INCYTE CORP
Form 10-Q
October 27, 2011
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 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 or 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 executive offices)	(Zip Code)

(302) 498-6700

(Registrant s telephone number, including area code)

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. x Yes o No

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). x Yes o No

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 x	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). o Yes x No

The number of outstanding shares of the registrant s Common Stock, $0.001 par value, was 126,305,547 as of October 20, 2011.

Table of Contents

INCYTE CORPORATION

INDEX

Table of Contents

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

INCYTE CORPORATION

Condensed Consolidated Balance Sheets

(in thousands)

	September 30, 2011 (unaudited)	December 31, 2010*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 312,328	$ 417,912
Marketable securities available-for-sale	4,647	6,256
Restricted cash and investments	18,997	18,985
Accounts receivable, net	2,462	5,701
Prepaid expenses and other current assets	7,984	6,600
Total current assets	346,418	455,454
Restricted cash and investments	9,985	18,891
Property and equipment, net	6,077	4,804
Other assets	8,744	10,432
Total assets	$ 371,224	$ 489,581
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 11,038	$ 10,773
Accrued compensation	13,608	14,678
Interest payable	9,500	4,750
Accrued and other current liabilities	19,838	15,703
Deferred revenue	66,973	66,973
Accrued restructuring		696
Total current liabilities	120,957	113,573
Convertible senior notes	292,566	276,445
Convertible subordinated notes	17,711	16,987
Deferred revenue	121,010	171,220
Total liabilities	552,244	578,225
Stockholders deficit:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of September 30, 2011 and December 31, 2010		

Common stock, $0.001 par value; 400,000,000 shares authorized; 126,289,976 and 123,280,474 shares issued and outstanding as of September 30, 2011 and December 31, 2010, respectively		126		123
Additional paid-in capital		1,371,524		1,332,277
Accumulated other comprehensive gain		1,821		1,986
Accumulated deficit		(1,554,491)		(1,423,030)
Total stockholders deficit		(181,020)		(88,644)
Total liabilities and stockholders deficit	$	371,224	$	489,581

* The condensed consolidated balance sheet at December 31, 2010 has been derived from the audited financial statements at that date.

See accompanying notes.

Table of Contents

INCYTE CORPORATION

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Contract revenues	$ 16,737	$ 16,737	$ 65,211	$ 83,212
License and royalty revenues	45	135	354	796
Total revenues	16,782	16,872	65,565	84,008
Costs and expenses:				
Research and development	44,604	30,609	126,830	91,106
Selling, general and administrative	14,282	8,458	37,067	21,563
Other expenses		(139)	712	(399)
Total costs and expenses	58,886	38,928	164,609	112,270
Loss from operations	(42,104)	(22,056)	(99,044)	(28,262)
Interest and other income, net	45	212	249	549
Interest expense	(11,019)	(10,515)	(32,666)	(32,686)
Loss on debt redemption				(3,988)
Loss before income taxes	(53,078)	(32,359)	(131,461)	(64,387)
Provision for income taxes		(658)		
Net loss	$ (53,078)	$ (31,701)	$ (131,461)	$ (64,387)
Basic and diluted net loss per share:	$ (0.42)	$ (0.26)	$ (1.05)	$ (0.53)
Shares used in computing basic and diluted net loss per share	126,260	122,189	125,019	121,182

See accompanying notes.

Table of Contents

INCYTE CORPORATION

Condensed Consolidated Statements of Comprehensive Income (loss)

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	**2010**	**2011**	**2010**
Net loss	$ (53,078)	$ (31,701)	$ (131,461)	$ (64,387)
Other comprehensive gain:				
Reclassification adjustment for realized gains on marketable securities		(183)		(183)
Unrealized gain (loss) on marketable securities	(130)	317	(165)	1,406
Other comprehensive gain (loss)	(130)	134	(165)	1,223
Comprehensive loss	$ (53,208)	$ (31,567)	$ (131,626)	$ (63,164)

See accompanying notes.

