INCYTE CORP
Form 10-Q
May 07, 2009
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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, 2009

or

o **TRANSITION REPORTS 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 97,339,849 as of May 1, 2009.

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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, 2009 (unaudited)	December 31, 2008*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 139,098	$ 178,767
Marketable securities available-for-sale	18,591	19,257
Accounts receivable, net	739	1,050
Prepaid expenses and other current assets	6,937	6,420
Total current assets	165,365	205,494
Marketable securities available-for-sale	17,938	19,759
Property and equipment, net	2,495	2,796
Intangible and other assets, net	3,837	4,339
Total assets	$ 189,635	$ 232,388
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 15,084	$ 15,679
Accrued compensation	6,024	9,330
Interest payable	1,758	5,273
Accrued and other current liabilities	14,015	14,893
Deferred revenue	72	62
Accrued restructuring	5,145	5,100
Total current liabilities	42,098	50,337
Convertible senior notes	133,263	130,969
Convertible subordinated notes	265,411	265,198
Other liabilities	5,614	6,634
Total liabilities	446,386	453,138
Stockholders deficit:		
Preferred stock		
Common stock, $0.001 par value; 200,000,000 shares authorized; 97,339,849 shares issued and outstanding as of March 31, 2009 and December 31, 2008	97	97
Additional paid-in capital	964,574	961,214

Accumulated other comprehensive loss	(2,072)	(2,747)
Accumulated deficit	(1,219,350)	(1,179,314)
Total stockholders deficit	(256,751)	(220,750)
Total liabilities and stockholders deficit	$ 189,635	$ 232,388

* The condensed consolidated balance sheet at December 31, 2008 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,	
	2009	**2008**
Revenues:		
Contract revenues	$	$ 587
License and royalty revenues	671	720
Total revenues	671	1,307
Costs and expenses:		
Research and development	29,587	32,955
Selling, general and administrative	4,821	4,354
Other expenses	509	123
Total costs and expenses	34,917	37,432
Loss from operations	(34,246)	(36,125)
Interest and other income, net	548	2,141
Interest expense	(6,338)	(6,173)
Net loss	(40,036)	(40,157)
Basic and diluted net loss per share	$ (0.41)	$ (0.47)
Shares used in computing basic and diluted net loss per share	97,340	84,602

See accompanying notes.

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INCYTE CORPORATION

Condensed Consolidated Statements of Comprehensive Loss

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2009	**2008**
Net loss	$ (40,036)	$ (40,157)
Other comprehensive gain (loss):		
Unrealized gain (loss) on marketable securities	675	(1,238)
Comprehensive loss	$ (39,361)	$ (41,395)

See accompanying notes.

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INCYTE CORPORATION

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2009	**2008**
Cash flows from operating activities:		
Net loss	$ (40,036)	$ (40,157)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash restructuring charges	509	123
Depreciation and amortization	2,509	3,288
Stock-based compensation	3,360	3,345
Changes in operating assets and liabilities:		
Accounts receivable	311	711
Prepaid expenses and other assets	380	(1,075)
Accounts payable	(595)	5,422
Accrued and other current liabilities	(9,183)	(8,462)
Deferred revenue	10	(577)
Net cash used in operating activities	(42,735)	(37,382)
Cash flows from investing activities:		
Capital expenditures	(95)	(122)
Purchases of marketable securities		1,241
Sales and maturities of marketable securities	3,161	89,630
Net cash provided by investing activities	3,066	90,749
Cash flows from financing activities:		
Proceeds from issuance of common stock under stock plans		520
Net cash provided by financing activities		520
Net (decrease) increase in cash and cash equivalents	(39,669)	53,887
Cash and cash equivalents at beginning of period	178,767	108,854
Cash and cash equivalents at end of period	$ 139,098	$ 162,741

See accompanying notes.

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INCYTE CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2009

(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, inflammation, and diabetes.

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, 2009 and the condensed consolidated statements of operations, comprehensive loss, and cash flows for the three months ended March 31, 2009 and 2008 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, 2008 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 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, 2008.

Recent Accounting Pronouncements

Effective January 1, 2009, we adopted Staff Position No. Accounting Principles Board 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement) (* FSP No. APB 14-1). FSP No. APB 14-1 requires that the liability and equity components of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) be separately accounted for in a manner that reflects an issuer s nonconvertible debt borrowing rate. FSP No. APB 14-1 was effective for us as of January 1, 2009. The adoption of APB 14-1 had no impact on our consolidated financial statements.

