings process, they are recognized ratably over the term of the agreement. We assess whether a substantive milestone exists at the inception of our agreements. For all milestones within our arrangements that are considered substantive, we recognize revenue upon the achievement of the associated milestone. If a milestone is not considered substantive, we would recognize the applicable milestone payment over the remaining period of performance under the arrangement. Further information about our collaborative arrangements can be found below in Note 5, *License Agreements*. As of December 31, 2011, all remaining potential milestones under our collaborative arrangements are considered substantive.

On January 1, 2011, updated guidance on the recognition of revenues for agreements with multiple deliverables became effective and applies to any agreements we may enter into on or after January 1, 2011. This updated guidance (i) relates to whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (ii) requires companies to allocate revenues in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (iii) eliminates the use of the residual method and requires companies to allocate revenues using the relative selling price method. During the year ended December 31, 2011, we did not enter into any agreements that are subject to this

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 1. Organization and Summary of Significant Accounting Policies (Continued)**

updated guidance. If we enter into an agreement with multiple deliverables after January 1, 2011, this updated guidance could have a material effect on our financial statements.

Our collaborations often include contractual milestones, which typically relate to the achievement of pre-specified development, regulatory and commercialization events. These three categories of milestone events reflect the three stages of the life-cycle of our drugs, which we describe in more detail in the following paragraph.

The regulatory review and approval process, which includes preclinical testing and clinical trials of each drug candidate, is lengthy, expensive and uncertain. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish a drug candidate's safety and efficacy. The approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Before commencing clinical investigations of a drug candidate in humans, we must submit an Investigational New Drug application ("IND"), which must be reviewed by the FDA.

The steps generally required before a drug may be marketed in the United States include preclinical laboratory tests, animal studies and formulation studies, submission to the FDA of an IND for human clinical testing, performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication, submission of a new drug application ("NDA") to the FDA for review and FDA approval of the NDA.

Similar requirements exist within foreign regulatory agencies as well. The time required to satisfy the FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity, which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. The FDA may raise concerns or questions about safety issues such as the conduct of the clinical trials as outlined in the IND, and any of these concerns or questions must be resolved before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence. Clinical trials involve the administration of the investigational drug or the marketed drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the institutional review board for a trial, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 1. Organization and Summary of Significant Accounting Policies (Continued)**

Generally, the milestone events contained in our collaboration agreements coincide with the progression of our drugs from development, to regulatory approval and then to commercialization. The process of successfully discovering a new development candidate, having it approved and successfully commercialized is highly uncertain. As such, the milestone payments we may earn from our partners involve a significant degree of risk to achieve. Therefore, as a drug candidate progresses through the stages of its life-cycle, the value of the drug candidate generally increases.

In connection with our collaborative research and license agreement with Novartis International Pharmaceutical Ltd. ("Novartis"), we received an upfront non-refundable payment of $150.0 million and an immediate $60.0 million milestone that was achieved prior to the execution of the collaboration. Accordingly, these milestones were not deemed substantive. The total amount of $210.0 million was recorded as deferred revenue and is being recognized on a straight-line basis through December 2013, our estimated performance period under the agreement. In connection with our collaborative research and license agreement with Eli Lilly and Company ("Lilly") executed in 2009, we received an upfront non-refundable payment of $90.0 million in January 2010. The $90.0 million upfront fee was recorded as deferred revenue in the accompanying balance sheet and is being recognized on a straight-line basis through December 2016, our estimated performance period under the agreement. In connection with our collaborative research and license agreement with Pfizer Inc. ("Pfizer"), we received an upfront non-refundable payment of $40.0 million in January 2006. The $40.0 million upfront fee was recorded as deferred revenue and was recognized on a straight-line basis over two years, our estimated performance period under the agreement. In February 2006 and October 2007, Pfizer purchased, for a total of $20.0 million, a convertible subordinated note due 2013 and a convertible subordinated note due 2014 (collectively, the "Pfizer Notes"). As the Pfizer Notes are non-interest bearing, they have been discounted to their net present value. The difference between the cash received and the present value of the Pfizer Notes, plus the related beneficial conversion feature, totals $3.2 million for each note, which represented additional consideration from Pfizer under the agreement. We have accounted for this additional consideration as deferred revenue and have recognized it over our estimated performance period under the agreement.

Revenues from licenses to our intellectual property are recognized when earned under the terms of the related agreements. Royalty revenues are recognized upon the sale of products or services to third parties by the licensee or other agreed upon terms. We estimate royalty revenues based on previous period royalties received and information provided by the third party licensee. We exercise judgment in determining whether the information provided by licensees is sufficiently reliable for us to base our royalty revenue recognition thereon.

*Research and Development.* It is our policy to expense research and development costs as incurred. We often contract with clinical research organizations ("CROs") to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Most professional fees, including project and clinical management, data management, monitoring, and medical

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 1. Organization and Summary of Significant Accounting Policies (Continued)**

writing fees are incurred throughout the contract period. These professional fees are expensed based on their percentage of completion at a particular date.

Our CRO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs, including shipping and printing fees. We expense the costs of pass through fees under our CRO contracts as they are incurred, based on the best information available to us at the time. The estimates of the pass through fees incurred are based on the amount of work completed for the clinical trial and are monitored through correspondence with the CROs, internal reviews and a review of contractual terms. The factors utilized to derive the estimates include the number of patients enrolled, duration of the clinical trial, estimated patient attrition, screening rate and length of the dosing regimen. CRO fees incurred to set up the clinical trial are expensed during the setup period.

*Other expenses.* We recognize other expenses in connection with our plans to exit certain activities including costs related to leased facilities to be abandoned or subleased, and other exit-related costs pursuant to formal plans developed by management. The recognition of other expenses requires our management to make judgments and estimates regarding the nature, timing, and amount of costs associated with the planned exit activity, including estimating sublease income and the fair value, less sales costs, of equipment to be disposed of. Management's estimates of future liabilities may change, requiring us to record additional restructuring charges or reduce the amount of liabilities already recorded. At the end of each reporting period, we evaluate the remaining accrued balances to ensure that they are adequate, that no excess accruals are retained, and that the utilization of the provisions are for their intended purposes in accordance with developed exit plans.

*Stock-Based Compensation.* Financial Accounting Standards Board ("FASB") accounting guidance for stock compensation requires all share-based payment transactions with employees, including grants of employee stock options, to be recognized as compensation expense over the requisite service period based on their fair values. The accounting guidance also requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value equity-based compensation and requires the recognition of the fair value of stock compensation in the statement of operations. We recorded $29.0 million, $14.9 million and $10.0 million of stock compensation expense for the years ended December 31, 2011, 2010 and 2009, respectively.

***Recent Accounting Pronouncements***

In April 2010, the FASB issued guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The guidance provides criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. We adopted this guidance on January 1, 2011, which had no impact on our consolidated financial statements.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Marketable Securities**

The following is a summary of our marketable security portfolio as of December 31, 2011 and 2010, respectively.

| | Amortized Cost | Net Unrealized Gains | Net Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| | | (in thousands) | | |
| December 31, 2011 | | | | |
| Mortgage backed securities | $ 3,343 | $ 1,087 | $ | $ 4,430 |
| | $ 3,343 | $ 1,087 | $ | $ 4,430 |
| December 31, 2010 | | | | |
| Mortgage backed securities | $ 4,904 | $ 1,352 | $ | $ 6,256 |
| | $ 4,904 | $ 1,352 | $ | $ 6,256 |

Because of the potential for prepayment on mortgage-backed securities, they are not categorized by contractual maturity.

***Fair Value Measurements***

FASB accounting guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability ("the exit price") in an orderly transaction between market participants at the measurement date. The standard outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value we use quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3 Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

Our marketable securities consist of investments in corporate debt securities, U.S. Treasury notes, and other U.S. government agency and non-agency mortgage-backed securities that are classified as available-for-sale.