Table of Contents

INCYTE CORPORATION

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (131,461)	$ (64,387)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash restructuring charges	20	(399)
Depreciation and amortization	19,948	17,659
Stock-based compensation	21,536	10,735
Loss on debt redemption		3,988
Realized gain on investments		134
Changes in operating assets and liabilities:		
Accounts receivable	3,239	158,926
Prepaid expenses and other assets	7,628	9,636
Accounts payable	265	(13,214)
Accrued and other current liabilities	7,099	(2,282)
Deferred revenue	(50,210)	(50,261)
Net cash (used in) provided by operating activities	(121,936)	70,535
Cash flows from investing activities:		
Capital expenditures	(2,807)	(1,370)
Sales and maturities of marketable securities	1,445	18,415
Net cash (used in) provided by investing activities	(1,362)	17,045
Cash flows from financing activities:		
Proceeds from issuance of common stock under stock plans	17,714	10,044
Redemption of convertible notes		(158,644)
Net cash provided by (used in) financing activities	17,714	(148,600)
Net decrease in cash and cash equivalents	(105,584)	(61,020)
Cash and cash equivalents at beginning of period	417,912	449,824
Cash and cash equivalents at end of period	$ 312,328	$ 388,804

See accompanying notes.

Table of Contents

INCYTE CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2011

(Unaudited)

1. Organization and business

Incyte Corporation (Incyte, we, us, or our) is a drug discovery and development company focused on developing small molecule drugs to treat serious unmet medical needs. Our pipeline is focused in the areas of oncology and inflammation and includes compounds in various stages of development, ranging from preclinical to late-stage development.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The condensed consolidated balance sheet as of September 30, 2011 and the condensed consolidated statements of operations, comprehensive loss and cash flows for the three and nine months ended September 30, 2011 and 2010, are unaudited, but include all adjustments, consisting of normal recurring adjustments, which we consider necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2010 has been derived from audited financial statements.

Although we believe that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2010.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (FASB) issued amendments to the accounting and disclosure guidance for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and the scope of what constitutes a non-software deliverable. We adopted this guidance prospectively on January 1, 2011 and the adoption had no impact on our condensed consolidated financial statements. The potential future impact of the adoption of these amendments will depend on the nature of any new arrangements that we enter into in the future or will depend on any material modifications made to any of our existing arrangements.

3. Fair value of financial instruments

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.

Table of Contents

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. We classify marketable securities available to fund current operations as current assets on the condensed consolidated balance sheet. Marketable securities are classified as long-term assets on the condensed 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.

At September 30, 2011, 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 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.

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 September 30, 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 September 30, 2011
Cash and cash equivalents	$ 312,328	$	$	$ 312,328
Mortgage backed securities		4,647		4,647
Restricted cash and investments	28,982			28,982
Total assets	$ 341,310	$ 4,647	$	$ 345,957

The following is a summary of our marketable security portfolio as of September 30, 2011 and December 31, 2010, respectively.

	Amortized Cost	Net Unrealized Gains	Net Unrealized Losses	Estimated Fair Value
	(in thousands)			
September 30, 2011				
Mortgage backed securities	$ 3,499	$ 1,148	$	$ 4,647
	$ 3,499	$ 1,148	$	$ 4,647
December 31, 2010				
Mortgage backed securities	$ 4,904	$ 1,352	$	$ 6,256
	$ 4,904	$ 1,352	$	$ 6,256

4. Concentration of credit risk

For the three and nine months ended September 30, 2011, one customer contributed 81% and 85%, respectively, of revenues. For the three and nine months ended September 30, 2010, one customer contributed 80% and 48%, respectively, of revenues.

Three customers comprised 100% of the accounts receivable balance at September 30, 2011. Three customers comprised 92% of the accounts receivable balance at December 31, 2010.

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.

Table of Contents

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. For the nine months ended September 30, 2011 we recognized $15 million 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. In 2010, we recognized and received $50 million in milestone payments for the initiation of the ruxolitinib global Phase III trial, RESPONSE, in patients with polycythemia vera. 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 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. All future milestone payments will be recognized as revenue upon the achievement of the associated milestone.

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 condensed 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 September 30, 2011 and December 31, 2010, $2.3 million and $4.6 million, respectively, of reimbursable costs were included in accounts receivable on the condensed consolidated balance sheet. Research and development expenses for the three and nine months ended September 30, 2011 were net of $0.7 million and $2.2 million, respectively, of costs reimbursed by Novartis. Research and development expenses for the three and nine months ended September 30, 2010 were net of $0.6 million and $6.2 million, respectively, of costs reimbursed by Novartis.