Effective January 1, 2009, we adopted Emerging Issues Task Force (EITF) Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* (EITF 07-5). EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity s own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting For Derivative Instruments and Hedging Activities* and/or EITF 00-19, *Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock*. EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and early application is not permitted. The adoption of EITF 07-5 had no impact on our consolidated financial statements.

In April 2009, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) FAS 157-4, *Determining Fair Value when the Volume and Level of Activity for the Asset or Liability have Significantly Decreased and Identifying Transactions that are not Orderly* (FSP 157-4), which is effective for our interim and annual periods commencing with our June 30, 2009 consolidated financial statements and will be applied on a prospective basis. FSP 157-4 affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. The FSP provides guidance for estimating fair value when the volume and level of market activity for an asset or liability have significantly decreased and determining whether a transaction was orderly. This FSP applies to all fair value measurements when appropriate. We are currently evaluating the impact of the adoption of this statement on our financial statements based on current market conditions.

In April 2009, the FASB issued FSP FAS 115-2, *Recognition and Presentation of Other-Than-Temporary Impairments* (FSP 115-2), which is effective for us for the quarterly period beginning April 1, 2009. FSP 115-2 amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing

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requirement that an entity s management assert it has the positive intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is not more likely than not it will be required to sell the security before recovery of its amortized cost basis. FAS 115-2 may require a cumulative effect adjustment upon adoption for the non-credit related component of previously recognized other-than-temporary impairments. We are currently evaluating the impact of the adoption of FSP 115-2 on our financial statements.

In April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments* (FSP 107-1), which is effective for us for the quarterly period beginning April 1, 2009. FSP 107-1 requires an entity to provide the annual disclosures required by FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, in its interim financial statements. We are currently evaluating the impact of the adoption of FSP 107-1 on our financial statements.

3. Marketable securities

We adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157) effective January 1, 2008. SFAS 157 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.

We have determined that our fair value requirements are in accordance with the requirements of SFAS 157, therefore, the implementation of SFAS 157 did not have any impact on our consolidated financial condition or results of operations. 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 consolidated balance sheets if (i) they have been in an unrealized loss position for longer than six months and (ii) we have the ability to hold them until the carrying value is recovered and such holding period may be longer than one year.

The following fair value hierarchy table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2009 (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, 2009
Cash and cash equivalents	$ 139,098	$	$	$ 139,098
Marketable securities available-for-sale	2,155	34,374		36,529
Total	$ 141,253	$ 34,374	$	$ 175,627

4. Revenues

For the three months ended March 31, 2009, one customer contributed 48% of revenues. For the three months ended March 31, 2008, one customer contributed 45% of revenues.

Three customers comprised 82% of the accounts receivable balance at March 31, 2009. Three customers comprised 78% of the accounts receivable balance at December 31, 2008.

Contract revenues related to the upfront consideration received, research services provided to Pfizer Inc. (Pfizer) under our collaborative research and license agreement with Pfizer, and the difference between the cash received and the present value of convertible subordinated notes issued to Pfizer (the Pfizer Notes), of approximately $0.0 million and $0.6 million, respectively, were recognized for the three months ended March 31, 2009 and 2008.

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5. Stock compensation

Under the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004) (SFAS 123R), we recorded $3.4 million and $3.3 million of stock compensation expense on our unaudited condensed consolidated statement of operations for the three months ended March 31, 2009 and 2008, 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,	
	2009	2008	2009	2008
Average risk-free interest rates	1.05%	2.03%	0.81%	1.62%
Average expected life (in years)	2.98	2.95	0.24	0.24
Volatility	72%	65%	99%	76%
Weighted-average fair value (in dollars)	1.45	5.22	1.49	1.44

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

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

The amortization of stock compensation under SFAS 123R for the period after its adoption was calculated in accordance with FASB Interpretation (FIN) No. 28. Total compensation cost of options granted but not yet vested, as of March 31, 2009, was $9.1 million, which is expected to be recognized over the weighted average period of 2.99 years.