At December 31, 2011 and 2010, our Level 2 mortgage backed securities are valued using readily available pricing sources which utilize market observable inputs, including the current interest rate and other characteristics for similar types of instruments.

Restricted cash and investments primarily consist of amounts held in escrow for interest payments on our 4.75% convertible senior notes through October 2012. The restricted investments consist of U.S. Treasury notes.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 2. Marketable Securities (Continued)**

The following fair value hierarchy table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2011 (in thousands):

| | Fair Value Measurement at Reporting Date Using: | | | |
|---|---|---|---|---|
| | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Balance as of December 31, 2011 |
| Cash and cash equivalents | $ 273,164 | $ | $ | $ 273,164 |
| Mortgage-backed securities | | 4,430 | | 4,430 |
| Restricted cash and investments | 19,294 | | | 19,294 |
| Total assets | $ 292,458 | $ 4,430 | $ | $ 296,888 |

The following fair value hierarchy table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2010 (in thousands):

| | Fair Value Measurement at Reporting Date Using: | | | |
|---|---|---|---|---|
| | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Balance as of December 31, 2010 |
| Cash and cash equivalents | $ 417,912 | $ | $ | $ 417,912 |
| Mortgage-backed securities | | 6,256 | | 6,256 |
| Restricted cash and investments | 37,876 | | | 37,876 |
| Total assets | $ 455,788 | $ 6,256 | $ | $ 462,044 |

Net realized gains (losses) of $0.2 million, 0.2 million and ($1.3) million from sale or impairment of marketable securities were included in "Interest and other income/(expense), net" in 2011, 2010 and 2009, respectively.

**Note 3. Concentrations of Credit Risk**

In November 2011 we began commercialization and distribution of JAKAFI to a limited number of specialty pharmacies. In December 2009, we entered into a license, development and commercialization agreement with Lilly. In November 2009, we entered into a collaboration and license agreement with Novartis. In November 2005, we entered into a collaborative research and license agreement with Pfizer, which became effective in January 2006.

A single customer contributed 84%, 61% and 58% of total revenues for the years ended December 31, 2011, 2010 and 2009, respectively.

Three customers comprised 72% and 92% of the accounts receivable balance as of December 31, 2011 and 2010, respectively.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 4. Inventory**

Inventories, stated at the lower of cost or market, consisted of raw materials of $3.5 million and $0.0 million at December 31, 2011 and 2010, respectively. For December 31, 2011 inventory is classified as non-current on the consolidated balance sheet as we do not expect this inventory to be consumed for commercial use within the next twelve months. We obtain a number of inventory components from single source suppliers due to technology, availability, price, quality or other considerations. The loss of a single source supplier, the deterioration of its relationship with a single source supplier, or any unilateral violation to the contractual terms under which we are supplied components by a single source supplier could adversely affect our total revenues and gross margins.

**Note 5. License Agreements**

***Novartis***

In November 2009, we entered into a Collaboration and License Agreement with Novartis International Pharmaceutical Ltd. Under the terms of the agreement, Novartis received exclusive development and commercialization rights outside of the United States to our JAK inhibitor 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 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 (also known as INC280) 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 $210.0 million and were initially eligible to receive up to $1.1 billion in milestone payments across multiple indications upon the achievement of pre-specified events, including up to $162.0 million for the achievement of development milestones, up to $450.0 million for the achievement of regulatory milestones and up to $500.0 million for the achievement of commercialization milestones. In 2011, we recognized and received a $15.0 million development milestone payment under this agreement for the achievement of a predefined milestone in an ongoing Phase I dose-escalation trial for INCB28060 in patients with solid tumors and a $10.0 million regulatory milestone payment for the JAKAFI approval in the United States. In 2010 we recognized and received $50.0 million in development milestone payments for the initiation of the global Phase III trial, RESPONSE, in patients with polycythemia vera. We determined the 2011 and 2010 milestones to be substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately 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 ruxolitinib in its respective territories, with costs of collaborative studies shared equally. Novartis is responsible for all costs relating to the development and commercialization of INCB28060 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.

We determined that there were two deliverables under the agreement: (i) the ex U.S. license for ruxolitinib and (ii) our obligations in connection with our participation on the joint development committee for myelofibrosis and polycythemia vera/essential thrombocythemia. We concluded that these

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 5. License Agreements (Continued)**

deliverables should be accounted for as a single unit of accounting and the $150.0 million upfront payment received in December 2009 and the immediate $60.0 million milestone payment received in January 2010 should be recognized on a straight line basis through December 2013 when we estimate we will complete our obligations in connection with our participation on the joint development committee, our estimated performance period under the agreement. We have no further substantive obligations to Novartis after the completion of our obligations in connection with the joint development committee.

At December 31, 2009, we recorded $10.9 million of reimbursable costs incurred prior to the effective date of the agreement as deferred revenue on the consolidated balance sheet. These costs will be recognized on a straight line basis through December 2013 consistent with the aforementioned upfront and milestone payments. Future reimbursable costs incurred after the effective date of the agreement with Novartis will be recorded net against the related research and development expenses. At December 31, 2011 and 2010, $2.3 million and $4.6 million of reimbursable costs are included in accounts receivable on the consolidated balance sheet. Research and development expenses for the year ended December 31, 2011, 2010 and 2009 were net of $3.6 million, $7.1 million and $1.5 million, respectively, of costs reimbursed by Novartis.

Contract revenue under the Novartis agreement was $79.1 million, $104.1 million and $5.4 million, respectively, for the years ended December 31, 2011, 2010 and 2009. Included in the amounts for December 31, 2011 and 2010, were $25.0 million and $50.0 million, respectively, in milestone payments received from Novartis.

***Lilly***

In December 2009, we entered into a License, Development and Commercialization Agreement with Eli Lilly and Company. Under the terms of the agreement, Lilly received exclusive worldwide development and commercialization rights to our JAK inhibitor INCB28050, now known as LY3009104, and certain back-up compounds for inflammatory and autoimmune diseases. We received an upfront payment of $90.0 million, and were initially eligible to receive up to $665.0 million in substantive milestone payments across multiple indications upon the achievement of pre-specified events, including up to $150.0 million for the achievement of development milestones, up to $365.0 million for the achievement of regulatory milestones and up to $150.0 million for the achievement of commercialization milestones. In 2010, we recognized and received a $30.0 million development milestone payment based upon the initial three month data in the Phase IIa clinical trial of LY3009104 for the treatment of rheumatoid arthritis and a $19.0 million development milestone payment for the Phase IIb clinical trial initiation of LY3009104 for the treatment of rheumatoid arthritis. We determined the 2010 milestones to be substantive as their achievement required substantive efforts by us and was at risk until the milestones were ultimately achieved. 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 JAK 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

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 5. License Agreements (Continued)**

funding 30% of the associated future global development costs for this indication from the initiation of a Phase IIb trial through regulatory approval. We have retained certain mechanisms to give us cost protection as LY3009104 advances in clinical development. We can defer our portion of co-development study costs by indication if they exceed a predetermined level. This deferment would be credited against future milestones or royalties and we would still be eligible for the full incremental royalties related to the co-development option. In addition, even if we have started co-development funding for any indication, we can at any time opt out for that indication and stop future co-development cost sharing. If we elect to do this we would still be eligible for our base royalties plus an incremental pro-rated royalty commensurate with our contribution to the total co-development cost for those indications for which we co-funded. 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.

We determined that there were two deliverables under the agreement: (i) the worldwide license and (ii) our obligations in connection with a co-development option. We concluded that these deliverables should be accounted for as a single unit of accounting and the $90.0 million upfront payment should be recognized on a straight line basis as revenue through December 2016, our estimated performance period under the agreement. Reimbursable costs incurred after the effective date with Lilly will be recorded net against the related research and development expenses. At December 31, 2011 and December 31, 2010, $0.0 million and $0.3 million, respectively, of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheet. Research and development expenses for the year ended December 31, 2011, 2010 and 2009 were net of $0.2 million, $2.8 million and $0.0 million, respectively, of costs reimbursed by Lilly.