Contract revenue under the Novartis agreement was $13.5 million and $55.6 million, respectively, for the three and nine months ended September 30, 2011, including a $15 million milestone for INCB28060 that was earned in the three months ended March 31, 2011. Contract revenue under the Novartis agreement was $13.5 million and $40.6 million, respectively, for the three and nine months ended September 30, 2010.

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 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. In 2010, we recognized and received $49 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 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. 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. 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

Table of Contents

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. All milestone payments will be recognized as revenue upon the achievement of the associated milestone. Reimbursable costs incurred after the effective date with Lilly will be recorded net against the related research and development expenses. At September 30, 2011 and December 31, 2010, $0.1 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 three and nine months ended September 30, 2011 were net of $0.0 million and $0.2 million, respectively, of costs reimbursed by Lilly. Research and development expenses for the three and nine months ended September 30, 2010 were net of $0.4 million and $2.6 million, respectively, of costs reimbursed by Lilly.

Contract revenue under the Lilly agreement was $3.2 million and $9.6 million, respectively, for the three and nine months ended September 30, 2011. Contract revenue under the Lilly agreement was $3.2 million and $39.6 million, respectively, for the three and nine months ended September 30, 2010. Included in these amounts was a $30.0 million payment in connection with a milestone received from Lilly during 2010.

6. Stock compensation

We recorded $7.4 million and $21.5 million of stock compensation expense on our unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2011, respectively. We recorded $4.1 million and $10.7 million of stock compensation expense on our unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2010, respectively. We utilized the Black-Scholes valuation model for estimating the fair value of the stock compensation granted, with the following weighted-average assumptions:

	Employee Stock Options				Employee Stock Purchase Plan			
	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2011	2010	2011	2010	2011	2010	2011	2010
Average risk-free interest rates	0.54%	0.75%	0.99%	1.12%	0.57%	0.72%	0.57%	0.72%
Average expected life (in years)	3.69	3.08	3.29	2.96	0.50	0.50	0.50	0.50
Volatility	70%	75%	71%	74%	35%	49%	35%	49%
Weighted-average fair value (in dollars)	8.15	6.72	7.35	5.09	1.13	0.65	1.13	0.65

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 the stock based compensation guidance, 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 September 30, 2011, was $23.0 million, which is expected to be recognized over the weighted average period of 3.09 years.

Table of Contents

The following table summarizes activity under all stock option plans:

	Shares Available for Grant	Number Outstanding	Weighted Average Exercise Price per Share
Balance at December 31, 2010	4,786,694	20,107,923	$ 8.44
Additional authorized	6,500,000		
Options granted	(4,865,333)	4,865,333	15.17
Options exercised		(2,220,565)	7.15
Options cancelled	87,134	(196,890)	18.58
Balance at September 30, 2011	6,508,495	22,555,801	$ 9.93
Exercisable, September 30, 2011		15,546,166	$ 8.31

7. Debt

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

	September 30, 2011		December 31, 2010	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Pfizer convertible subordinated note due 2013	$ 9,283	$ 9,283	$ 8,903	$ 8,903
Pfizer convertible subordinated note due 2014	8,428	8,428	8,084	8,084
4.75% convertible senior notes due 2015	292,566	708,000	276,445	832,400
	$ 310,277	$ 725,711	$ 293,432	$ 849,387

The fair value of the 4.75% convertible senior notes due 2015 was calculated based on quoted market prices.

8. Net loss per share

The following potential common shares were excluded from the calculations as their effect would be anti-dilutive:

	Nine months ended September 30,	
	2011	2010
Stock options	22,555,801	20,380,322
	45,584,040	45,584,040

Common shares issuable upon conversion of 4.75% convertible senior notes due 2015		
Common shares issuable upon conversion of Pfizer convertible subordinated note due 2013	1,461,496	1,461,496
Common shares issuable upon conversion of Pfizer convertible subordinated note due 2014	1,025,641	1,025,641
Total potential common shares excluded from diluted net loss per share computation	70,626,978	68,451,499

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations as of and for the three and nine months ended September 30, 2011 should be read in conjunction with the financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K previously filed with the SEC.

