INCYTE CORP
Form 10-Q
November 05, 2009
Table of Contents

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 September 30, 2009

or

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

For the transition period from to

Commission File Number: 0-27488

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3136539**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

Experimental Station, Route 141 & Henry Clay Road,

Building E336, Wilmington, DE 19880

(Address of principal executive offices)

(302) 498-6700

(Registrant s telephone number, including area code)

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

o Yes x No

The number of outstanding shares of the registrant s Common Stock, $0.001 par value, was 118,540,444 as of October 30, 2009.

Table of Contents

INCYTE CORPORATION

INDEX

PART I: FINANCIAL INFORMATION		3
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Operations	4
	Condensed Consolidated Statements of Comprehensive Loss	5
	Condensed Consolidated Statements of Cash Flows	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management_s Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	24
Item 4.	Controls and Procedures	24
PART II: OTHER INFORMATION		24
Item 1A.	Risk Factors	24
Item 6.	Exhibits	36
	Signatures	37
	Exhibit Index	38

Table of Contents

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

INCYTE CORPORATION

Condensed Consolidated Balance Sheets

(in thousands)

	September 30, 2009 (unaudited)	December 31, 2008*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 367,478	$ 178,767
Marketable securities available-for-sale	20,767	19,257
Restricted cash (1)	9,544	
Accounts receivable, net	862	1,050
Prepaid expenses and other current assets	4,006	6,420
Total current assets	402,657	205,494
Marketable securities available-for-sale	6,914	19,759
Restricted cash(1)	46,623	
Property and equipment, net	1,981	2,796
Intangible and other assets, net	14,641	4,339
Total assets	$ 472,816	$ 232,388
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 14,176	$ 15,679
Accrued compensation	9,133	9,330
Interest payable	987	5,273
Accrued and other current liabilities	13,219	14,893
Deferred revenue	32	62
Accrued restructuring	6,729	5,100
Total current liabilities	44,276	50,337
Convertible senior notes	311,503	130,969
Convertible subordinated notes	165,916	265,198
Embedded derivative liability on 4.75% Convertible Senior Notes	148,105	
Other liabilities	2,372	6,634
Total liabilities	672,172	453,138
Stockholders deficit:		

Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued or outstanding as of September 30, 2009 and December 31, 2008				
Common stock, $0.001 par value; 200,000,000 shares authorized; 118,540,444 and 97,339,849 shares issued and outstanding as of September 30, 2009 and December 31, 2008, respectively		119		97
Additional paid-in capital		1,102,765		961,214
Accumulated other comprehensive gain (loss)		502		(2,747)
Accumulated deficit		(1,302,742)		(1,179,314)
Total stockholders deficit		(199,356)		(220,750)
Total liabilities and stockholders deficit	$	472,816	$	232,388

* The condensed consolidated balance sheet at December 31, 2008 has been derived from the audited financial statements at that date.

(1) The restricted cash balance at September 30, 2009 represents funds escrowed for the first three years of interest payments for our 4.75% Convertible Senior Notes due 2015.

See accompanying notes.

Table of Contents

INCYTE CORPORATION

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues:				
Contract revenues	$	$ 15	$	$ 659
License and royalty revenues	939	1,046	2,399	2,322
Total revenues	939	1,061	2,399	2,981
Costs and expenses:				
Research and development	26,535	36,949	85,159	108,036
Selling, general and administrative	4,841	4,005	13,747	12,462
Other expenses	1,126	(100)	2,040	(895)
Total costs and expenses	32,502	40,854	100,946	119,603
Loss from operations	(31,563)	(39,793)	(98,547)	(116,622)
Interest and other income (expense), net	105	1,253	(263)	4,746
Interest expense	(6,531)	(6,254)	(19,250)	(18,639)
Loss on debt repurchases	(5,368)		(5,368)	
Net loss	(43,357)	(44,794)	(123,428)	(130,515)
Basic and diluted net loss per share:	$ (0.44)	$ (0.48)	$ (1.26)	$ (1.50)
Shares used in computing basic and diluted net loss per share	98,030	92,385	97,671	87,286

See accompanying notes.

