INCYTE CORP
Form 10-Q
May 06, 2010
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2010

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)

(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). o 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 o	Accelerated filer x
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 121,133,647 as of April 30, 2010.

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INCYTE CORPORATION

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

INCYTE CORPORATION

Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2010 (unaudited)	December 31, 2009*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 404,746	$ 449,824
Marketable securities available-for-sale	17,494	20,594
Restricted cash	19,045	19,032
Accounts receivable, net	5,253	163,661
Prepaid expenses and other current assets	4,269	2,944
Total current assets	450,807	656,055
Marketable securities available-for-sale	14	3,513
Restricted cash	37,447	37,191
Property and equipment, net	1,808	1,752
Other assets	12,587	13,879
Total assets	$ 502,663	$ 712,390
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 13,304	$ 20,964
Accrued compensation	7,842	13,418
Interest payable	9,553	7,094
Accrued and other current liabilities	14,537	17,441
Deferred revenue	67,020	67,030
Accrued restructuring	5,688	6,879
Total current liabilities	117,944	132,826
Convertible senior notes	261,408	308,059
Convertible subordinated notes	16,292	135,079
Deferred revenue	221,432	238,169
Other liabilities		641
Total liabilities	617,076	814,774
Stockholders deficit:		

Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of March 31, 2010 and December 31, 2009				
Common stock, $0.001 par value; 400,000,000 shares authorized; 121,079,606 and 118,893,326 shares issued and outstanding as of March 31, 2010 and December 31, 2009, respectively		121		119
Additional paid-in capital		1,311,181		1,287,974
Accumulated other comprehensive gain		1,198		707
Accumulated deficit		(1,426,913)		(1,391,184)
Total stockholders deficit		(114,413)		(102,384)
Total liabilities and stockholders deficit	$	502,663	$	712,390

* The condensed consolidated balance sheet at December 31, 2009 has been derived from the audited financial statements at that date.

See accompanying notes.

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INCYTE CORPORATION

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2010	**2009**
Revenues:		
Contract revenues	$ 16,737	$
License and royalty revenues	551	671
Total revenues	17,288	671
Costs and expenses:		
Research and development	31,439	29,587
Selling, general and administrative	5,794	4,821
Other expenses	(115)	509
Total costs and expenses	37,118	34,917
Loss from operations	(19,830)	(34,246)
Interest and other income (expense), net	195	548
Interest expense	(11,779)	(6,338)
Loss on debt redemption	(3,988)	
Loss before income taxes	(35,402)	(40,036)
Provision for income taxes	327	
Net loss	(35,729)	(40,036)
Basic and diluted net loss per share:	$ (0.30)	$ (0.41)
Shares used in computing basic and diluted net loss per share	119,727	97,340

See accompanying notes.

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INCYTE CORPORATION

Condensed Consolidated Statements of Comprehensive Loss

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2010	**2009**
Net loss	$ (35,729)	$ (40,036)
Other comprehensive gain:		
Unrealized gain on marketable securities	491	675
Other comprehensive gain	491	675
Comprehensive loss	$ (35,238)	$ (39,361)

See accompanying notes.

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INCYTE CORPORATION

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2010	**2009**
Cash flows from operating activities:		
Net loss	$ (35,729)	$ (40,036)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash restructuring charges	(115)	509
Depreciation and amortization	6,396	2,509
Stock-based compensation	3,121	3,360
Loss on debt redemption	3,988	
Changes in operating assets and liabilities:		
Accounts receivable	158,408	311
Prepaid expenses and other assets	(1,661)	380
Accounts payable	(7,660)	(595)
Accrued and other current liabilities	(7,178)	(9,183)
Deferred revenue	(16,747)	10
Net cash provided by (used in) operating activities	102,823	(42,735)
Cash flows from investing activities:		
Capital expenditures	(306)	(95)
Sales and maturities of marketable securities	6,822	3,161
Net cash provided by investing activities	6,516	3,066
Cash flows from financing activities:		
Proceeds from issuance of common stock under stock plans	4,227	
Redemption of convertible notes	(158,644)	
Net cash used in financing activities	(154,417)	
Net decrease in cash and cash equivalents	(45,078)	(39,669)
Cash and cash equivalents at beginning of period	449,824	178,767
Cash and cash equivalents at end of period	$ 404,746	$ 139,098

See accompanying notes.

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INCYTE CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2010

(Unaudited)

1. Organization and business

Incyte Corporation (Incyte, we, us, or our) is a drug discovery and development company focused on developing proprietary small molecule drugs to treat serious unmet medical needs. We have a pipeline with programs focused primarily in the areas of oncology and inflammation.