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, 2008	5,390,467	14,982,476	$	8.67
Options granted	(2,916,000)	2,916,000		3.10
Options exercised				
Options cancelled	43,531	(43,531)		7.55
Balance at March 31, 2009	2,517,998	17,854,945	$	7.76
Exercisable, March 31, 2009		11,110,089	$	8.47

6. 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 our 3 1/2% convertible senior notes due 2011 (the 3 1/2% Senior Notes), 3 1/2% convertible subordinated notes due 2011 (the 3 1/2% Subordinated Notes) and the Pfizer Notes were excluded from the computation of diluted net loss per share, as their share effect was anti-dilutive for all periods presented. The potential common shares that were excluded from the diluted net loss per share computation are as follows:

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	2009	2008
Outstanding stock options	17,854,945	15,318,055
Common shares issuable upon conversion of 31/2% Senior Notes	13,531,224	13,531,224
Common shares issuable upon conversion of 31/2% Subordinated Notes	22,284,625	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	56,157,931	53,621,041

7. Segment reporting

Our operations are treated as one operating segment, drug discovery and development, in accordance with Statement of Financial Accounting Standards No. 131 *Disclosures about Segments of an Enterprise and Related Information*.

8. Other expenses

Below is a summary of the activity related to our restructuring programs for the three months ended March 31, 2009. 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, 2008	2009 Charges to Operations	2009 Charges Utilized	Accrual Balance at March 31, 2009
			(in thousands)		
Lease commitment and related costs	$ 15,497	$ 5,788	$ 85	$ (652)	$ 5,221
Other costs			35	(35)	
Restructuring expenses	$ 15,497	$ 5,788	$ 120	$ (687)	$ 5,221

2002 Restructuring

	Original Charge Recorded in 2002	Accrual Balance at December 31, 2008	2009 Charges to Operations (in thousands)	2009 Charges Utilized	Accrual Balance at March 31, 2009
Lease commitment and related costs	$ 16,155	$ 5,931	$ 389	$ (782)	$ 5,538

Maxia Acquisition Costs

	Original Charge	Accrual Balance at December 31, 2008	2009 Charges to Operations (in thousands)	2009 Charges Utilized	Accrual Balance at March 31, 2009
Lease commitment and related costs	$ 2,373	$ 15	$	$ (15)	$

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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, 2009 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, 2008 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 alliance strategy; anticipated benefits and disadvantages of entering into collaboration agreements;*
- *our licensing, investment and commercialization strategies;*
- *the regulatory approval process, including determinations to seek U.S. Food and Drug Administration (FDA) and other international health authorities approval for, and plans to commercialize, our products in the United States and abroad;*
- *the safety, effectiveness and potential benefits and indications of our product candidates and other compounds under development; potential uses for our product candidates and our other compounds;*
- *the timing and size of our clinical trials; the compounds expected to enter clinical trials; timing of clinical trial results;*

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

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

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

- *the receipt from or payments pursuant to collaboration or license agreements resulting from milestones or royalties; the decrease in revenues from our information product-related activities;*

- *plans to develop and commercialize products on our own;*

- *plans to use third party manufacturers;*

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

- *expected losses; fluctuation of losses;*

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

- *the need to raise additional capital;*

- *the costs associated with resolving matters in litigation;*

- *our expectations regarding competition;*

- *our investments, including anticipated expenditures, losses and expenses;*

- *our gene and genomics-related 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;*

- *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;*

- *the impact of past or future acquisitions on our business;*

- *the results of businesses in which we have made investments;*

- *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, inflammation, and diabetes.

Our wholly-owned pipeline includes the following compounds:

Drug Target	Drug Compound	Indication	Development Status
Active Programs			
JAK			
	INCB18424 (Oral)	Myelofibrosis	Phase II
		Polycythemia Vera/Essential Thrombocythemia	Phase II
	INCB18424 (Topical)	Psoriasis	Phase IIb
	INCB28050	Rheumatoid Arthritis	Phase II
HSD1			
	INCB13739	Type 2 Diabetes	Phase IIb
	INCB20817	Type 2 Diabetes	Phase I
Sheddase			
	INCB7839	Solid Tumors	Phase IIa
		Breast Cancer	Phase II
Currently Inactive Programs pending additional funding or seeking collaborative partner			
c-MET			
	INCB28060	Solid Cancers	IND Cleared
IDO			
	INCB24360	Oncology	IND Cleared
JAK			
	INCB18424 (Oral)	Rheumatoid Arthritis	Phase II
		Refractory Prostate Cancer	Phase IIa
		Multiple Myeloma	Phase IIa
HM74a			
	INCB19602	Type 2 Diabetes	Phase IIa
CCR2			
	INCB8696	Multiple Sclerosis	Phase I