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 and our product candidates including the date ruxolitinib could be available to myelofibrosis patients in the United States;*

- *focus on our drug discovery, development and commercialization efforts;*

- *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 launch ruxolitinib;*

- *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 and the possible date for completion of priority review of ruxolitinib;*

- *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;*
- *the decrease in revenues from our information product-related activities;*
- *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;*

Table of Contents

- *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.*

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 obtain regulatory approval for and commercialize ruxolitinib;*

- *our ability to maintain at anticipated levels, reimbursement for ruxolitinib 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 ruxolitinib, which could result in a short supply of ruxolitinib, increased costs, and withdrawal of regulatory approval;*

- *our ability to maintain regulatory approvals to market ruxolitinib;*

- *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 ruxolitinib in a manner that violates health care fraud and abuse laws;*

- *our ability to discover, develop, formulate, manufacture and commercialize a drug candidate or product;*
- *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;*

Table of Contents

- *the impact of technological advances and competition;*

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

- *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. We also refer to trademarks of other corporations and organizations in this Quarterly Report on Form 10-Q.

Table of Contents

Overview

Incyte is a drug discovery and development company, focused on developing small molecule drugs to treat serious unmet medical needs. Our pipeline is focused in the areas of oncology and inflammation and includes compounds in various stages of development, ranging from preclinical to late-stage development.

Our two most advanced programs involve our janus kinase (JAK) inhibitors. Oral ruxolitinib (INCB18424) is in clinical development for the treatment of several myeloproliferative neoplasms and is part of a collaboration agreement with Novartis International Pharmaceutical Ltd. in which Novartis received exclusive development and commercialization rights outside of the United States to ruxolitinib for hematologic and oncology indications, including all hematological malignancies, solid tumors and myeloproliferative diseases. We submitted a New Drug Application (NDA) for ruxolitinib for the treatment of myelofibrosis in June 2011 and, in August 2011, the U.S. Food and Drug Administration (FDA) accepted our NDA filing. The FDA also granted our request for priority review, which is given to investigational drugs that may offer either a major advance in treatment or provide a treatment where no adequate therapy exists. The FDA has a goal to complete the priority review within six months. Therefore, if the NDA is approved, we anticipate that ruxolitinib could be available for U.S. patients with myelofibrosis in the fourth quarter of 2011.

Oral LY3009104 is in clinical development for rheumatoid arthritis by Eli Lilly and Company under our collaboration agreement with Lilly. Lilly received exclusive worldwide development and commercialization rights for the compound for inflammatory and autoimmune diseases; however, last year we exercised our co-development rights for rheumatoid arthritis in exchange for tiered royalty rates ranging up to the high twenties. We believe these strategic relationships increase the likelihood of the successful development and commercialization of these compounds.

We are engaged in a number of other development programs evaluating our novel c-METand IDO inhibitors and are also continuing to invest in our discovery efforts.

Our pipeline includes the following compounds:

Target/Drug Compound	Indication	Development Status
JAK1 and JAK2		
Ruxolitinib(INCB18424)(1)	Myelofibrosis(5)	Phase III
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/Other Hematologic Malignancies (6)	Phase I & Phase II
INCB18424(2)	Psoriasis	Phase IIb
LY3009104(INCB28050)(3)	Rheumatoid Arthritis	Phase IIb
c-MET		
INCB28060(4)	Solid Tumors	Phase I
IDO		
INCB24360	Solid Tumors	Phase I

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

(2) This compound is a topical formulation; all others are an oral formulation.

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

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

(5) This includes several other myelofibrosis studies, including a joint global Phase II trial with Novartis in thrombocytopenic patients and a Phase II trial in patients using a sustained-release formulation.

(6) These studies are investigator sponsored trials.

In September 2011, we announced that we had discontinued development of our lead sheddase inhibitor, INCB7839, for the treatment of metastatic breast cancer.

We expect to continue to expand our drug discovery and development program in the future. Conducting clinical trials for our drug candidates in development is a lengthy, time-consuming and expensive process. If we are unable to successfully develop and market pharmaceutical products over the next several years, our business, financial condition and results of operations would be adversely

Table of Contents

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 quarter to quarter and that those fluctuations may be substantial.

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; and
- Convertible debt and derivative accounting.

Revenue Recognition. Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and 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.

Under agreements involving multiple deliverables, services and/or rights to use assets, 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. All milestone payments are recognized as revenue upon the achievement of the associated milestone.