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 March 31, 2010 and the condensed consolidated statements of operations, comprehensive loss and cash flows for the three months ended March 31, 2010 and 2009, are unaudited, but include all adjustments, consisting only 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, 2009 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, 2009.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (FASB) issued amendments to the accounting and disclosure 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. The impact of the adoption of these amendments will depend on the nature of the arrangements that we enter into subsequent to the date we adopt the amendments.

In January 2010, an amendment to the FASB fair value guidance was issued. This amendment requires disclosures of transfers into and out of Levels 1 and 2, more detailed roll forward reconciliations of Level 3 recurring fair value measurements on a gross basis, fair value information by class of assets and liabilities, and descriptions of valuation techniques and inputs for Level 2 and 3 measurements. We adopted the amendment during the first quarter 2010, which had no impact on our condensed consolidated financial statements as this change is disclosure-only in nature.

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.

Our marketable securities consist of investments in corporate debt securities, mortgage and asset-backed securities, U.S. Treasury notes, and other U.S. government agency 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

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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.

Our Level 2 mortgage backed securities and corporate debt 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.

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

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Balance as of March 31, 2010
Cash and cash equivalents	$ 404,746	$	$	$ 404,746
Mortgage backed securities		8,695		8,695
Corporate debt securities		8,813		8,813
Restricted cash	56,492			56,492
Total assets	$ 461,238	$ 17,508	$	$ 478,746

The following is a summary of our marketable security portfolio as of March 31, 2010 and December 31, 2009, respectively.

	Amortized Cost	Net Unrealized Gains	Net Unrealized Losses	Estimated Fair Value
		(in thousands)		
March 31, 2010				
Mortgage backed securities	$ 7,724	$ 971	$	$ 8,695
Corporate debt securities	8,809	4		8,813
	$ 16,533	$ 975	$	$ 17,508
December 31, 2009				
Mortgage backed securities	$ 8,546	$ 781	$ (33)	$ 9,294
Asset-backed securities	3,500		(1)	3,499
Corporate debt securities	11,309	7	(2)	11,314
	$ 23,355	$ 788	$ (36)	$ 24,107

4. Concentration of credit risk

For the three months ended March 31, 2010, one customer contributed 78% of revenues. For the three months ended March 31, 2009, one customer contributed 48% of revenues.

Three customers comprised 89% of the accounts receivable balance at March 31, 2010. Three customers comprised 100% of the accounts receivable balance at December 31, 2009.

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 collaboration and license agreement, Novartis received exclusive development and commercialization rights outside of the United States to INCB18424 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 INCB18424 in the United States and in certain other indications. Novartis also received worldwide exclusive development and commercialization rights to our c-MET inhibitor compound INCB28060 and certain back-up compounds in all indications. We retained options to co-develop and to co-promote INCB28060 in the United States.

We received an upfront payment of $150.0 million in December 2009 plus an immediate $60.0 million milestone payment in January 2010 earned for the start of the Phase III study for INCB18424 in Europe. We may be eligible to receive future additional payments if defined development and commercialization milestones are achieved and could receive tiered, double digit royalties on future INCB18424 sales outside of the United States. Each company is responsible for costs relating to the development and commercialization of the JAK inhibitor compound in its respective territories, with costs of collaborative studies shared equally. Novartis is responsible for all costs relating to the development and commercialization of the c-MET inhibitor compound after the initial Phase I clinical trial.

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

We determined that there were two deliverables under the agreement: (i) the ex U.S. license for INCB18424 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 consolidated balance sheet. These costs will be recognized on a straight line basis through December 2013 consistent with the aforementioned upfront and milestone payment. Future reimbursable costs incurred after the effective date of

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the agreement with Novartis will be recorded on a net basis. At March 31, 2010, $3.5 million of reimbursable costs are included in accounts receivable on the condensed consolidated balance sheet.

Contract revenue under the Novartis agreement was $13.5 million for the three months ended March 31, 2010.

Lilly

In December 2009, we entered into a License, Development and Commercialization Agreement with Eli Lilly and Company. Under the terms of the Lilly agreement, Lilly received exclusive worldwide development and commercialization rights to INCB28050 and certain back-up compounds for inflammatory and autoimmune diseases. We received an initial payment of $90.0 million, and we may be eligible to receive future additional payments based on the achievement of defined development, regulatory and commercialization milestones and could receive tiered, double-digit royalty payments on future global sales with rates ranging up to 20% if the product is successfully commercialized.