CCR5

INCB9471	Human Immunodeficiency Virus (HIV)	Phase II
INCB15050	HIV	Phase I

In early 2009, we announced that due to the challenging economic environment, we intend to focus our efforts on clinical programs that we believe have a greater likelihood of creating near-term value. We do not intend to initiate clinical trials in 2009 for our c-MET inhibitor or our selective inhibitor of the enzyme IDO unless we are successful in securing additional funding. We also intend to move INCB28050 forward as our lead oral anti-inflammatory compound and have discontinued the development of INCB18424 in rheumatoid arthritis. Programs that will not receive funding in 2009 include: our JAK inhibitor programs for hormone refractory prostate cancer and multiple myeloma; our HM74a agonist for type 2 diabetes; our CCR2 receptor antagonist for multiple sclerosis; and our CCR5 receptor antagonist for HIV.

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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. We do not expect to generate product sales from our drug discovery and development efforts for several years, if at all. 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 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:

- Investments;
- Revenue recognition;
- Research and development costs;
- Valuation of long-lived assets;
- Restructuring charges; and
- Stock compensation.

Investments. We account for investments in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. 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 our intent and ability to hold the security until the market values recover, which may be maturity. 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.

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 collectibility is reasonably assured. We have entered into various types of agreements for access to our information databases and use of our intellectual property. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectibility 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 collectibility based primarily on the customer s payment history and on the creditworthiness of the customer.

Revenues from ongoing database agreements are recognized evenly over the access period. 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.

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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. In accordance with SFAS No. 2, *Accounting for Research and Development Costs*, it is our policy to expense research and development costs as incurred. We often contract with clinical research organizations (CROs) to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contract.

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed in accordance with Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities.* 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.

Valuation of Long-Lived Assets. We assess the impairment of long-lived assets, which includes property and equipment as well as intangible and other assets, whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important that could indicate the need for an impairment review include the following:

- Significant changes in the strategy of our overall business;

- Significant underperformance relative to expected historical or projected future operating results;

- Significant changes in the manner of use of the acquired assets;

- Significant negative industry or economic trends;

- Significant decline in our stock price for a sustained period; and

- Our market capitalization relative to net book value.

When we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long Lived Assets*, we perform an undiscounted cash flow analysis to determine if impairment exists. If impairment exists, we measure the impairment based on the difference between the asset s carrying amount and its fair value.

Restructuring Charges. Costs associated with restructuring activities initiated after December 31, 2002, are accounted for in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146). Costs associated with restructuring activities initiated prior to December 31, 2002 have been recorded in accordance with EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)* and Staff Accounting Bulletin No. 100, *Restructuring and Impairment Charges*. Restructuring costs resulting from the acquisition of Maxia Pharmaceuticals, Inc. (Maxia) have been recorded in accordance with EITF Issue No. 95-3*, Recognition of Liabilities in Connection with a Purchase Business Combination*. The restructuring charges are comprised primarily of costs to exit facilities, reduce our workforce, write-off fixed assets, and pay for outside services incurred in the restructuring. The workforce reduction charge is determined based on the estimated severance and fringe benefit charge for identified employees. In calculating the

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cost to exit the facilities, we estimate for each location the amount to be paid in lease termination payments, the future lease and operating costs to be paid until the lease is terminated, the amount, if any, of sublease receipts and real estate broker fees. This requires us to estimate the timing and costs of each lease to be terminated, the amount of operating costs, and the timing and rate at which we might be able to sublease the site. 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 in accordance with SFAS 146. Estimates are also used in our calculation of the estimated realizable value on equipment that is being held for sale. These estimates are formed based on recent history of sales of similar equipment and market conditions. 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.

Stock Compensation. Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004) (SFAS 123R), *Share-Based Payment*, which revised SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS 123R 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 relative fair values. SFAS 123R 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. SFAS 123R requires the recognition of the fair value of stock compensation in the statement of operations. Under the provisions of SFAS 123R, we recorded $3.4 million and $3.3 million of stock compensation expense for the three months ended March 31, 2009 and 2008, respectively.

Results of Operations

We recorded a net loss of $40.0 million and basic and diluted net loss per share of $0.41 for the three months ended March 31, 2009 as compared to a net loss of $40.2 million and basic and diluted net loss per share of $0.47 in the corresponding period in 2008.

Revenues.