Contract revenue under the Lilly agreement was $12.9 million, $61.9 million and $0.3 million, respectively, for the years ended December 31, 2011, 2010 and 2009. Included in the amount for the year ended December 31, 2010 was $49.0 million in connection with milestone payments received from Lilly.

***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 milestone payments.

Contract revenue under the Pfizer agreement was $3.0 million for the year ended December 31, 2010 in connection with the milestone payment received from Pfizer upon the initiation of a Phase I clinical trial involving a backup compound discovered by us subsequent to the effective date of the Pfizer agreement. We determined the 2010 milestone to be substantive since its achievement required substantive efforts by us and was at risk until the milestone was ultimately achieved.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 6. Property and Equipment**

Property and equipment consists of the following:

| | December 31, | |
|---|---|---|
| | 2011 | 2010 |
| | (in thousands) | |
| Office equipment | $ 1,490 | $ 888 |
| Laboratory equipment | 17,140 | 16,353 |
| Computer equipment | 12,354 | 10,375 |
| Leasehold improvements | 2,382 | 2,179 |
| | 33,366 | 29,795 |
| Less accumulated depreciation and amortization | (26,935) | (24,991) |
| | $ 6,431 | $ 4,804 |

Depreciation expense, including amortization expense of leasehold improvements, was $2.2 million, $1.1 million and $1.4 million for 2011, 2010 and 2009, respectively.

**Note 7. Intangible and Other Assets**

Intangible and other assets consist of the following (in thousands):

| | December 31, 2011 | | | December 31, 2010 | | |
|---|---|---|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Intangible Assets, Net | Gross Carrying Amount | Accumulated Amortization | Intangible Assets, Net |
| Debt issuance costs | $ 12,897 | $ (4,680) | $ 8,217 | $ 12,897 | $ (2,583) | $ 10,314 |
| Other assets | 2,105 | (2,105) | | 2,105 | (1,987) | 118 |
| Total intangible and other assets | $ 15,002 | $ (6,785) | $ 8,217 | $ 15,002 | $ (4,570) | $ 10,432 |

Debt issuance costs include costs incurred in connection with the private placements of our 4.75% Convertible Senior Notes due 2015 (the "4.75% Senior Notes"). Amortization expense for the years ended December 31, 2011, 2010 and 2009 related to intangible assets was $2.2 million, $2.1 million and $2.6 million, respectively.

**Note 8. Convertible Notes**

The components of the Convertible Notes are as follows (in thousands):

| | | | December 31, | |
|---|---|---|---|---|
| | December 31, | | Carrying Amount | |
| Debt | 2011 Interest Rates | Maturities | 2011 | 2010 |
| 4.75% Convertible Senior Notes due 2015 | 4.75% | 2015 | $ 298,193 | $ 276,445 |
| Pfizer Convertible Subordinated Note due 2013 | 0.0% | 2013 | 9,415 | 8,903 |
| Pfizer Convertible Subordinated Note due 2014 | 0.0% | 2014 | 8,545 | 8,084 |

| | | |
|---|---|---|
| Less current portion | | |
| | $ 316,153 | $ 293,432 |

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 8. Convertible Notes (Continued)**

Annual maturities of all Convertible Notes are as follows:

| | |
|---|---|
| 2012 | $ |
| 2013 | 10,000 |
| 2014 | 10,000 |
| 2015 | 400,000 |
| Thereafter | |
| | $ 420,000 |

The carrying amount and fair value of our Convertible Notes are as follows (in thousands):

| | December 31, | | | |
|---|---|---|---|---|
| | 2011 | | 2010 | |
| | Carrying Amount | Fair Value | Carrying Amount | Fair Value |
| 4.75% Convertible Senior Notes due 2015 | $ 298,193 | 753,760 | $ 276,445 | $ 832,400 |
| Pfizer Convertible Subordinated Note due 2013 | 9,415 | 9,415 | 8,903 | 8,903 |
| Pfizer Convertible Subordinated Note due 2014 | 8,545 | 8,545 | 8,084 | 8,084 |
| | $ 316,153 | $ 771,720 | $ 293,432 | $ 849,387 |

In September 2009, we completed the sale, in a private placement, of $400.0 million aggregate principal amount of our 4.75% Senior Notes, which resulted in net proceeds of approximately $387.4 million. Entities affiliated with Julian C. Baker, one of our directors and principal stockholders (the "Baker Entities"), purchased $160.0 million aggregate principal amount of 4.75% Senior Notes in this private placement.

The 4.75% Senior Notes bear interest at the rate of 4.75% per year, payable semi-annually on April 1 and October 1, and are due October 1, 2015. The Indenture governing the 4.75% Senior Notes (the "Indenture") contains a covenant that, among other things, limits our ability and the ability of any of our subsidiaries to incur additional indebtedness, create liens, or sell, lease, license, transfer or otherwise dispose of certain of our or their assets. This covenant is subject to a number of exceptions, limitations and qualifications set forth in the Indenture. We may not redeem the 4.75% Senior Notes prior to their scheduled maturity date. If we undergo a fundamental change, as defined in the Indenture, subject to certain conditions, holders may require us to repurchase their 4.75% Senior Notes at a purchase price equal to 100% of the principal amount being purchased, plus accrued and unpaid interest, up to the date of purchase. The 4.75% Senior Notes are convertible into shares of our common stock at an initial conversion rate of 113.9601 shares per $1,000 principal amount of the 4.75% Senior Notes, equivalent to an initial conversion price of approximately $8.78 per share. In addition, if, and to the extent, a holder elects to convert any 4.75% Senior Notes in connection with a make-whole fundamental change transaction, as defined in the Indenture, we will, under certain circumstances, increase the applicable conversion rate by a number of additional shares of our common stock.

In connection with the private placement of the 4.75% Senior Notes, we entered into a Pledge and Escrow Agreement, pursuant to which an aggregate of approximately $56.2 million was placed into an escrow account. Funds in the escrow account will be invested in Permitted Securities (as defined in the Pledge and Escrow Agreement), and a portion of the Permitted Securities may be redeemed or sold for cash to make each of the first six scheduled semi-annual interest payments on the 4.75% Senior Notes.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 8. Convertible Notes (Continued)**

Pursuant to the Pledge and Escrow Agreement, we have pledged our interest in the escrow account to the Trustee under the Indenture as security for these interest payments. The amounts held in escrow, totaling $19.0 million as of December 31, 2011, are included within restricted cash (short-term) in the consolidated balance sheet.

During the year ended December 31, 2009, through various privately negotiated transactions, we repurchased $96.2 million in face value of our 3½% Convertible Senior Notes due 2011 (the "3½% Senior Notes") and $131.0 million in face value of our 3½% Convertible Subordinated Notes due 2011 (the "3½% Subordinated Notes") . Among these transactions were the repurchases from the Baker Entities, a related party, of $38.3 million in face value of our 3½% Senior Notes at a purchase price equal to 98.74% of face value and $59.1 million in face value of our 3½% Subordinated Notes at a purchase price equal to 97.88% of face value. The prices paid by us in the repurchase transactions with the Baker Entities were equal to the weighted average prices paid by us to independent third parties in comparable transactions for the balance of the notes repurchased during this period.

In February 2010, the holders of $15.5 million aggregate principal amount of our 3½% Senior Notes and $1.4 million aggregate principal amount of our 3½% Subordinated Notes elected to convert their holdings into 1,502,851 shares of our common stock. On February 22, 2010 we redeemed all of the remaining outstanding 3½% Senior Notes and 3½% Subordinated Notes at a price equal to 100.5% of the principal amount of the notes plus accrued and unpaid interest of $0.1 million to the redemption date. We used a total of $158.6 million in cash to fund this redemption.