We retained options to co-develop our JAK1/JAK2 inhibitors with Lilly on a compound-by-compound and indication-by-indication basis. Lilly will be responsible for all costs relating to the development and commercialization of the compounds unless we elect to co-develop any compounds or indications. If we elect to co-develop any compounds and/or indications, we would be responsible for funding 30% of the associated future global development costs from the initiation of a Phase IIb trial. 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. 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 on a net basis. At March 31, 2010, $0.8 million of reimbursable costs are included in accounts receivable on the condensed consolidated balance sheet.

Contract revenue under the Lilly agreement was $3.2 million for the three months ended March 31, 2010.

6. Stock compensation

We recorded $3.1 million and $3.4 million of stock compensation expense on our unaudited condensed consolidated statement of operations for the three months ended March 31, 2010 and 2009, 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 For the Three Months Ended March 31,		Employee Stock Purchase Plan For the Three Months Ended March 31,	
	2010	2009	2010	2009
Average risk-free interest rates	1.20%	1.05%	1.02%	0.81%
Average expected life (in years)	2.99	2.98	0.24	0.24
Volatility	75%	72%	49%	99%
Weighted-average fair value (in dollars)	4.61	1.45	0.58	1.49

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. 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 March 31, 2010, was $12.6 million, which is expected to be recognized over the weighted average period of 2.94 years.

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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, 2009	3,487,333	17,980,691	$ 7.71
Options granted	(2,771,753)	2,771,753	9.48
Options exercised		(692,429)	6.10
Options cancelled	9,895	(9,895)	8.00
Balance at March 31, 2010	725,475	20,050,120	$ 8.00
Exercisable, March 31, 2010		14,002,199	$ 8.20

7. Debt

In February, 2010 we redeemed all of the remaining outstanding 3½% convertible senior notes due 2011 (the 3½% Senior Notes) and 3½% convertible subordinated notes due 2011 (the 3½% Subordinated Notes) at a price equal to 100.5% of the principal amount of the notes plus accrued and unpaid interest of $0.1 million to the redemption date. We used a total of $158.6 million in cash to fund these redemptions. These redemptions resulted in a loss of $4.0 million for the three months ended March 31, 2010 primarily related to the unamortized debt discount from the 3½% Senior Notes we redeemed. Also in February 2010, the holders of $15.5 million aggregate principal amount of our 3½% Senior Notes and $1.4 million aggregate principal amount of our 3½% Subordinated Notes elected to convert their holdings into 1,502,851 shares of our common stock.

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

	March 31, 2010		December 31, 2009	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
3½% Senior Notes	$	$	$ 51,435	$ 58,774
3½% Subordinated Notes			119,011	119,457
Pfizer Convertible Subordinated Note due 2013	8,538	8,538	8,420	8,420
Pfizer Convertible Subordinated Note due 2014	7,754	7,754	7,648	7,648
4.75% Convertible Senior Notes due 2015	261,408	400,000	256,624	400,000
	$ 277,700	$ 416,292	$ 443,138	$ 594,299

8. Income Taxes

The provision for income taxes for the three months ended March 31, 2010 is for the estimated alternative minimum tax liability which results in 2010 from the recognition for tax purposes of the remaining deferred revenue related to the upfront payments received from Novartis and Lilly. There was no similar alternative minimum tax liability in 2009.

9. Net loss per share

For all periods presented, both basic and diluted net loss per common share are computed by dividing the net loss by the number of weighted average common shares outstanding during the period. Stock options and potential common shares issuable upon conversion of the 4.75% convertible senior notes due 2015 (the 4.75% Senior Notes), the 3½% Senior Notes, the 3½% Subordinated Notes and the convertible subordinated notes issued to Pfizer Inc. were excluded from the computation of diluted net loss per share, as their share effect was anti-dilutive for all periods presented. The potential common shares that were excluded from the diluted net loss per share computation are as follows:

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	March 31,	
	2010	2009
Outstanding stock options	20,050,120	17,854,945
Common shares issuable upon conversion of 4.75% Senior Notes	45,584,040	
Common shares issuable upon conversion of 3½% Senior Notes		13,531,224
Common shares issuable upon conversion of 3½% Subordinated Notes		22,284,625
Common shares issuable upon conversion of Pfizer Note due 2013	1,461,496	1,461,496
Common shares issuable upon conversion of Pfizer Note due 2014	1,025,641	1,025,641
Total potential common shares excluded from diluted net loss per share computation	68,121,297	56,157,931

10. Segment reporting

Our operations are treated as one operating segment, drug discovery and development**.**

11. Other expenses

Below is a summary of the activity related to our restructuring programs for the three months ended March 31, 2010. The estimates below have been made based upon management s best estimate of the amounts and timing of certain events included in the restructuring plan that will occur in the future. It is possible that the actual outcome of certain events may differ from the estimates. Changes will be made to the restructuring accrual at the point that the differences become determinable. The accrual balances for the restructuring plans are included in accrued restructuring and other liabilities (long-term) in the consolidated balance sheets.