	For the three months ended, March 31,	
	2009	2008
	(in millions)	
Contract revenues	$	$ 0.6
License and royalty revenues	0.7	0.7
Total revenues	$ 0.7	$ 1.3

Our contract revenues for the three months ended March 31, 2009 decreased to $0.0 million from $0.6 million for the three months ended March 31, 2008, as, by June 30, 2008, we had fully recognized contract revenues associated with the Pfizer $40.0 million upfront fee, the debt discount and beneficial conversion feature related to the Pfizer Notes and the reimbursement of certain expenses by Pfizer for research and development expenses pursuant to the collaborative research and license agreement.

Our license and royalty revenues for the three months ended March 31, 2009 and 2008 were the same, $0.7 million. License and royalty revenues were derived from the licensing of our gene- and genomic-related intellectual property. We expect that revenues generated from information products, including licensing of gene- and genomic-related intellectual property, 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,	
	2009	**2008**
	(in millions)	
Salary and benefits related	$ 9.5	$ 9.1
Stock compensation	2.5	2.4
Clinical research and outside services	14.0	17.4
Occupancy and all other costs	3.6	4.1
Total research and development expenses	$ 29.6	$ 33.0

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We currently track research and development costs by natural expense line and not costs by project. For salary and benefit related costs, the increase from the three months ended March 31, 2008 to the three months ended March 31, 2009 was primarily the result of increased headcount to sustain our development pipeline. Stock compensation was essentially flat for the three months ended March 31, 2009 as compared to the three months ended March 31, 2008. 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. For clinical research and outside services, the decrease from the three months ended March 31, 2008 to the three months ended March 31, 2009 is due to prioritization of our pipeline to focus on products we believe have a greater likelihood of creating near-term value. The decrease in occupancy and all other costs for the three months ended March 31, 2009 as compared to the three months ended March 31, 2008 was due to a decrease in depreciation and patent expense.

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.

Selling, general and administrative expenses.

	For the three months ended, March 31,	
	2009	2008
	(in millions)	
Salary and benefits related	$ 1.9	$ 1.6
Stock compensation	0.9	0.9
Other contract service and outside costs	2.0	1.9
Total selling, general and administrative expenses	$ 4.8	$ 4.4

For salary and benefit related costs, the increase from the three months ended March 31, 2008 to the three months ended March 31, 2009 was primarily the result of increased headcount. The increased headcount was due to initial sales and marketing preparations for the potential commercialization of INCB18424 for myeloproliferative disorders. Stock compensation expense and other contract service and outside costs were essentially flat for the three months ended March 31, 2009 as compared to the corresponding period in 2008.

Other expenses. Total other expenses for the three months ended March 31, 2009 were $0.5 million compared to $0.1 million for the corresponding period in 2008, and represent charges recorded in connection with previously announced restructuring programs.

Interest and Other Income, Net. Interest and other income, net, for the three months ended March 31, 2009 was $0.5 million compared to $2.1 million for the corresponding period in 2008. The decrease is due primarily to a lower average cash balance and yield for the three months ended March 31, 2009 as compared to the corresponding period in 2008.

Interest Expense. Interest expense for the three months ended March 31, 2009 was $6.3 million compared to $6.2 million for the corresponding period in 2008.

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, 2009. 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. As of March 31, 2009, approximately $17.9 million of marketable securities were classified as long-term assets on the consolidated balance sheet as they had been in an unrealized loss position for longer than six months and we have the intent and ability to hold them until the carrying value recovers, which may be longer than one year. At March 31, 2009, we had available cash, cash equivalents, and short-term and long-term marketable securities of $175.6 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

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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, 2009.

Net cash used in operating activities was $42.7 million for the three months ended March 31, 2009, compared to $37.4 million for the three months ended March 31, 2008. The $5.3 million increase was due primarily to changes in working capital.

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 $3.1 million for the three months ended March 31, 2009, which represented primarily sales and maturities of marketable securities of $3.2 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.

Net cash provided by financing activities was $0.0 million and $0.5 million for the three months ended March 31, 2009 and 2008, respectively. For the three months ended March 31, 2008, we received $0.5 million 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, 2009 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
Contractual Obligations:					
Principal on convertible subordinated debt	$ 270.0	$	$ 250.0	$ 20.0	$
Principal on convertible senior debt	151.8		151.8		
Interest on convertible subordinated debt	17.5	8.7	8.8		
Interest on convertible senior debt	10.6	5.3	5.3		
Non-cancelable operating lease obligations:					
Related to current operations	6.7	5.4	1.3		
Related to vacated space	15.3	8.0	7.3		
Total contractual obligations	$ 471.9	$ 27.4	$ 424.5	$ 20.0	$

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 $2.7 million (less than 1 year) and $2.3 million (years 1-3); these scheduled payments are not reflected in the above table.