Due to the variable mix of common stock and series A preferred stock that would have been issued to satisfy the conversion of the 4.75% Senior Notes until we had reserved sufficient shares of our common stock, the embedded conversion feature was not considered indexed to our stock. As a result, the embedded conversion feature was not eligible for equity classification and was required to be bifurcated from the underlying debt instrument until we had reserved sufficient shares of our common stock. Accordingly, the fair value of the embedded conversion feature on September 30, 2009 of $148.1 million was recorded as a derivative liability and the carrying value of the 4.75% Senior Notes was reduced to reflect a debt discount equal to the fair value of the embedded conversion feature. The derivative liability related to the conversion feature was revalued on November 24, 2009, the date we increased the number of shares of our common stock authorized for issuance in an amount sufficient to satisfy conversion of the 4.75% Senior Notes. The fair value of the derivative liability was increased to $182.4 million as, among other factors, our stock price increased from September 30, 2009, and the change in fair market value of $34.3 million was recorded in earnings. As we had reserved sufficient shares of our common stock to satisfy the conversion provisions of the 4.75% Senior Notes, the conversion feature is considered indexed to our stock and the fair value of the conversion feature has been reclassified from a liability into stockholders' deficit at December 31, 2009. The debt discount related to the derivative liability is being amortized to interest expense over the six year term of the 4.75% Senior Notes using the effective interest method. We valued the embedded conversion feature using a single factor binomial lattice model, with the assistance of a valuation consultant. This model incorporates inputs such as stock price, historical volatility, risk free interest rate, equivalent bond yield, as well as assumptions about fundamental change and note holder behavior.

In connection with the collaborative research and license agreement, Pfizer purchased a $10.0 million principal amount Pfizer Note in February 2006 and an additional $10.0 million principal amount Pfizer Note in October 2007. The Pfizer Notes bear no interest, are due seven years from the date of issuance and are convertible into our common stock at initial conversion prices of $6.8423 and $9.75 per share,

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 8. Convertible Notes (Continued)**

respectively, subject to adjustments. At December 31, 2011 and 2010 the Pfizer Notes are subordinated to the 4.75% Senior Notes. We may, at our option, repay the Pfizer Notes beginning February 3, 2009 and October 10, 2010, respectively. Pfizer may require us to repay the Pfizer Notes upon a change of control, as defined. As the Pfizer Notes are non interest bearing, they have been discounted to their net present value of $6.8 million each by imputing interest at a rate of 4.5% and 3.9%, respectively, which represented market conditions in place at the time the notes were issued. The carrying value of the Pfizer Notes were $9.4 million and $8.5 million, respectively, at December 31, 2011. We will accrete the Pfizer Notes up to their face value over their term of seven years by recording interest expense under the effective interest method.

**Note 9. Stockholders' Deficit**

*Preferred Stock.* We are authorized to issue 5,000,000 shares of preferred stock, none of which was outstanding as of December 31, 2011. The Board of Directors may determine the rights, preferences and privileges of any preferred stock issued in the future. From September 30, 2009 to November 24, 2009 we had reserved 100,000 shares of preferred stock designated as series A preferred stock for issuance in connection with our 4.75% Senior Notes, as described in Note 7 above. On November 25, 2009, we filed a Certificate of Elimination of the Certificate of Designation of Series A Preferred Stock (the "Certificate of Elimination") with the Secretary of State of the State of Delaware relating to our Certificate of Designation of Series A Preferred Stock, which we had originally filed with the Secretary of State of the State of Delaware on September 29, 2009 (the "Certificate of Designation"). The Certificate of Elimination had the effect of eliminating from our Restated Certificate of Incorporation all matters set forth in the Certificate of Designation.

*Common Stock.* At the Special Meeting of Stockholders held on November 24, 2009, our stockholders approved an amendment to our Restated Certificate of Incorporation to increase the number of shares of common stock authorized for issuance from 200,000,000 shares to 400,000,000 shares. Following the Special Meeting of Stockholders, we filed a Certificate of Amendment of the Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to amend our Restated Certificate of Incorporation to effect the increase in the number of authorized shares of our common stock.

On September 30, 2009, we completed a public offering of 20,700,000 shares of our authorized but unissued common stock at a price to the public of $6.75 per share pursuant to an effective shelf registration statement, which resulted in net proceeds of approximately $132.3 million. The Baker Entities purchased an aggregate of 2,000,000 shares of common stock in this offering.

*Stock Compensation Plans.* As of December 31, 2011, we had reserved a total of 30,319,989 shares of our common stock for future issuance related to our stock plans as described below. Summaries of stock option activity for our stock option plans as of December 31, 2011, 2010 and 2009, and related information for the years ended December 31 are included in the plan descriptions below.

*1991 Stock Plan.* In November 1991, the Board of Directors adopted the 1991 Stock Plan (the "Stock Plan"), which was amended and restated for issuance of common stock to employees, consultants, and scientific advisors. Options issued under the plan are, at the discretion of the compensation committee of the Board of Directors, either incentive stock options, non-statutory stock options or restricted stock units. The exercise prices of incentive and non-statutory stock options granted under the plan are not less than the fair market value on the date of the grant, as determined by the Board of Directors. Options granted after February 2007 generally vest over three years, pursuant to a formula determined by our Board of

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 9. Stockholders' Deficit (Continued)**

Directors, and expire after seven years. Options granted prior to February 2007 generally vest over four years, pursuant to a formula determined by our Board of Directors, and expire after ten years. Certain options granted in 2002 vest pro rata monthly over three years and expire after ten years. In May 2009, our stockholders approved an increase in the number of shares of common stock reserved for issuance under the 1991 Plan from 29,350,000 to 30,475,000.

*2010 Stock Incentive Plan.* In May 2010 the Board of Directors adopted the 2010 Stock Incentive Plan (the "2010 Plan") for issuance of common stock to employees, non-employee directors, consultants, and scientific advisors. Options granted to employees, consultants, and scientific advisors under the 2010 Plan vest over three years, pursuant to a formula determined by our Board of Directors, and expire after seven years. Each new non-employee director joining the Board will receive an option to purchase 35,000 shares of common stock which vest over four years. Additionally, members who continue to serve on the Board will receive annual option grants for 20,000 shares exercisable in full on the first anniversary of the date of the grant. All options are exercisable at the fair market value of the stock on the date of grant. Non-employee director options expire after ten years. In May 2010, our stockholders approved the number of shares of common stock reserved for issuance under the 2010 Plan of 5,400,000 plus the number of shares of Common Stock previously approved by our stockholders and remaining available for issuance and not subject to outstanding awards under the 1991 Plan and the 1993 Directors' Stock Option Plan (the "Directors' Plan"), which was 653,475 shares. Upon the approval of the 2010 Plan, no further grants could be made under the 1991 Plan or the Directors' Plan. In May 2011, our stockholders approved an increase in the number of shares of common stock reserved for issuance under the 2010 Plan from 6,053,475 to 12,553,475.

Activity under the combined plans was as follows:

| | | Shares Subject to Outstanding Options | |
|---|---|---|---|
| | Shares Available for Grant | Shares | Weighted Average Exercise Price |
| Balance at December 31, 2008 | 5,390,467 | 14,982,476 | $ 8.67 |
| Additional authorization | 1,200,000 | | |
| Options granted | (3,250,000) | 3,250,000 | $ 3.24 |
| Options exercised | | (104,919) | $ 5.49 |
| Options expired | 76,974 | (76,974) | $ 10.45 |
| Options cancelled | 69,892 | (69,892) | $ 6.84 |
| Balance at December 31, 2009 | 3,487,333 | 17,980,691 | $ 7.71 |
| Additional authorization | 5,400,000 | | |
| Options granted | (4,138,584) | 4,138,584 | $ 10.87 |
| Options exercised | | (1,701,368) | $ 6.56 |
| Options expired | | (650) | $ 32.13 |
| Options cancelled | 37,945 | (309,334) | $ 8.54 |
| Balance at December 31, 2010 | 4,786,694 | 20,107,923 | $ 8.44 |
| Additional authorization | 6,500,000 | | |
| Options granted | (5,095,333) | 5,095,333 | $ 15.12 |
| Options exercised | | (2,294,586) | $ 7.17 |
| Options expired | | (592,085) | $ 17.44 |
| Options cancelled | 264,740 | (320,006) | $ 13.89 |

| | | | | |
|---|---|---|---|---|
| Balance at December 31, 2011 | 6,456,101 | 21,996,579 | $ | 9.78 |

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 9. Stockholders' Deficit (Continued)**

Options to purchase a total of 15,604,786, 14,795,496 and 13,083,297 shares as of December 31, 2011, 2010 and 2009, respectively, were exercisable and vested. The aggregate intrinsic value of options exercised for the years ended December 31, 2011, 2010 and 2009 were $23.5 million, $12.3 million and $0.2 million, respectively. At December 31, 2011 the aggregate intrinsic value of options outstanding and vested options are $117.0 million and $108.6 million, respectively.