Table of Contents

INCYTE CORPORATION

Condensed Consolidated Statements of Comprehensive Loss

(in thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	**2008**	**2009**	**2008**
Net loss	$ (43,357)	$ (44,794)	$ (123,428)	$ (130,515)
Other comprehensive gain (loss):				
Reclassification adjustment for realized losses on marketable securities			1,255	
Unrealized gain (loss) on marketable securities	609	(1,506)	1,994	(2,835)
Other comprehensive gain (loss)	609	(1,506)	3,249	(2,835)
Comprehensive loss	$ (42,748)	$ (46,300)	$ (120,179)	$ (133,350)

See accompanying notes.

Table of Contents

INCYTE CORPORATION

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2009	**2008**
Cash flows from operating activities:		
Net loss	$ (123,428)	$ (130,515)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash restructuring charges	2,040	(895)
Depreciation and amortization	9,418	9,810
Stock-based compensation	8,053	11,147
Loss on debt repurchases	5,368	
Impairment of marketable securities	1,255	
Changes in operating assets and liabilities:		
Accounts receivable	189	672
Prepaid expenses and other assets	2,820	502
Accounts payable	(1,503)	5,659
Accrued and other current liabilities	(10,409)	(4,411)
Deferred revenue	(30)	(617)
Net cash used in operating activities	(106,227)	(108,648)
Cash flows from investing activities:		
Capital expenditures	(313)	(332)
Purchases of marketable securities	15	29
Sales and maturities of marketable securities	13,308	103,351
Net cash provided by investing activities	13,010	103,048
Cash flows from financing activities:		
Proceeds from issuance of common stock under stock plans	1,176	2,632
Proceeds from issuance of common stock, net of offering costs	132,739	101,711
Repurchases of convertible senior notes and convertible subordinated notes	(183,820)	
Proceeds from issuance of convertible senior notes, net of offering costs	388,000	
Changes in restricted cash	(56,167)	
Net cash provided by financing activities	281,928	104,343
Net increase in cash and cash equivalents	188,711	98,743
Cash and cash equivalents at beginning of period	178,767	108,854
Cash and cash equivalents at end of period	$ 367,478	$ 207,597

See accompanying notes.

Table of Contents

INCYTE CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 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 September 30, 2009 and the condensed consolidated statements of operations, comprehensive loss for the three and nine months ended September 30, 2009 and 2008, and cash flows for the nine months ended September 30, 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 (U.S. GAAP) have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2008.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued new accounting guidance on fair value measurements. This guidance establishes a common definition for fair value to be applied to U.S. GAAP requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. We adopted this new accounting guidance effective January 1, 2008. Issued in February 2008, an FASB staff position removed leasing transactions from the scope of the new fair value guidance. Also in February 2008, the FASB issued authoritative guidance deferring the effective date of the fair value guidance for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. We adopted this new accounting guidance for all nonfinancial assets and nonfinancial liabilities effective January 1, 2009.

In April 2009, the FASB issued a staff position providing additional guidance on factors to consider in estimating fair value when there has been a significant decrease in market activity for a financial asset. The guidance was effective for interim and annual periods ending after June 15, 2009, and we adopted this guidance commencing with our June 30, 2009 consolidated financial statements. The implementation of this standard had no material impact on our consolidated financial statements.

In June 2008, the FASB issued new guidance related to assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity s own stock for the purposes of determining whether such equity-linked financial instrument (or embedded feature) is subject to derivative accounting We adopted this new guidance effective January 1, 2009. Pursuant to this guidance, at September 30, 2009, in connection with the issuance of our 4.75% convertible senior notes due 2015 (the 4.75% Senior Notes), we recorded a liability of $148.1 million, which is included in embedded derivative liability on 4.75% convertible senior notes in the accompanying consolidated balance sheet.

In April 2009, the FASB issued a staff position which changes the method for determining whether an other-than-temporary impairment exists for debt securities and the amount of the impairment to be recorded in earnings. The guidance is effective for interim and annual periods ending after June 15, 2009, and we adopted this guidance commencing with our June 30, 2009 consolidated financial statements. During the three months ended June 30, 2009, we recorded an other than temporary impairment charge on our marketable securities of $1.3 million, which is included in interest and other income (expense), net in the accompanying consolidated statement of operations.