2004 Restructuring

	Original Charge Recorded in 2004	Accrual Balance at December 31, 2009	2010 Charges to Operations	2010 Charges Utilized	Accrual Balance at March 31, 2010
			(in thousands)		
Lease commitment and related costs	$ 15,497	$ 3,364	$ 48	$ (675)	$ 2,737
Other costs			35	(35)	
Restructuring expenses	$ 15,497	$ 3,364	$ 83	$ (710)	$ 2,737

2002 Restructuring

	Original Charge	Accrual Balance at	2010 Charges to	2010 Charges	Accrual Balance at

	Recorded in 2002	December 31, 2009	Operations	Utilized	March 31, 2010
			(in thousands)		
Lease commitment and related costs	$ 16,155	$ 4,156	$ (198)	$ (1,007)	$ 2,951

12. Subsequent event

We expect to receive $30.0 million from Lilly in connection with a milestone for our JAK1/JAK2 inhibitor, INCB28050 and a $3.0 million milestone payment from Pfizer for our CCR2 antagonist program. We expect to receive these milestone payments in the quarter ending June 30, 2010.

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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 months ended March 31, 2010 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, 2009 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. These statements can often be identified by the use of forward-looking terminology such as expects, believes, intends, anticipates, estimates, plans, may, or will, 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;*
- *focus on our drug discovery and development 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;*
- *the regulatory approval process and plans to commercialize our products in the United States and abroad;*
- *potential benefits and indications of our product candidates and other compounds under development;*
- *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;*
- *our expectations regarding competition;*
- *our investments, including anticipated expenditures, losses and expenses;*
- *our patent prosecution and maintenance efforts; and*

- *our indebtedness, and debt service obligations.*

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

- *our ability to 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;*

- *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 used by 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.

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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.

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Overview

Incyte is a drug discovery and development company focused on developing proprietary small molecule drugs to treat serious unmet medical needs. We have a broad pipeline with programs focused primarily in the areas of oncology and inflammation. We focus our efforts on clinical programs that we believe have the greatest likelihood of creating near-and long-term value and on compounds that we believe a company of our size can effectively develop and commercialize on its own. For compounds that are outside of our core therapeutic and/or geographic areas, target large primary care indications or require lengthy and expensive clinical development programs, we have established or are seeking to establish strategic relationships to support development and commercialization. Our highest priority programs involve our janus kinase (JAK) inhibitors, which include oral INCB18424 for hematologic and oncology indications and oral INCB28050 for chronic inflammatory and autoimmune diseases.

Oral INCB18424 is in Phase III development as a treatment for myelofibrosis, the most advanced of the myeloproliferative neoplasms, and Phase II development for two of the other myeloproliferative neoplasms, polycythemia vera and essential thrombocythemia. In November 2009, we established a collaboration for this program with Novartis International Pharmaceutical Ltd. in which Novartis received exclusive development and commercialization rights outside of the United States to oral INCB18424 for all hematologic and oncology indications, as well as worldwide rights to our cMET inhibitor, INCB28060. We retained exclusive development and commercialization rights to oral INCB18424 in the United States for all hematologic and oncology indications.

Oral INCB28050 is in Phase II development for rheumatoid arthritis. In December 2009 we established a collaboration for this program with Eli Lilly and Company. Lilly received exclusive worldwide development and commercialization rights to INCB28050. We retained a co-development and co-promotion option. We believe these strategic relationships increase the likelihood of the successful development and commercialization of these compounds.

Our pipeline includes the following compounds:

Target/Drug Compound	Indication	Development Status
JAK1/2		
INCB18424(1)	Myelofibrosis	Phase III
INCB18424(1)	Polycythemia Vera/Essential Thrombocythemia	Phase II
INCB18424(1)	Other Hematologic Tumors	Phase I/II
INCB18424(2)	Psoriasis	Phase IIb
INCB28050(3)	Rheumatoid Arthritis	Phase II
c-MET		
INCB28060(4)	Solid Cancers	Phase I
Sheddase		
INCB7839	Breast Cancer	Phase II
IDO		
INCB24360	Oncology	IND Cleared
HSD1		
INCB13739	Type 2 Diabetes	Phase IIb

(1) We licensed rights outside the United States 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 retained a co-development and co-promotion options

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

We anticipate incurring additional losses for several years as we expand our drug discovery and development programs. We also expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. 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 impacted.