The following table summarizes information about stock options outstanding as of December 31, 2011 for 2010 Plan:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number Outstanding | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $2.46 - $2.46 | 26,000 | 4.34 | $ 2.46 | 22,222 | $ 2.46 |
| $2.67 - $3.11 | 2,347,564 | 4.15 | $ 3.08 | 2,272,258 | $ 3.08 |
| $3.36 - $5.97 | 2,351,729 | 3.26 | $ 5.28 | 2,345,729 | $ 5.29 |
| $6.01 - $7.19 | 2,242,361 | 2.19 | $ 7.01 | 2,219,472 | $ 7.01 |
| $7.25 - $8.99 | 3,016,320 | 2.71 | $ 8.58 | 3,010,986 | $ 8.58 |
| $9.03 - $9.12 | 16,200 | 3.30 | $ 9.06 | 16,200 | $ 9.06 |
| $9.41 - $9.41 | 2,455,491 | 4.88 | $ 9.41 | 1,591,089 | $ 9.41 |
| $9.50 - $11.89 | 958,152 | 3.11 | $ 10.88 | 833,511 | $ 10.78 |
| $11.98 - $11.98 | 2,534,629 | 2.91 | $ 11.98 | 2,534,629 | $ 11.98 |
| $12.00 - $19.56 | 5,948,133 | 6.12 | $ 14.91 | 758,690 | $ 13.78 |
| | 21,896,579 | | | 15,604,786 | |

The above table excludes 100,000 restricted stock units granted to our Chief Executive Officer in December 2011.

*Employee Stock Purchase Plan.* On May 21, 1997, our stockholders adopted the 1997 Employee Stock Purchase Plan (the "ESPP"). In May 2009, our stockholders approved an increase in the number of shares of common stock available for grant from 4,600,000 shares to 5,350,000 shares. In May 2010, our stockholders approved an increase in the number of shares available for grant from 5,350,000 shares to 7,350,000 shares. In May 2011, our stockholders approved an increase in the number of shares available for grant from 7,350,000 shares to 8,350,000 shares. Each regular full-time and part-time employee working 20 hours or more per week is eligible to participate after one month of employment. We issued 896,939, 1,182,929 and 748,558 shares under the ESPP in 2011, 2010 and 2009, respectively. For the year ended December 31, 2011, 2010 and 2009 we recorded stock compensation expense of $1.0 million, $0.8 million and $0.6 million, respectively, as the ESPP is considered compensatory under the FASB stock compensation rules. As of December 31, 2011, 1,867,309 shares remain available for issuance under the ESPP.

**Note 10. Stock Compensation**

Under FASB accounting guidance for stock compensation, we recorded $29.0 million, $14.9 million and $10.0 million, respectively, of stock compensation expense on our audited consolidated statement of operations for the year ended December 31, 2011, 2010 and 2009. We utilized the Black-Scholes valuation

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 10. Stock Compensation (Continued)**

model for estimating the fair value of the stock compensation granted, with the following weighted-average assumptions:

| | Employee Stock Options For the Year Ended December 31, | | | Employee Stock Purchase Plan For the Year Ended December 31, | | |
|---|---|---|---|---|---|---|
| | 2011 | 2010 | 2009 | 2011 | 2010 | 2009 |
| Average risk-free interest rates | 0.97% | 1.10% | 1.06% | 0.53% | 0.66% | 0.96% |
| Average expected life (in years) | 3.30 | 2.97 | 2.95 | 0.50 | 0.50 | 0.50 |
| Volatility | 71% | 74% | 72% | 36% | 46% | 78% |
| Weighted-average fair value (in dollars) | 7.33 | 5.23 | 1.52 | 1.28 | 0.64 | 0.78 |

The risk-free interest rate is derived from the U.S. Federal Reserve rate in effect at the time of grant. The expected life calculation is based on the observed and expected time to the exercise of options by our employees based on historical exercise patterns for similar type options. Expected volatility is based on the historical volatility of our common stock over the period commensurate with the expected life of the options. A dividend yield of zero is assumed based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

Based on our historical experience, we have assumed an annualized forfeiture rate of 5% for our options. Under the true-up provisions of SFAS 123R, we will record additional expense if the actual forfeiture rate is lower than we estimated, and will record a recovery of prior expense if the actual forfeiture is higher than we estimated.

Total compensation cost of options granted but not yet vested, as of December 31, 2011, was $18.2 million, which is expected to be recognized over the weighted average period of 3.10 years.

**Note 11. Income Taxes**

A reconciliation of income taxes at the U.S. federal statutory rate to the provision for income taxes is as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2011 | 2010 | 2009 |
| Benefit at U.S. federal statutory rate | $ (65,289) | $ (11,146) | $ (74,155) |
| Unbenefitted net operating losses and tax credits | 57,102 | (1,451) | 59,012 |
| Non-deductible derivative liabilities | | | 12,005 |
| Non-deductible amortization of debt discount | 7,612 | 6,937 | 1,655 |
| Expiring capital loss carryforward | | 5,371 | |
| Other | 575 | 289 | 1,483 |
| Provision for income taxes | $ | $ | $ |

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 11. Income Taxes (Continued)**

Significant components of our deferred tax assets are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2011 | 2010 |
| Deferred tax assets: | | |
| Federal and state net operating loss carryforwards | $ 488,000 | $ 408,000 |
| Federal and state research credits | 91,000 | 73,000 |
| Capitalized research and development | 20,000 | 25,000 |
| Deferred revenue and accruals | 72,000 | 98,000 |
| Non-cash compensation | 17,000 | 11,000 |
| Investments | 6,000 | 5,000 |
| Other, net | (1,000) | 1,000 |
| Total gross deferred tax assets | 693,000 | 621,000 |
| Less valuation allowance for deferred tax assets | (693,000) | (621,000) |
| Net deferred tax assets | $ | $ |

The valuation allowance for deferred tax assets increased by approximately $72.0 million, $11.0 million and $68.0 million during the years ended December 31, 2011, 2010 and 2009, respectively. Management believes the uncertainty regarding the realization of net deferred tax assets requires a full valuation allowance.

As of December 31, 2011, we had federal and state net operating loss carryforwards of approximately $1.2 billion that will expire at various dates beginning in 2021 through 2031, if not utilized. Our ability to utilize these NOLs may be limited under Internal Revenue Code Section 382 ("Section 382"). Section 382 imposes annual limitations on the utilization of NOL carryfowards and other tax attributes upon an ownership change. In general terms, an ownership change may result from transactions that increase the aggregate ownership of certain stockholders in our stock by more than 50 percentage points over a testing period (generally three years). These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

We completed a Section 382 analysis during 2010. Based on this analysis, our NOLs and other tax attributes accumulated through 2010 should not be limited under Section 382. We have not yet updated our Section 382 analysis through 2011. Our future utilization of all of our NOLs and other tax attributes is dependent upon our ability to generate sufficient income during the carryforward periods and no future significant changes in ownership. When tax attributes are used, NOLs are used before tax credits and this will likely result in expiration of the tax credits.