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

Table of Contents

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. 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 $7.4 million and $21.5 million, respectively, of stock compensation expense on our condensed consolidated statement of operations for the three and nine months ended September 30, 2011 and $4.1 million and $10.7 million, respectively, for the three and nine months ended September 30, 2010.

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.

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.

Results of Operations

We recorded a net loss of $53.1 million, or $0.42 per share (basic and diluted) for the three months ended September 30, 2011, as compared to a net loss of $31.7 million, or $0.26 per share (basic and diluted) for the same period in 2010. The net loss for the nine months ended September 30, 2011 was $131.5 million, or $1.05 per share (basic and diluted), as compared to $64.4 million, or $0.53 per share (basic and diluted), for the same period in 2010.

Revenues.

	For the three months ended, September 30,		For the nine months ended, September 30,	
	2011	2010	2011	2010
	(in millions)		(in millions)	
Contract revenues	$ 16.8	$ 16.8	$ 65.2	$ 83.2
License and royalty revenues		0.1	0.4	0.8
Total revenues	$ 16.8	$ 16.9	$ 65.6	$ 84.0

Table of Contents

Our total revenues were $16.8 million and $65.6 million and $16.9 million and $84.0 million for the three and nine months ended September 30, 2011 and 2010, respectively, which included a $15.0 million milestone for INCB28060 recognized under the Novartis agreement during the nine months ended September 30, 2011. For the nine months ended September 30, 2010 we recognized $30.0 million and $3.0 million, respectively, in contract revenues relating to milestone payments under our Lilly and Pfizer agreements. In addition, for the three and nine months ended September 30, 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.

Operating Expenses.

Research and development expenses.

	For the three months ended, September 30,		For the nine months ended, September 30,	
	2011	2010	2011	2010
	(in millions)		(in millions)	
Salary and benefits related	$ 13.1	$ 10.1	$ 38.9	$ 31.0
Stock compensation	4.8	2.6	14.0	7.3
Clinical research and outside services	20.7	13.3	57.9	40.0
Occupancy and all other costs	6.0	4.6	16.0	12.8
Total research and development expenses	$ 44.6	$ 30.6	$ 126.8	$ 91.1

We currently track research and development costs by natural expense line and not costs by project. Salary and benefits related expense increased from the three and nine months ended September 30, 2010 to the three and nine months ended September 30, 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 the three and nine months ended September 30, 2010 to the three and nine months ended September 30, 2011 was primarily the result of increased development costs due to timing of our clinical trial activities and increased medical affairs costs. Research and development expenses for the three and nine months ended September 30, 2011 and 2010 were net of $0.7 million and $2.4 million and $0.9 million and $8.8 million, respectively, of costs reimbursed by our collaborative partners. The increase in occupancy and all other costs from the three and nine months ended September 30, 2010 to the three and nine months ended September 30, 2011 was primarily the result of increased depreciation and 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 will receive an incremental royalty rate increase across all tiers for this indication. 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.

Table of Contents

Selling, general and administrative expenses.

	For the three months ended, September 30,		For the nine months ended, September 30,	
	2011	2010	2011	2010
	(in millions)		(in millions)	
Salary and benefits related	$ 5.1	$ 2.6	$ 11.8	$ 7.0
Stock compensation	2.6	1.5	7.5	3.4
Other contract service and outside costs	6.6	4.4	17.8	11.2
Total selling, general and administrative expenses	$ 14.3	$ 8.5	$ 37.1	$ 21.6

Salary and benefits related expense increased from the three and nine months ended September 30, 2010 to the three and nine months ended September 30, 2011 due to increased headcount. This increased headcount was due to preparation for the potential commercialization of ruxolitinib for myelofibrosis, including the hiring of a sales force. 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 due to preparation for the potential commercialization of ruxolitinib for myelofibrosis.

Interest Expense. Interest expense for the three and nine months ended September 30, 2011 was $11.0 million and $32.7 million, respectively, compared to $10.5 million and $32.7 million, respectively, for the corresponding periods in 2010. The increase in the three months ended September 30, 2011 from the 2010 period is primarily attributable to the increase in non-cash amortization of our debt discount related to our 4.75% convertible senior notes due 2015.