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 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, 2009.

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 potential repayments of our 31/2% convertible senior notes due 2011, 31/2% convertible subordinated notes due 2011, and the Pfizer Notes; expenditures in connection with our drug discovery and development programs; expenditures in connection with litigation or other legal proceedings; competing technological and market developments; the cost of filing, prosecuting, defending and enforcing patent

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claims and other intellectual property rights; our receipt of any milestone or other payments under any collaborative agreements we may enter into, including the agreement with Pfizer; and expenditures in connection with alliances and license agreements. Changes in our research and development 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 as we focus on drug discovery and development programs and, in 2009, will not represent a significant source of cash inflow for us. We intend to continue to evaluate options to repurchase or refinance our outstanding convertible notes that mature in February 2011. Repurchases might occur through cash purchases and/or exchanges for other securities in open market transactions, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material. Any issuance of equity securities in exchange for our outstanding convertible notes may be dilutive to our stockholders.

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. We do not know whether additional funding will be available on acceptable terms, if at all. Recently, the credit markets and the financial services industry have been experiencing 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 have generally made equity and debt financing difficult to obtain. 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 collaborative partner 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, 2009, cash, cash equivalents and short-term and long-term marketable securities were $175.6 million. 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, 2009 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 at the early stage of our drug discovery and development efforts and we may be unsuccessful in our efforts.

We are in the early stage of building our drug discovery and development 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;

- 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.

Our drug candidates in clinical trials are in Phase I and Phase II trials. Our other drug candidates are still undergoing preclinical testing. We have also licensed to Pfizer our portfolio of CCR2 antagonist compounds. We have no control over the further clinical development of any compounds we licensed to Pfizer. 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 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.

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, our research and development efforts may be unsuccessful, which could adversely affect our results of operations and financial condition.

An important element of our business strategy will be to enter into collaborative or license arrangements with other parties, such as our collaboration with Pfizer, under which we license our drug candidates to those parties for development and commercialization. We expect that while we plan to conduct initial clinical trials on our drug candidates, we may need to seek collaborators for our drug candidates such as our chemokine receptor antagonists because of the expense, effort and expertise required to continue additional clinical trials and further develop those drug candidates. We may also seek collaborators for our drug candidates that target large primary care indications such as diabetes because of the expense involved in further clinical development of these indications and in establishing a sales and marketing organization to address these indications. Because collaboration arrangements are complex to

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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 agreements, 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 or do not devote adequate resources to the program, the relationship will not be successful. 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.

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

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

We depend on our collaboration with Pfizer for the development and commercialization of CCR2 antagonist compounds.

Under our collaborative research and license agreement with Pfizer, Pfizer gained worldwide development and commercialization rights to our portfolio of CCR2 antagonist compounds. Pfizer s rights extend to the full scope of potential indications, with the exception of multiple sclerosis and autoimmune nephritides.

Although Pfizer is required to use commercially reasonable efforts to develop and commercialize CCR2 antagonists for the indications for which they are responsible, we cannot control the amount and timing of resources Pfizer may devote to the development of CCR2 antagonists. Any failure of Pfizer to perform its obligations under our agreement could negatively impact the development of CCR2 antagonists, lead to our loss of potential revenues from product sales and milestones and delay our achievement, if any, of profitability.

Pfizer has certain rights to terminate the license agreement, including the right to terminate upon 90 days notice for any reason. Pfizer also has the right to terminate its rights and obligations with respect to certain indications and licensed compounds. If Pfizer terminates the license agreement or its rights with respect to certain indications, we may not be able to find a new collaborator to replace Pfizer, and our business could be adversely affected.

If conflicts arise between our collaborators, including Pfizer, licensees, or advisors and us, our collaborators, licensees, or advisors may act in their self-interest, which may adversely affect our business.

If conflicts arise between us and our collaborators or licensees, including Pfizer, or our scientific advisors, the other party may act in its self-interest and not in the interest of our stockholders. Conflicts may arise with our collaborators or 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, either developed by these future collaborators or licensees or to which these future collaborators or licensees have rights, may result in their withdrawal of support for our product candidates.