We adopted the FASB uncertain tax positions guidance on January 1, 2007. We had no unrecognized tax benefits as of January 1, 2007 and provide a full valuation allowance on the net deferred tax asset recognized in the consolidated financial statements. As a result, the adoption effective January 1, 2007 had no effect on our financial position as of such date, or on net operating losses available to offset future taxable income.

We recognize interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2011 and 2010, we did not accrue any interest related to uncertain tax positions. Due

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 11. Income Taxes (Continued)**

to NOL and tax credit carryforwards, all income tax returns filed by us are subject to examination by the taxing jurisdictions.

In connection with the adoption of stock-based compensation guidance in 2006, we elected to follow the with-and-without approach to determine the sequence in which deductions and NOL carryforwards are utilized. Accordingly, no tax benefit related to stock options was recognized in any year as a result of the utilization of NOL carryforwards to offset any taxable income. The table of deferred tax assets shown above does not include certain deferred tax assets at December 31, 2011 and 2010 that arose directly from tax deductions related to equity compensation in excess of compensation recognized for book purposes. Additional paid in capital will be increased by approximately $72.2 million if and when such deferred tax assets are ultimately realized.

At December 31, 2011, we also had federal and state research and development tax credit carryforwards of approximately $93.1 million that will expire at various dates, beginning in 2012 through 2031, if not utilized.

**Note 12. Net Loss Per Share**

For all periods presented, both basic and diluted net loss per common share are computed by dividing the net loss by the number of weighted average common shares outstanding during the period. Stock options and potential common shares issuable upon conversion of the 4.75% Senior Notes, the 3 1/2% Senior Notes, the 3 1/2% Subordinated Notes and the Pfizer Notes were excluded from the computation of diluted net loss per share, as their share effect was anti-dilutive for all periods presented.

The potential common shares that were excluded from the diluted net loss per share computation are as follows:

| | 2011 | 2010 | 2009 |
|---|---|---|---|
| Outstanding stock options | 21,996,579 | 20,107,923 | 17,980,691 |
| Common shares issuable upon conversion of 4.75% Senior Notes | 45,584,040 | 45,584,040 | 45,584,040 |
| Common shares issuable upon conversion of 3 1/2% Senior Notes(1) | | | 4,991,667 |
| Common shares issuable upon conversion of 3 1/2% Subordinated Notes(1) | | | 10,608,462 |
| Common shares issuable upon conversion of Pfizer Note due 2013 | 1,461,496 | 1,461,496 | 1,461,496 |
| Common shares issuable upon conversion of Pfizer Note due 2014 | 1,025,641 | 1,025,641 | 1,025,641 |
| Total potential common shares excluded from diluted net loss per share computation | 70,067,756 | 68,179,100 | 81,651,997 |

(1) In February 2010, the holders of $15.5 million of aggregate principal amount of the 3 1/2% Senior Notes and $1.4 million aggregate principal amount of the 3 1/2% Subordinated Notes elected to convert their holdings into 1,502,851 shares of common stock. On February 22, 2010 we redeemed all of the remaining outstanding 3 1/2% Senior Notes and 3 1/2%

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 12. Net Loss Per Share (Continued)**

Subordinated Notes and, as such, common shares issuable upon conversion of the 3 1/2% Senior Notes and 3 1/2% Subordinated Notes will no longer be excluded from the diluted net loss per share computation.

**Note 13. Defined Contribution Plan**

We have a defined contribution plan qualified under Section 401(k) of the Internal Revenue Code covering all domestic employees. Employees may contribute a portion of their compensation, which is then matched by us, subject to certain limitations. Defined contribution expense was $0.9 million, $0.7 million and $0.6 million in 2011, 2010 and 2009, respectively.

**Note 14. Related Party Transactions**

The following summarizes our related party transactions. In each of the transactions noted in which a director of Incyte was at the time of the transaction in some way affiliated with the other party to the transaction, such director recused himself from voting on the related party transaction.

On September 30, 2009, we completed a public offering of 20,700,000 shares of our authorized but unissued common stock at a price to the public of $6.75 per share pursuant to an effective shelf registration statement, which resulted in net proceeds of approximately $132.3 million. The Baker Entities purchased an aggregate of 2,000,000 shares of our common stock in this offering.

On September 30, 2009, we completed the sale, in a private placement, of $400.0 million aggregate principal amount of our 4.75% Senior Notes, which resulted in net proceeds of approximately $387.4 million. The Baker Entities purchased $160.0 million aggregate principal amount of 4.75% Senior Notes in this private placement, which they hold as of December 31, 2011. Through various privately negotiated transactions, we repurchased $96.2 million in face value of our 3 1/2% Senior Notes and $131.0 million in face value of our 3 1/2% Subordinated Notes. Among these transactions were the repurchases from the Baker Entities of $38.3 million in face value of our 3 1/2% Senior Notes at a purchase price equal to 98.74% of face value and $59.1 million in face value of our 3 1/2% Subordinated Notes at a purchase price equal to 97.88% of face value. The prices paid by us in the repurchase transactions with the Baker Entities were equal to the weighted average prices paid by us to independent third parties in comparable transactions for the balance of the notes repurchased during this period.

**Note 15. Commitments**

As of December 31, 2011, we had a non-cancelable operating lease for our corporate headquarters facility in Wilmington, Delaware. This lease expires in June 2013. Rent expense for the years ended December 31, 2011, 2010 and 2009, was approximately $5.8 million, $5.4 million and $5.4 million, respectively.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 15. Commitments (Continued)**

As of December 31, 2011, future non-cancelable minimum payments under operating leases, including leases for sites included in the restructuring programs were as follows:

| Year ended December 31, | Operating Leases (in thousands) |
|---|---|
| 2012 | $ 6.2 |
| 2013 | 3.1 |
| 2014 | |
| Total minimum lease payments | $ 9.3 |

The table above excludes certain commitments that are contingent upon future events. The most significant of these contractual commitments that we consider to be contingent obligations are summarized below.

Commitments related to Maxia Pharmaceuticals, Inc. are considered contingent commitments as future events must occur to cause these commitments to be enforceable. In February 2003, we completed our acquisition of Maxia. Under the merger agreement, former Maxia stockholders have the right to receive certain earn out amounts of up to a potential aggregate amount of $14.0 million upon the occurrence of certain research and development milestones set forth in the merger agreement. None of these milestones has been achieved as of December 31, 2011.

We have entered into and may in the future seek to license additional 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, milestone payments, and royalties on sales of future products.

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**INCYTE CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 16. Interim Consolidated Financial Information (Unaudited)**

**(in thousands, except per share data)**

| | Fiscal 2011 Quarter Ended | | | |
|---|---|---|---|---|
| | **March 31** | **June 30** | **September 30** | **December 31** |
| Revenues(1) | 31,973 | 16,811 | 16,782 | 28,889 |
| Net loss | (26,512) | (51,870) | (53,078) | (55,080) |
| Basic and diluted net loss per share | (0.21) | (0.41) | (0.42) | (0.44) |
| Shares used in computation of basic and diluted net loss per share | 123,467 | 125,330 | 126,260 | 126,388 |

| | Fiscal 2010 Quarter Ended | | | |
|---|---|---|---|---|
| | **March 31** | **June 30** | **September 30** | **December 31** |
| Revenues(2) | 17,288 | 49,847 | 16,872 | 85,870 |
| Net income (loss) | (35,729) | 3,044 | (31,701) | 32,541 |
| Basic net income (loss) per share | (0.30) | 0.03 | (0.26) | 0.26 |
| Diluted net income (loss) per share | (0.30) | 0.02 | (0.26) | 0.24 |
| Shares used in computation of basic net income (loss) per share | 119,727 | 121,630 | 122,189 | 122,966 |
| Shares used in computation of diluted net income (loss) per share | 119,727 | 128,291 | 122,189 | 180,204 |

(1) In November 2009 and December 2009, we entered into a collaborative research and license agreements with Novartis and Lilly, respectively. The quarters ended March 31, 2011, June 30, 2011, September 30, 2011 and December 31, 2011 include $31.8 million, $16.7 million, $16.7 million and $26.7 million, respectively of contract revenues relating to these agreements. The quarter ended December 31, 2011 also includes product revenues, net of $2.0 million related to JAKAFI.