Loss on redemption of convertible senior and subordinated notes. During the nine months ended September 30, 2010, we redeemed the remaining $55.6 million principal amount of our 3½% convertible senior notes due 2011 and $119.0 million principal amount of our 3½% convertible subordinated notes due 2011. These redemptions resulted in a loss of $4.0 million primarily related to the unamortized debt discount from the 3½% convertible senior notes we redeemed.

Liquidity and Capital Resources

We had net losses from inception in 1991 through 1996 and in 1999 through the first nine months of 2011. Because of those losses, we had an accumulated deficit of $1.6 billion as of September 30, 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 September 30, 2011, we had available cash, cash equivalents, and marketable securities of $317.0 million, excluding a funded restricted cash and investment escrow account of $28.5 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.

Net cash used in operating activities was $121.9 million for the nine months ended September 30, 2011, compared to $70.5 million provided by operating activities for the nine months ended September 30, 2010. The $192.4 million decrease was due primarily to the upfront and milestone payments received from our collaborators for the nine months ended September 30, 2010.

Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures. Net cash used in investing activities was $1.4 million for the nine months ended September 30, 2011, which represented primarily sales and maturities of marketable securities of $1.4 million offset by capital expenditures of $2.8 million. Net cash provided by investing activities was $17.0 million for the nine months ended September 30, 2010, which represented primarily sales and maturities of marketable securities of $18.4 million offset by capital expenditures of $1.4 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of capital expenditures, maturities/sales and purchases of marketable securities, and acquisitions, including possible earn-out payments to former stockholders of Maxia Pharmaceuticals, Inc.

Net cash provided by financing activities was $17.7 million for the nine months ended September 30, 2011 and net cash used in financing activities was $148.6 million for the nine months ended September 30, 2010. For the nine months ended September 30, 2011 and 2010, we received $17.7 million and $10.0 million, respectively, from issuance of common stock under our stock plans and employee stock purchase plan. For the nine months ended September 30, 2010, we used $158.6 million, to redeem the remaining 3 ½% convertible senior notes and 3 ½% convertible subordinated notes, including interest.

Table of Contents

The following summarizes our significant contractual obligations as of September 30, 2011 and the effect those obligations are expected to have on our liquidity and cash flow in future periods:

	Total	Less Than 1 Year	Years 1 - 3	Years 4 - 5	Over 5 Years
			(in millions)		
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	85.5	19.0	38.0	28.5	
Non-cancelable operating lease obligations:					
Related to current operations	10.9	6.3	4.6		
Total contractual obligations	$ 516.4	$ 25.3	$ 62.6	$ 428.5	$

We have funded an escrow account of $28.5 million for interest payments on our 4.75% convertible senior notes through October 2012, which the table above excludes.

The table above also 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 September 30, 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; if our NDA for ruxolitinib is approved, the extent to which commercialization of ruxolitinib 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 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.

Table of Contents

Item 3. 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 September 30, 2011, cash, cash equivalents and marketable securities were $317.0 million, excluding a funded restricted cash and investment escrow account of $28.5 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 September 30, 2011, the decline in fair value would not be material.

Item 4. 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 Quarterly Report on Form 10-Q, 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 was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1A. Risk Factors

RISKS RELATING TO OUR LEAD PRODUCT RUXOLITINIB

If we are unable to successfully obtain regulatory approval for and commercialize ruxolitinib for the treatment of myelofibrosis or for additional indications, or if we are significantly delayed or limited in doing so, our business may be materially harmed.

In June 2011, we submitted a new drug application, or NDA, to the U. S. Food and Drug Administration, or FDA, for ruxolitinib for the treatment of myelofibrosis. In August 2011, the FDA accepted the NDA and granted our request for priority review. The FDA has a goal to complete the priority review within six months. If the NDA is approved, we could begin to market ruxolitinib in the United States for the treatment of myelofibrosis as early as the fourth quarter of 2011. Even if the NDA is approved, such approval does not guarantee future revenues. The commercial success of ruxolitinib and our ability to generate and maintain revenues from the sale of ruxolitinib will depend on a number of factors, including:

- our ability to successfully launch commercial sales in the United States for the treatment of myelofibrosis;

- the number of patients with myelofibrosis who are diagnosed with the disease and identified to us and the number of patients with myelofibrosis that may be treated with ruxolitinib;

- the acceptance of ruxolitinib by patients and the healthcare community;

- whether physicians, patients and healthcare payors view ruxolitinib as therapeutically effective and safe relative to cost and

Table of Contents

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 ruxolitinib in sufficient quantities with acceptable quality;
- the ability of our company and our third-party providers to provide marketing and distribution support for ruxolitinib;
- the label and promotional claims allowed by the FDA;
- the maintenance of regulatory approval for the treatment of myelofibrosis in the United States; and
- our ability to develop, obtain regulatory approval for and commercialize ruxolitinib in the United States for indications in addition to myelofibrosis.