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

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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 consolidated financial statements:

- Revenue recognition;
- Research and development costs;
- Stock compensation;
- Restructuring charges;
- 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.

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.

Under agreements involving multiple products, 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.

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

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

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

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Stock Compensation. Financial Accounting Standards Board (FASB) accounting guidance for stock compensation requires all share-based payment transactions with employees, including grants of employee stock options, to be recognized as compensation expense over the requisite service period based on their fair values. The accounting guidance also requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value equity-based compensation and requires the recognition of the fair value of stock compensation in the statement of operations. We recorded stock compensation expense of $3.1 million and $3.4 million, for the three months ended March 31, 2010 and 2009, respectively.

Restructuring Charges. We estimate costs associated with restructuring activities initiated after December 31, 2002, including costs resulting from the cost to exit the facilities used for our genomics business, the amount to be paid in lease termination payments, the future lease and operating costs to be paid until the lease is terminated, and the amount, if any, of sublease receipts and real estate broker fees. To form our estimates for these costs, we perform an assessment of the affected facilities and consider the current market conditions for each site. We also estimate our credit adjusted risk free interest rate in order to discount our projected lease payments. Our assumptions on either the lease termination payments, operating costs until terminated, the offsetting sublease receipts and estimated realizable value of fixed assets held for sale may turn out to be incorrect and our actual cost may be materially different from our estimates. Our estimates of future liabilities may change, requiring us to record additional restructuring charges or reduce the amount of liabilities recorded.

At the end of each reporting period, we evaluate the remaining accrued balances to ensure their adequacy, that no excess accruals are retained and the utilization of the provisions are for their intended purposes in accordance with developed exit plans. We periodically evaluate current available information and adjust our restructuring reserve as necessary. We also make adjustments related to accrued professional fees to adjust estimated amounts to actual.

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 not more likely than not that the 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 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 liability. 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 consolidated balance sheet, and remeasured each reporting period. Any changes in fair value are recorded in the consolidated statement of operations. We monitor, on an ongoing basis, whether events or circumstances could give rise to a change in our classification of embedded features.

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Results of Operations

We recorded a net loss of $35.7 million and basic and diluted net loss per share of $0.30 for the three months ended March 31, 2010 as compared to a net loss of $40.0 million and basic and diluted net loss per share of $0.41 in the corresponding period in 2009.

Revenues.

	For the three months ended, March 31,	
	2010	2009
	(in millions)	
Contract revenues	$ 16.7	$
License and royalty revenues	0.6	0.7
Total revenues	$ 17.3	$ 0.7

Our contract revenues were $16.7 million and $0.0 million for the three months ended March 31, 2010 and 2009, respectively. For the three months ended March 31, 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 includes 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 consist of a $90.0 million upfront payment received in 2010.

Our license and royalty revenues were $0.6 million and $0.7 million for the three months ended March 31, 2010 and 2009, respectively. License and royalty revenues were derived from licensing of our gene- and genomic-related intellectual property. We expect that license and royalty revenues will decline as we focus on our drug discovery and development programs.

Operating Expenses.

Research and development expenses.

	For the three months ended, March 31,	
	2010	2009
	(in millions)	
Salary and benefits related	$ 10.6	$ 9.5
Stock compensation	2.2	2.5
Clinical research and outside services	14.7	14.0
Occupancy and all other costs	3.9	3.6

Total research and development expenses	$	31.4	$	29.6

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 months ended March 31, 2009 to the three months ended March 31, 2010 due to increased development headcount to sustain our development pipeline. Stock compensation expense may fluctuate from period to period based on the number of options granted, stock price volatility and expected option lives, as well as expected option forfeiture rates which are used to value equity-based compensation. The increase in clinical research and outside services from the three months ended March 31, 2009 to the three months ended March 31, 2010 is primarily due the advancement of our pipeline and expenses related to our Phase III oncology program. The increase in occupancy and all other costs from the three months ended March 31, 2009 to the three months ended March 31, 2010 was primarily the result of increased laboratory expenses. Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial-related activities. Many factors can affect the cost and timing of our clinical trials, including requests by regulatory agencies for more information, inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects among patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of our investigational drugs in our clinical trials. In addition, the development of all of our products will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development and approval of our products. Research and development expenses for the three months ended March 31, 2010 are net of $2.6 million of costs reimbursed by our collaborative partners.

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Selling, general and administrative expenses.