(2) In November 2009 and December 2009, we entered into a collaborative research and license agreements with Novartis and Lilly, respectively. The quarters ended March 31, 2010, June 30, 2010, September 30, 2010 and December 31, 2010 include $16.7 million, $46.7 million, $16.7 million and $85.7 million, respectively of contract revenues relating to these agreements. In November 2005, we entered into a collaborative research and license agreement with Pfizer, which became effective in January 2006. The June 30, 2010 quarter includes $3.0 million of contract revenues relating to this agreement.

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**Item 9.** ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

**Item 9A.** ***Controls and Procedures***

*Evaluation of disclosure controls and procedures.* We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Changes in internal control over financial reporting.* There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the quarter ended December 31, 2011, that materially affected or are reasonably likely to materially affect our internal control over financial reporting, except as follows: we added additional controls related to the commercialization of JAKAFI, including controls related to product revenue recognition, inventory costing and inventory management.

*Management's annual report on internal control over financial reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2011. The effectiveness of our internal control over financial reporting as of December 31, 2011 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Incyte Corporation

We have audited Incyte Corporation's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control  Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Incyte Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Incyte Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Incyte Corporation as of December 31, 2011 and 2010, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2011 of Incyte Corporation and our report dated February 22, 2012 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Philadelphia, Pennsylvania
February 22, 2012

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**Item 9B.** ***Other Information***

None.

## PART III

**Item 10.** ***Directors, Executive Officers and Corporate Governance***

The information required by this item (with respect to Directors) is incorporated by reference from the information under the caption "Election of Directors" contained in our Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for our 2012 Annual Meeting of Stockholders to be held on May 30, 2012 (the "Proxy Statement"). Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption "Executive Officers of the Registrant" and is incorporated herein by reference.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. This disclosure is contained in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees, including our Chief Executive Officer, Chief Financial Officer, Corporate Controller and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics sets forth the basic principles that guide the business conduct of our employees. We have also adopted a Senior Financial Officers' Code of Ethics that specifically applies to our Chief Executive Officer, Chief Financial Officer, Corporate Controller, and others providing similar functions. Stockholders may request a free copy of our Code of Business Conduct and Ethics and our Senior Financial Officers' Code of Ethics by contacting Incyte Corporation, Attention: Investor Relations, Experimental Station, Route 141 & Henry Clay Road, Building E336, Wilmington, DE 19880.

To date, there have been no waivers under our Code of Business Conduct and Ethics or Senior Financial Officers' Code of Ethics. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics or Senior Financial Officers' Code of Ethics or any waivers, if and when granted, of our Code of Business Conduct and Ethics or Senior Financial Officers' Code of Ethics on our website at *http://www.incyte.com* within four business days following the date of such amendment or waiver.

Our Board of Directors has appointed an Audit Committee of three directors, currently comprised of Mr. Barry M. Ariko, as Chairman, Mr. Roy A. Whitfield and Ms. Wendy Dixon. The Board of Directors has also determined that Mr. Ariko and Mr. Whitfield are each qualified as Audit Committee Financial Experts under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an "independent director" under the applicable standards of The NASDAQ Stock Market.

**Item 11.** ***Executive Compensation***

The information required by this item is incorporated by reference from the information under the captions "Election of Directors  Compensation of Directors" and "Executive Compensation" contained in the Proxy Statement.

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**Item 12.** ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item is incorporated by reference from the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement.

**Item 13.** ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item is incorporated by reference from the information under the captions "Certain Relationships and Related Transactions" and "Election of Directors  Director Independence" contained in the Proxy Statement.

**Item 14.** ***Principal Accountant Fees and Services***

The information required by this item is incorporated by reference from the information under the caption "Principal Accountant Fees and Services" contained in the Proxy Statement.

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**PART IV**

**Item 15.** ***Exhibits, Financial Statement Schedules***

**(a)**

**Documents filed as part of this report:**

(1)

Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Incyte Corporation under Item 8 of Part II hereof.

(2)

Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Consolidated Financial Statements or the Notes thereto.

(3)

Exhibits
See Item 15(b) below. Each management contract or compensatory plan or arrangement required to be filed has been identified.

**(b)**

**Exhibits**

| Exhibit Number | Description of Document |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated as of November 11, 2002, by and among the Company, Maxia Pharmaceuticals, Inc. and other parties signatory thereto (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed February 25, 2003). |
| 2.2 | Amendment to Agreement and Plan of Merger, dated as of December 19, 2002, by and among the Company, Monaco Acquisition Corporation, Maxia Pharmaceuticals, Inc. and Maxia Pharmaceuticals, LLC (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed February 25, 2003). |
| 3(i) | Integrated copy of the Restated Certificate of Incorporation, as amended, of the Company (incorporated by reference to Exhibit 3(i) to the Company's Annual Report on Form 10-K for the year ended December 31, 2009). |
| 3(ii) | Bylaws of the Company, as amended as of September 16, 2008 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed September 18, 2008). |
| 4.1 | Form of Common Stock Certificate (incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the year ended December 31, 2002). |
| 4.2.1 | Form of Convertible Subordinated Promissory Note (incorporated by reference to Exhibit 4.1 the Company's Current Report on Form 8-K/A filed February 6, 2006). |
| 4.2.2 | Schedule of notes issued by the Company in the form of Exhibit 4.2.1 (incorporated by reference to the Exhibit 4.3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008). |
| 4.3 | Indenture, dated as of September 30, 2009, between the Company and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 30, 2009). |

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| Exhibit Number | Description of Document |
|---|---|
| 10.1# | 1991 Stock Plan of Incyte Corporation, as amended (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009). |
| 10.2# | Form of Incentive Stock Option Agreement under the 1991 Plan (incorporated by reference to the exhibit of the same number to the Company's Registration Statement on Form S-1 (File No. 33-68138)). |
| 10.3# | Form of Nonstatutory Stock Option Agreement under the 1991 Plan (incorporated by reference to the exhibit of the same number to the Company's Registration Statement on Form S-1 (File No. 33-68138)). |
| 10.4# | 1993 Directors' Stock Option Plan of Incyte Corporation, as amended (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009). |
| 10.5# | Form of Indemnity Agreement between the Company and its directors and officers (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 33-68138)). |
| 10.7# | 1997 Employee Stock Purchase Plan of Incyte Corporation, as amended (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 20, 2011). |
| 10.8# | Form of Restricted Stock Unit Agreement under the 1991 Stock Plan of Incyte Corporation (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001). |
| 10.9# | Offer of Employment Letter, dated November 21, 2001, from the Company to Paul A. Friedman (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001). |
| 10.10.1# | Employment Agreement, dated November 26, 2001, between Paul A. Friedman and the Company (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001). |
| 10.10.2# | Amendment to Employment Agreement, effective as of January 1, 2009, between the Company and Paul A. Friedman. (incorporated by reference to Exhibit 10.10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008). |
| 10.11.1 | Sublease Agreement, dated June 16, 2003, between E. I. DuPont de Nemours and Company and the Company (incorporated by reference to Exhibit 10.45 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003). |
| 10.11.2 | Sixth Amendment of Lease, dated December 15, 2009, by and between E. I. DuPont de Nemours and Company and the Company (incorporated by reference to Exhibit 10.11.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009). |
| 10.12# | Offer of Employment Letter, dated September 2, 2003, from the Company to David C. Hastings (incorporated by reference to Exhibit 10.46 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003). |
| 10.13# | Offer of Employment Letter, dated September 10, 2008, from the Company to Patricia S. Andrews (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008). |