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 the relationship. Similarly, the parties to a collaboration or license agreement may disagree as to which party owns newly developed products. Should an agreement be terminated as a result of a dispute and before we have realized the benefits of the collaboration or license, our reputation could be harmed and we may not obtain revenues that we anticipated receiving.

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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 only 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 a result, we intend to continue 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 plan to contract with collaborators or licensees to advance those candidates through later-stage, more expensive clinical trials, rather than invest our own resources to perform these clinical trials. Depending on the terms of our agreements with these collaborators or licensees, we may not have any control over the conduct of these clinical trials, and in any event we would be subject to the risks associated with depending on collaborators or licensees to develop these drug candidates.

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

In order to manufacture and commercialize drug products in the United States, our drug candidates will have to obtain regulatory approval from the 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.

Regulatory authorities may delay or prevent the initiation of clinical trials for our drug candidates. For example, we may be unable to successfully complete discussions with the FDA regarding trial design, including agreement on appropriate dosing and specific endpoints, for the registration trials for our JAK inhibitor for myelofibrosis.

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. Our drug candidates in clinical trials are in Phase I and Phase II trials. Our other drug candidates are still undergoing preclinical testing. We have also licensed to Pfizer our portfolio of CCR2 antagonist compounds. We have no control over the further clinical development of any compounds we licensed to Pfizer. 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

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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 may not obtain 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 filed a request with the FDA for a special protocol assessment, or SPA, for the registration trials for our JAK inhibitor for myelofibrosis. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of 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. However, an SPA must be agreed to by the FDA before a trial conducted under an SPA can be initiated, and there is no guarantee that an SPA would be agreed to on a timely basis. Accordingly, if we submit a request for an SPA, the initiation of this trial may be delayed. If we believe that the submission of a request for an SPA or the failure to reach agreement on an SPA will significantly delay the initiation of this trial, we may determine not to revise an SPA request in an attempt to reach agreement with the FDA or to proceed with the trial and not to wait for agreement on an SPA. Without the FDA s concurrence on an SPA, we cannot be certain that the design, conduct and data analysis approach for this clinical trial will be sufficient to allow us to submit or receive approval of a JAK inhibitor for the treatment of myelofibrosis.

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 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 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 an 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.

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 the regulatory authority s approval.

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates. We expect to continue to rely on third parties for the manufacture of our drug candidates and any drug products that we may develop. The FDA requires that drug products be manufactured according to its current Good Manufacturing Practices, or cGMP, regulations and a limited number of manufacturers comply with these requirements. If the other parties that we choose to manufacture our drug products are not compliant with cGMP, the FDA may not approve our application to manufacture our drug products. 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. Failure to comply with cGMP in the manufacture of our products could result in the FDA withdrawing or denying regulatory approval of our drug product or other enforcement actions.

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. Also, raw materials that may be required to manufacture any products we develop may only be available from a limited number of suppliers. 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. 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

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approval processes typically include all of the risks associated with the FDA approval process for manufacturing and may also include additional risks.

We may incur additional expense in order to market our drug products.

We do not have experience marketing drug products. If the FDA grants regulatory approval to one or more of our drug candidates, we would have to employ additional personnel or engage another party to market our drug products, which would be an additional expense to us.

We might not be able to commercialize our drug candidates successfully, and we may spend significant time and money attempting to do so.

We have a limited number of drug candidates in Phase I and Phase II clinical trials. We have also licensed to Pfizer our portfolio of CCR2 antagonist compounds. 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 are 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 and 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 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 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 delivery technology or other technology or if these arrangements are unsuccessful, our research and development efforts could be adversely affected.

Our ability to generate revenues will be diminished if we are unable to obtain acceptable prices or an adequate level of reimbursement from payors of healthcare costs.

The continuing efforts of government and insurance companies, health maintenance organizations, or HMOs, and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative or license partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could reduce the price that we or any of our collaborators or licensees receive for any products in the future.

Our ability to commercialize our products successfully will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. 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. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our ability to generate revenues.

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

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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 scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials as well as for the establishment of collaborations with other companies. If we lose the services of any of these people or if we are unable to recruit sufficient qualified personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed. We do not maintain key person insurance on any of our employees.

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

We expect that if our clinical drug candidates continue to progress in development, we continue to build our development organization 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 2008. Because of those losses, we had an accumulated deficit of $1.2 billion as of March 31, 2009. 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 2009 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.