If we receive regulatory approval for the sale of ruxolitinib but are not successful in commercializing sales of ruxolitinib 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 for the treatment of myelofibrosis 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 receive regulatory approval to market ruxolitinib in the United States but are unable to obtain, or maintain at anticipated levels, reimbursement for ruxolitinib 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.

If we receive regulatory approval to market ruxolitinib in the United States, we may not be able to sell ruxolitinib on a profitable basis or our profitability may be reduced if we are required to sell ruxolitinib at lower than anticipated prices or reimbursement is unavailable or limited in scope or amount. Ruxolitinib 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 depend on government and other third-party payors to defray the cost of ruxolitinib to the patient. If these entities refuse to provide coverage and reimbursement with respect to ruxolitinib, 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 ruxolitinib 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 ruxolitinib 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 ruxolitinib in the United States may have a material adverse effect on our business.

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

If we receive regulatory approval for the sale of ruxolitinib in the United States, we plan to sell ruxolitinib to specialty pharmacies, which in turn will dispense ruxolitinib to patients in fulfillment of prescriptions. We do not intend to promote ruxolitinib to specialty pharmacies, and specialty pharmacies will not set or determine demand for ruxolitinib. Our ability to successfully commercialize ruxolitinib will depend, in part, on the extent to which we are able to provide adequate distribution of ruxolitinib to patients. Although we have contracted with a number of specialty pharmacies in preparation for the potential regulatory approval of ruxolitinib, 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 ruxolitinib, 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 ruxolitinib 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

Table of Contents

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 ruxolitinib.

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 ruxolitinib in the United States. We have established commercial capabilities in the United States in preparation for the potential commercialization of ruxolitinib for the treatment of myelofibrosis, 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 ruxolitinib. 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 ruxolitinib. We cannot guarantee that we will be successful in commercializing ruxolitinib.

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

We do not currently operate manufacturing facilities for commercial production of ruxolitinib. 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 are able to secure regulatory approval to market ruxolitinib, and we fail to comply with continuing regulations, we could lose our approval to market ruxolitinib.

If we are able to secure regulatory approval to market ruxolitinib in the United States, we cannot guarantee that we will be able to maintain such regulatory approval. If we do not maintain our regulatory approval to market ruxolitinib, 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.

If we succeed in obtaining regulatory approval for ruxolitinib, our commercialization of ruxolitinib will be subject to post-regulatory approval surveillance, and ruxolitinib 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 ruxolitinib, and ruxolitinib 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 a previously granted regulatory approval for ruxolitinib;
- interruption of production;
- operating restrictions;
- product recall or seizure;
- injunctions; and

Table of Contents

- criminal prosecution.

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

If the use of ruxolitinib harms patients, or is perceived to harm patients even when such harm is unrelated to ruxolitinib, 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 ruxolitinib, and if regulatory approval is obtained, the manufacturing, marketing and sale of ruxolitinib expose us to product liability and other risks. Side effects and other problems experienced by patients from the use of ruxolitinib could:

- lessen the frequency with which physicians decide to prescribe ruxolitinib;

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

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

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

If we receive regulatory approval to market ruxolitinib and ruxolitinib is used by a wider 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 ruxolitinib may also be discovered in connection with unapproved, or off-label, uses of ruxolitinib. If we are able to obtain regulatory approval to market ruxolitinib, we will be prohibited by law from promoting or in any way supporting or encouraging the promotion of ruxolitinib 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 ruxolitinib in diseases other than 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 myelofibrosis and as ruxolitinib 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 ruxolitinib, reformulate ruxolitinib or make changes and obtain new approvals. We may also experience a significant drop in the potential sales of ruxolitinib, experience harm to our reputation and the reputation of ruxolitinib in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of ruxolitinib or substantially increase the costs and expenses of commercializing and marketing ruxolitinib.