	For the three months ended, March 31,	
	2010	2009
	(in millions)	
Salary and benefits related	$ 2.3	$ 1.9
Stock compensation	0.9	0.9
Other contract service and outside costs	2.6	2.0
Total selling, general and administrative expenses	$ 5.8	$ 4.8

Salary and benefits related expense increased from the three months ended March 31, 2009 to the three months ended March 31, 2010 due to increased headcount. This increased headcount was due to initial sales and marketing preparations for the potential commercialization of INCB18424 for myelofibrosis. Stock compensation expense may fluctuate from period to period based on the number of options granted, stock price volatility and expected option lives, as well as expected option forfeiture rates which are used to value equity-based compensation. The increase in other contract services and outside costs was primarily the result of initial marketing preparations for the potential commercialization of INCB18424 for myelofibrosis.

Other expenses. Total other expenses for the three months ended March 31, 2010 was $(0.1) million compared to $0.5 million for the corresponding period in 2009, and represent (benefits) charges recorded in connection with previously announced restructuring programs.

Interest and Other Income (Expense), Net. Interest income for the three months ended March 31, 2010 was $0.2 million as compared to $0.5 million for the corresponding period in 2009. The decrease is due to a lower yield for the three months ended March 31, 2010 as compared to the corresponding period in 2009.

Interest Expense. Interest expense for the three months ended March 31, 2010 and 2009 was $11.8 million and $6.3 million, respectively. The increase from the 2009 period to the 2010 period is primarily attributable to the increase in coupon interest and accretion of the discount related to our 4.75% convertible senior notes due 2015 issued in September 2009.

Loss on redemption of convertible senior and subordinated notes. During the three months ended March 31, 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.

Provision for income taxes. The provision for income taxes for the three months ended March 31, 2010 is for the estimated alternative minimum tax liability which results in 2010 from the recognition for tax purposes of the remaining deferred revenue related to the upfront payments received from Novartis and Lilly. There was no similar alternative minimum tax liability in 2009.

Liquidity and Capital Resources

Due to our significant research and development expenditures, we have not been profitable and have generated operating losses since we were incorporated in 1991 through 1996 and in 1999 through March 31, 2010. As such, 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 March 31, 2010, we had available cash, cash equivalents, and short-term and long-term marketable securities of $422.3 million. Our cash and marketable securities balances are held in a variety of interest- bearing instruments including money market accounts, obligations of U.S. government agencies, high-grade corporate bonds, and asset backed and 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. Recent distress in the financial markets has had an adverse impact on financial market activities including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. We have assessed the implications of these factors on our current business and determined that there had not been a significant impact to our financial position, results of operations or liquidity for the period ended March 31, 2010.

Net cash provided by operating activities was $102.8 million for the three months ended March 31, 2010, compared to $42.7 million used in operating activities for the three months ended March 31, 2009. The $145.5 million increase was due primarily to remaining upfront payments received from our collaborators during the three months ended March 31, 2010.

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Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures. Net cash provided by investing activities was $6.5 million for the three months ended March 31, 2010, which represented primarily sales and maturities of marketable securities of $6.8 million offset by capital expenditures of $0.3 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 used in financing activities was $154.4 million and $0.0 million for the three months ended March 31, 2010 and 2009, respectively. For the three months ended March 31, 2010, we used $158.6 million to redeem the remaining 3½% convertible senior notes and 3½% convertible subordinated notes. For the three months ended March 31, 2010 and 2009, we received $4.2 million and $0.0 million, respectively, from issuance of common stock under our stock plans and employee stock purchase plan.

The following summarizes our significant contractual obligations as of March 31, 2010 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	$	$ 10.0	$ 10.0	$
Principal on convertible senior debt	400.0				400.0
Interest on convertible senior debt	114.1	19.1	38.0	38.0	19.0
Non-cancelable operating lease obligations:					
Related to current operations	18.2	5.5	11.3	1.4	
Related to vacated space	7.3	7.3			
Total contractual obligations	$ 559.6	$ 31.9	$ 59.3	$ 49.4	$ 419.0

The amounts and timing of payments related to vacated facilities may vary based on negotiated timing of lease terminations. We have entered into sublease agreements for our vacated space with scheduled payments to us of $2.1 million (less than 1 year); these scheduled payments are not reflected in the above table. In addition, we have funded an escrow account of $56.5 million for the first six semi-annual interest payments on our 4.75% convertible senior notes due 2015.