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| Exhibit Number | Description of Document |
|---|---|
| 10.14.1# | Form of Employment Agreement, effective as of November 21, 2003 between the Company and David C. Hastings, Richard S. Levy, Paula J. Swain, (effective date of December 8, 2003) and Patricia S. Andrews (effective date of October 20, 2008) (incorporated by reference to Exhibit 10.48 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003). |
| 10.14.2# | Form of Amendment to Employment Agreement, effective as of January 1, 2009, between the Company and Patricia S. Andrews, David C. Hastings, Richard S. Levy, and Paula J. Swain. (incorporated by reference to Exhibit 10.15.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008). |
| 10.14.3# | Form of Employment Agreement, effective as of August 8, 2011, between the Company and Eric H. Siegel (incorporated by reference to Exhibit 10.14.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011. |
| 10.15 | Collaborative Research and License Agreement, dated as of November 18, 2005, by and between the Company and Pfizer Inc. (incorporated by reference to Exhibit 10.49 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005). |
| 10.16 | Note Purchase Agreement, dated as of November 18, 2005, by and between the Company and Pfizer Overseas Pharmaceuticals (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed February 6, 2006). |
| 10.17 | Amendment No. 1 to the Note Purchase Agreement, by and between the Company and Pfizer Overseas Pharmaceuticals, dated as of January 4, 2007 (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the year ended December 31, 2006). |
| 10.18 | Amendment No. 2 to the Note Purchase Agreement, by and among the Company, Pfizer Ireland Pharmaceuticals, and Pfizer Inc., dated as of October 10, 2007 (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2007). |
| 10.19 | Pledge and Escrow Agreement, dated as of September 30, 2009, by and among the Company, U.S. Bank National Association, as trustee, and U.S. Bank National Association, as escrow agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 30, 2009). |
| 10.20 | Letter Agreement dated September 24, 2009 among the Company and the entities named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 30, 2009). |
| 10.21 | Collaboration and License Agreement, entered into as of November 24, 2009, by and between the Company and Novartis International Pharmaceutical Ltd. (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009). |
| 10.22 | License, Development and Commercialization Agreement, entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009). |
| 10.23# | Incyte Corporation 2010 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 20, 2011). |

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| Exhibit Number | Description of Document |
|---|---|
| 10.24# | Form of Incentive Stock Option Agreement under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 20, 2010). |
| 10.25# | Form of Nonstatutory Stock Option Agreement under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 20, 2010) |
| 10.26# | Form of Nonstatutory Stock Option Agreement for Outside Directors under the 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed May 20, 2010). |
| 10.27 | Amendment, dated June 22, 2010, to License, Development and Commercialization Agreement entered into as of December 18, 2009, by and between the Company and Eli Lilly and Company (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010). |
| 10.28#* | Form of Restricted Stock Unit Agreement under the 2010 Stock Incentive Plan. |
| 10.29#* | Letter agreement, dated December 20, 2011, between the Company and Paul A. Friedman. |
| 12.1* | Computation of Ratios of Earnings to Fixed Charges. |
| 21.1* | Subsidiaries of the Company. |
| 23.1* | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. |
| 24.1* | Power of Attorney (see page 104 of this Form 10-K). |
| 31.1* | Rule 13a-14(a) Certification of the Chief Executive Officer. |
| 31.2* | Rule 13a-14(a) Certification of the Chief Financial Officer. |
| 32.1** | Statement of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C Section 1350). |
| 32.2** | Statement of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C Section 1350). |
| 101.INS*** | XBRL Instance Document |
| 101.SCH*** | XBRL Taxonomy Extension Schema Document |
| 101.CAL*** | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB*** | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE*** | XBRL Taxonomy Presentation Linkbase Document |
| 101.DEF*** | XBRL Taxonomy Definition Linkbase Document |

*
Filed herewith.

**
In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for

purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be

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incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

***

In accordance with Rule 406T of Regulation S-T, the information furnished in these exhibits will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act or Exchange Act.

Confidential treatment has been requested with respect to certain portions of these agreements.

#

Indicates management contract or compensatory plan or arrangement.

**(c) Financial Statements and Schedules**

Reference is made to Item 15(a)(2) above.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INCYTE CORPORATION

By: /s/ PAUL A. FRIEDMAN

Paul A. Friedman
*Chief Executive Officer*

Date: February 22, 2012

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul A. Friedman, David C. Hastings, and Eric H. Siegel, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ PAUL A. FRIEDMAN<br>Paul A. Friedman | Chief Executive Officer (Principal Executive Officer) and Director | February 22, 2012 |
| /s/ DAVID C. HASTINGS<br>David C. Hastings | Chief Financial Officer (Principal Financial Officer) and Director | February 22, 2012 |
| /s/ LAURENT CHARDONNET<br>Laurent Chardonnet | Vice President, Finance and Treasurer (Principal Accounting Officer) | February 22, 2012 |
| /s/ RICHARD U. DESCHUTTER<br>Richard U. Deschutter | Chairman | February 22, 2012 |
| /s/ BARRY M. ARIKO<br>Barry M. Ariko | Director | February 22, 2012 |
| /s/ JULIAN C. BAKER<br>Julian C. Baker | Director | February 22, 2012 |
| /s/ PAUL A. BROOKE<br>Paul A. Brooke | Director | February 22, 2012 |
| /s/ WENDY L. DIXON<br>Wendy L. Dixon | Director | February 22, 2012 |
| /s/ JOHN F. NIBLACK<br>John F. Niblack | Director | February 22, 2012 |
| /s/ ROY A. WHITFIELD | Director | February 22, 2012 |

Roy A. Whitfield

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**EXHIBIT INDEX**

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|---|---|
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| 4.1 | Form of Common Stock Certificate (incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the year ended December 31, 2002). |
| 4.2.1 | Form of Convertible Subordinated Promissory Note (incorporated by reference to Exhibit 4.1 the Company's Current Report on Form 8-K/A filed February 6, 2006). |
| 4.2.2 | Schedule of notes issued by the Company in the form of Exhibit 4.2.1 (incorporated by reference to the Exhibit 4.3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008). |
| 4.3 | Indenture, dated as of September 30, 2009, between the Company and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 30, 2009). |
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|---|---|
| 10.7# | 1997 Employee Stock Purchase Plan of Incyte Corporation, as amended (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 20, 2011). |
| 10.8# | Form of Restricted Stock Unit Agreement under the 1991 Stock Plan of Incyte Corporation (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001). |
| 10.9# | Offer of Employment Letter, dated November 21, 2001, from the Company to Paul A. Friedman (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001). |
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| 10.10.2# | Amendment to Employment Agreement, effective as of January 1, 2009, between the Company and Paul A. Friedman. (incorporated by reference to Exhibit 10.10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008). |
| 10.11.1 | Sublease Agreement, dated June 16, 2003, between E. I. DuPont de Nemours and Company and the Company (incorporated by reference to Exhibit 10.45 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003). |
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|---|---|
| 10.16 | Note Purchase Agreement, dated as of November 18, 2005, by and between the Company and Pfizer Overseas Pharmaceuticals (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed February 6, 2006). |
| 10.17 | Amendment No. 1 to the Note Purchase Agreement, by and between the Company and Pfizer Overseas Pharmaceuticals, dated as of January 4, 2007 (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the year ended December 31, 2006). |
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| 10.28#* | Form of Restricted Stock Unit Agreement under the 2010 Stock Incentive Plan. |

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|---|---|
| 10.29#* | Letter agreement, dated December 20, 2011, between the Company and Paul A. Friedman. |
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| 101.LAB*** | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE*** | XBRL Taxonomy Presentation Linkbase Document |
| 101.DEF*** | XBRL Taxonomy Definition Linkbase Document |

*
Filed herewith.

**
In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

***
In accordance with Rule 406T of Regulation S-T, the information furnished in these exhibits will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act or Exchange Act.

Confidential treatment has been requested with respect to certain portions of these agreements.

#
Indicates management contract or compensatory plan or arrangement.

Copies of above exhibits not contained herein are available to any stockholder upon written request to: Investor Relations, Incyte Corporation, Experimental Station, Route 141 & Henry Clay Road, Building E336, Wilmington, DE 19880.

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