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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.

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. 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 collaborative partners 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 collaborative partner that would result in terms that are not favorable to us or relinquishing our rights in certain of our proprietary technologies or drug candidates. For example, we recently decided not to advance compounds from our c-MET and IDO programs into Phase I clinical trials until additional funding is obtained. 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.

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 which historically have been highly liquid and carried relatively low risk. However, with recent credit market conditions, similar types of investments have experienced losses in value or liquidity issues which differ from their historical pattern. Should a portion of our 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 quarter ended March 31, 2009 from licensing our intellectual property to others. We may be unable to enter into additional collaborative agreements. 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 revenues contemplated under our collaborative agreements. Part of our prior strategy was to license to our database customers and

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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.

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, 2009, the aggregate principal amount of total consolidated debt was $421.8 million and our stockholders deficit was $256.8 million. The documents pursuant to which our outstanding convertible senior and subordinated notes were issued do not limit the issuance of additional indebtedness. 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;

In the past five years, 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 debt service requirements with respect to our outstanding convertible senior notes and convertible subordinated notes. As of March 31, 2009, $151.8 million aggregate principal amount of our 3½% convertible senior notes due 2011 was outstanding. Our annual interest payments, beginning in 2007, for the 3½% convertible senior notes through 2010, assuming none of these notes are converted, redeemed, repurchased or exchanged, are $5.3 million, and an additional $2.6 million in interest is

payable in 2011. As of March 31, 2009, $250.0 million aggregate principal amount of our 31/2% convertible subordinated notes due 2011 was outstanding. Our annual interest payments for the 31/2% convertible subordinated notes through 2010, assuming none of these notes are converted, redeemed, repurchased or exchanged, are $8.8 million, and an additional $4.4 million in interest is payable in 2011. As of March 31, 2009, $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. If we are unable to generate cash from our operations or raise additional cash through financings sufficient to meet these obligations, 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. We may from time to time seek to repurchase or refinance our outstanding convertible notes that mature in February 2011. Repurchases might occur through cash purchases and/or exchanges for other securities in open market transactions, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material. Any issuance of equity securities in exchange for our outstanding convertible notes may be dilutive to our stockholders.

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

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these patents are asserted against us or if we choose to license any of these patents, our ability to commercialize our products could be harmed or the potential return to us from any product that may be successfully commercialized could be diminished.

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

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

- assert claims of infringement;
- enforce our patents or trademarks;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

We may be unsuccessful in defending or pursuing these lawsuits, claims or other legal proceedings. Regardless of the outcome, litigation or other legal proceedings can be very costly and can divert management s efforts. For example, we settled patent litigation with Invitrogen Corporation in 2006. We incurred significant expenses related to this litigation and, as part of the settlement, paid Invitrogen $3.4 million. An adverse determination may subject us to significant liabilities or require us or our collaborators or licensees to seek licenses to other parties patents or proprietary rights. We or our collaborators or licensees may also be restricted or prevented from manufacturing or selling a drug or other product that we or they develop. Further, we or our future collaborators or licensees may not be able to obtain any necessary licenses on acceptable terms, if at all. If we are unable to develop non-infringing technology or license technology on a timely basis or on reasonable terms, our business could be harmed.

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.

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

The value of our patents depends in part on their duration. A shorter period of patent protection could lessen the value of our rights under any patents that we obtain and may decrease the revenues we derive from our patents. The United States patent laws were amended in 1995 to change the term of patent protection from 17 years from patent issuance to 20 years from the earliest effective filing date of the application. Because the time from filing to issuance of biotechnology applications may be more than three years depending on the subject matter, a 20-year patent term from the filing date may result in substantially shorter patent protection. Also, we may need to refile some of our applications filed before 1995 that claim large numbers of genes or other additional subject matter and, in these situations, the patent term will be measured from the date of the earliest priority application. This would shorten our period of patent exclusivity and may decrease the revenues that we might derive from the patents.

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

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

Item 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 7, 2009	By:	/s/ PAUL A. FRIEDMAN PAUL A. FRIEDMAN Chief Executive Officer (Principal Executive Officer)
Dated:	May 7, 2009	By:	/s/ DAVID C. HASTINGS DAVID C. HASTINGS Chief Financial Officer (Principal Financial Officer)

INCYTE CORPORATION

EXHIBIT INDEX

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.