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

Commitments related to Maxia Pharmaceuticals, Inc. are considered contingent commitments as future events must occur to cause these commitments to be enforceable. In February 2003, we completed our acquisition of Maxia. Under the merger agreement, former Maxia stockholders have the right to receive certain earn out amounts of up to a potential aggregate amount of $14.0 million upon the occurrence of certain research and development milestones set forth in the merger agreement. Twenty percent of each earn out payment, if earned, will be paid in cash and the remaining eighty percent will be paid in shares of our common stock such that an aggregate of $2.8 million in cash and $11.2 million in our common stock (based upon the then fair value) could potentially be paid pursuant to the earn out milestones. The milestones are set to occur as Maxia products enter various stages of human clinical trials and may be earned at any time prior to the tenth anniversary of

the consummation of the merger. In any event, no more than 13,531,138 shares of our common stock may be issued to former Maxia stockholders in the aggregate pursuant to the merger agreement. None of these milestones has been achieved as of March 31, 2010.

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

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; 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. We expect that future revenues generated from information products, including licensing of intellectual property, will continue to decline or remain steady as we focus on drug discovery and development programs and, in 2010, will not represent a significant source of cash inflow for us.

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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. The credit markets and the financial services industry recently experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events generally made equity and debt financing difficult to obtain since their occurrence. If we are not able to secure additional funding when needed, we may have to scale back our operations, delay or eliminate one or more of our research or development programs, or attempt to obtain funds by entering into an agreement with a collaborator or licensee that would result in terms that are not favorable to us or relinquishing our rights in certain of our proprietary technologies or drug candidates.

Off Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investments in marketable securities, which are composed primarily of investment-grade corporate bonds, U.S. government agency debt securities, mortgage and asset-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 March 31, 2010, cash, cash equivalents and short-term and long-term marketable securities were $422.3 million, excluding a funded restricted cash escrow account of $56.5 million associated with the first six semi-annual interest payments 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 March 31, 2010 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.

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PART II: OTHER INFORMATION

Item 1A. Risk Factors

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;

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

- lease facilities at reasonable rates to support our growth; and

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

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

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

None of our drug candidates has, to date, been submitted for approval for sale in the United States or any foreign market. 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. For example, in 2006, we discontinued the development of dexelvucitabine, or DFC, which was at the time our most advanced drug candidate and was in Phase IIb clinical trials. Prior to discontinuation of the DFC program, we expended a significant amount of effort and money on that program. 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.

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

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

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

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

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

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

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

we anticipated receiving, and our business could be adversely affected.

Although we obtained a special protocol assessment for our JAK inhibitor for myelofibrosis, a special protocol assessment does not guarantee any particular outcome from regulatory review, including any regulatory approval.

We have obtained a special protocol assessment, or SPA, for the registration trial for our JAK inhibitor for the treatment of myelofibrosis in the United States. The SPA process allows for Food and Drug Administration, or FDA, evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application, or NDA, and provides a product sponsor with an agreement confirming that the design and size of the 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. An SPA is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, the 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 if issues arise essential to determining safety or efficacy. In addition, 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

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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.

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. We have one drug candidate, INCB18424, in Phase III clinical trials. 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. We discontinued development of DFC in April 2006 for safety reasons. In March 2008, we announced that we would not advance our lead CCR5 antagonist into Phase IIb trials and that we were seeking to out-license this program. 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. 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. For example, drugs that receive approval are subject to post-regulatory surveillance and may have to be withdrawn from the market if previously unknown side effects occur. At this point, the regulatory agencies may require additional clinical trials or testing. Once a drug is marketed, if it causes side effects, 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.

If we do not develop effective sales and marketing capabilities or establish third-party relationships for the commercialization of our drug candidates, we will not be able to successfully commercialize any drug candidates that obtain regulatory approval, and we may incur significant additional costs or difficulties in doing so.

We do not have experience selling or marketing drug products or with respect to pricing and obtaining adequate third-party reimbursement for drugs. We will need to either develop sales and marketing capabilities or enter into arrangements with third parties to sell and market our drug candidates, if they are approved for sale by regulatory authorities. Under our collaboration and license agreement with Novartis, we have retained commercialization rights to INCB18424 in the United States. In anticipation of the regulatory approval of INCB18424 for myelofibrosis, we have started to build the sales and marketing and operational infrastructure to support commercialization. This will require substantial efforts and significant management and financial resources. We will need such an infrastructure to market any of our drug candidates for which we have retained commercialization rights, if they receive regulatory approval. We will need to devote significant effort and investment, in particular, to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is very high, and we will be competing with companies that are currently marketing successful drugs. We may not be able to successfully develop our own sales and marketing capabilities for INCB18424 in the United States in order to support an effective launch

of INCB18424 if it is approved for sale. If we do not obtain regulatory approval for INCB18424 for myelofibrosis, we will have incurred significant expenses to build this commercialization infrastructure.

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, or whether we will be able to leverage the sales and marketing capabilities we intend to build for INCB18424 for myelofibrosis in order to market and sell any other drug candidate if it is approved for sale.