Patients who have been enrolled in our clinical trials or who may use ruxolitinib in the future if we are able to secure regulatory approval 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 ruxolitinib. 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 ruxolitinib, 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 ruxolitinib, 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 ruxolitinib receives or maintains.

If we obtain regulatory approval and subsequently market ruxolitinib 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 programs for reimbursement; and submitting inflated best price information to the Medicaid Rebate Program.

Table of Contents

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. If we are able to obtain regulatory approval, we intend to market ruxolitinib for myelofibrosis and provide promotional materials to physicians regarding the use of ruxolitinib for myelofibrosis. Although we may believe that our marketing materials for physicians do not constitute off-label promotion of ruxolitinib, the FDA may disagree. If the FDA determines that our promotional materials or other activities constitute off-label promotion of ruxolitinib, 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.

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;

- 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;

Table of Contents

- 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 being subject to an NDA for the treatment of 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 would 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.

Ruxolitinib is our only drug candidate that has, to date, been submitted for 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 JAK 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.

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

Table of Contents

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.

Although we obtained special protocol assessment agreements for ruxolitinib for each of myelofibrosis and 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 agreement, or SPA, for the registration trial for ruxolitinib for the treatment of myelofibrosis in the United States and 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.

Table of Contents

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.

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, 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 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

Table of Contents

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 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 submitted an NDA for ruxolitinib for the treatment of myelofibrosis in June 2011, we cannot predict whether or when regulatory approval will be obtained for any 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.

Table of Contents

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 ruxolitinib 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 ruxolitinib and most of our drug candidates, we rely on one third party to manufacture the raw materials, another to manufacture the API, another to make the finished drug product and a fourth to package and label the finished product. The 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, or cGMP, 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 cGMP 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 ruxolitinib, 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 ruxolitinib 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 ruxolitinib, however, there is no assurance that we will be able to identify and qualify a second source of supply for ruxolitinib. 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.

Table of Contents

In order to obtain approval of our products, including ruxolitinib, 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 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 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

Table of Contents

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 shutdown 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.

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.

Table of Contents

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 2010. Because of those losses, we had an accumulated deficit of $1.6 billion as of September 30, 2011. We will continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we expect to continue to incur losses in 2011 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 revenues and we cannot assure you that we will generate revenues from the drug candidates that we license or develop, including ruxolitinib, for several years, if ever.

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. 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 will 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:

- 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 amount of revenues generated from our business activities, if any;

Table of Contents

- 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.

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 September 30, 2011, the aggregate principal amount of our total consolidated debt was $420.0 million and our stockholders deficit was $181.0 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 September 30, 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 September 30, 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. However, with recent credit market conditions, similar types of investments and money market funds have experienced losses in value or liquidity issues which differ from their historical pattern.

Table of Contents

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.

Our current revenues are derived from 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 three and nine months ended September 30, 2011 from 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 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.

Table of Contents

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.

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.

Table of Contents

Item 6. Exhibits

Exhibit Number	Description of Document
10.14.3#	Form of Employment Agreement, effective as of August 8, 2011, between the Company and Eric H. Siegel
31.1	Rule 13a 14(a) Certification of Chief Executive Officer
31.2	Rule 13a 14(a) Certification of 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

# Indicates management contract or compensatory plan or arrangement.

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed filed for purposes 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.

** 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.

Table of Contents

SIGNATURES

Pursuant to the requirements 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

Dated:	October 27, 2011	By:	/s/ PAUL A. FRIEDMAN PAUL A. FRIEDMAN Chief Executive Officer (Principal Executive Officer)
Dated:	October 27, 2011	By:	/s/ DAVID C. HASTINGS DAVID C. HASTINGS Chief Financial Officer (Principal Financial Officer)

Table of Contents

INCYTE CORPORATION

EXHIBIT INDEX

Exhibit Number	Description of Document
10.14.3#	Form of Employment Agreement, effective as of August 8, 2011, between the Company and Eric H. Siegel
31.1	Rule 13a 14(a) Certification of Chief Executive Officer
31.2	Rule 13a 14(a) Certification of 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

# Indicates management contract or compensatory plan or arrangement.

* In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed filed for purposes 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.

** 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.