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

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

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

Even if we are successful in gaining regulatory approval of our products, 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 will 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 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.

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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 Food and Drug Administration, or 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.

Due, in part, to the early stage of our drug candidate research and development process, we cannot predict whether regulatory approval will be obtained for any product we develop. None of our drug candidates has, to date, been submitted for approval for sale in the United States of any foreign market. We have licensed to Novartis rights to INCB18424 in certain indications outside of the United States and worldwide rights to c-MET and licensed to Lilly worldwide rights to INCB28050. We have also licensed to Pfizer our portfolio of CCR2 antagonist compounds. We have no or limited control over the further clinical development of any compounds we licensed to these collaborators. Compounds developed by us, alone or with other parties, may not prove to be safe and effective in clinical trials and may not meet all of the applicable regulatory requirements needed to receive marketing approval. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective. Failure to obtain regulatory approval would delay or prevent us from commercializing products.

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

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our drug discovery and development efforts may target diseases and conditions that are already subject to existing therapies or that are being developed by our competitors, many of which have substantially greater resources, larger research and development staffs and facilities, more experience in completing preclinical testing and clinical trials, and formulation, marketing

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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 both the active pharmaceutical ingredient, or API, and finished drug product of our drug candidates for clinical trials. In addition, we expect to continue to rely on third parties for the manufacture of commercial supplies of API and finished drug product for any drugs that we successfully develop. For most of our drug candidates, including our lead drug candidate INCB18424, we rely on one third party to manufacture the API, another to make finished drug product and a third to package and label the finished product. The FDA requires that the 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. Generally, we have only a single source that is qualified to supply the API and finished product of our drug candidates. If any of these single source suppliers were to become unable or unwilling to supply us with API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply which could have a material adverse effect on our business. We are currently seeking to qualify a second source of supply for the API for our lead drug candidate, INCB18424, however, there is no assurance that we will be able to identify and qualify a second source of supply for INCB18424 or any of our other drug candidates or drug products on a timely basis. If we have promised delivery of a new product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs would be delayed, and 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. This expense would adversely affect our operating results.

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

In order to obtain approval of our products, including INCB18424, 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. With respect to INCB18424, although we have manufactured the product at commercial scale, we have started, but not yet completed, this process validation requirement. If the required testing or process validation is delayed or produces unfavorable results, we may not obtain approval to launch the product or product launch may be delayed.

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.

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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 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 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

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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.

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 2009. Because of those losses, we had an accumulated deficit of $1.4 billion as of March 31, 2010. 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 2010 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 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.

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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;
- 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;
- 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 March 31, 2010, the aggregate principal amount of our total consolidated debt was $420.0 million and our stockholders deficit was $114.4 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.

Historically, we have had negative cash flow from operations. We likely will 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

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convertible senior notes. As of March 31, 2010, $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 March 31, 2010, $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, redeemed, repurchased or exchanged, are $19.0 million. Funds sufficient to pay the first six scheduled semi-annual interest payments 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. 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 from our gene and genomics-related intellectual property may not contribute significantly to revenues for several years, and may never result in revenues.

We derived all of our revenues for the three months ended March 31, 2010 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. Part of our prior strategy was to license to our database customers and to other pharmaceutical and biotechnology companies our know-how and patent rights associated with the information we have generated in the creation of our proprietary databases, for use in the discovery and development of potential pharmaceutical, diagnostic or other products. Any potential product that is the subject of such a license will require several years of further development, clinical trials and regulatory approval before commercialization, all of which is beyond our control, and possibly beyond the control of our licensee. These licensees may not develop the potential product if they do not devote the necessary resources or decide that they do not want to expend the resources to do the clinical trials necessary to obtain the necessary regulatory approvals. Therefore, milestone or royalty payments from these licenses may not contribute to our revenues for several years, if at all. We have decided to discontinue some of our gene and genomics-related patent prosecution and maintenance, and may in the future decide to discontinue additional gene and genomics-related patent prosecution and maintenance, which could limit our ability to receive license-based revenues from our gene and genomics-related patent portfolio.

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

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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.

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

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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.

Item 6. Exhibits

Exhibit Number	Description of Document
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)

* 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.

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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:	May 6, 2010	By:	/s/ PAUL A. FRIEDMAN PAUL A. FRIEDMAN Chief Executive Officer (Principal Executive Officer)
Dated:	May 6, 2010	By:	/s/ DAVID C. HASTINGS DAVID C. HASTINGS Chief Financial Officer (Principal Financial Officer)

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INCYTE CORPORATION

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