Table of Contents

In April 2009, the FASB issued a staff position requiring fair value disclosures in both interim as well as annual financial statements in order to provide more timely information about the effects of current market conditions on financial instruments. The guidance is effective for interim and annual periods ending after June 15, 2009, and we adopted this guidance commencing with our June 30, 2009 consolidated financial statements. The implementation of this standard did not have a material impact on our consolidated balance sheet and results of operations.

In May 2009, the FASB issued new guidance on subsequent events. The standard provides guidance on management s assessment of subsequent events and incorporates this guidance into accounting literature. The standard is effective prospectively for interim and annual periods ending after June 15, 2009, and we adopted this guidance commencing with our June 30, 2009 consolidated financial statements. The implementation of this standard did not have a material impact on our consolidated financial position and results of operations. We have evaluated subsequent events through November 5, 2009, the date of issuance of our consolidated balance sheet and results of operations.

On July 1, 2009, the FASB issued the FASB Accounting Standards Codification (the Codification). The Codification became the single source of authoritative nongovernmental U.S. GAAP, superseding existing literature of the FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force and other sources. The Codification was effective for interim and annual periods ending after September 15, 2009. We adopted the Codification for the quarter ended September 30, 2009. There was no impact on our consolidated balance sheet and results of operations as this change is disclosure-only in nature.

In October 2009, the FASB issued amendments to the accounting and disclosure for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and the scope of what constitutes a non-software deliverable. The impact of the adoption of these amendments will depend on the nature of the arrangements that we enter into subsequent to the date we adopt the amendments.

3. Fair value of financial instruments

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

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

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

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

Our marketable securities consist of investments in corporate debt securities, mortgage and asset-backed securities, U.S. Treasury notes, and other U.S. government agency securities that are classified as available-for-sale. We classify marketable securities available to fund current operations as current assets on the condensed consolidated balance sheet. Marketable securities are classified as long-term assets on the 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 September 30, 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 September 30, 2009**
Cash and cash equivalents	$ 367,478	$	$	$ 367,478
Marketable securities available-for-sale		27,681		27,681
Restricted cash	56,167			56,167
Total assets	423,645	27,681		451,326
Embedded derivative liability on 4.75% Convertible Senior Notes			148,105	148,105
Total liabilities	$	$	$ 148,105	$ 148,105

Table of Contents

The table below sets forth a summary of changes in fair value of our level 3 liabilities at September 30, 2009.

Level 3 Liabilities		**September 30, 2009**
Embedded derivative liability on 4.75% Convertible Senior Notes		
Balance, beginning of year	$	
Initial value of embedded derivative upon issuance of the 4.75% Convertible Senior Notes		148,105
Change in market value of embedded derivative		
Balance, September 30, 2009	$	148,105

Due to the variable mix of common stock and series A preferred stock that would be issued to satisfy the conversion of the 4.75% Senior Notes, until we have reserved sufficient shares of our common stock, the embedded conversion feature is not considered indexed to our stock. As a result, the embedded conversion feature is not eligible for equity classification and is required to be bifurcated from the underlying debt instrument. The fair value of the embedded conversion feature on September 30, 2009 of $148.1 million was recorded as a derivative liability and the carrying value of the 4.75% Senior Notes was reduced to reflect a debt discount equal to the fair value of the embedded conversion feature . The derivative liability related to the conversion feature will be revalued on a quarterly basis with changes in fair market value recorded through earnings until we have reserved sufficient shares of our common stock. Once we have reserved sufficient shares of our common stock to satisfy the conversion provisions of the 4.75% Senior Notes, we expect the conversion feature to be considered indexed to our stock at which point the fair value of the conversion feature will be reclassified from a liability into stockholders deficit. We valued the embedded conversion feature using a single factor binomial lattice model, with the assistance of a valuation consultant. This model incorporates inputs such as stock price, historical volatility, risk free interest rate, equivalent bond yield, as well as assumptions about fundamental change and note holder behavior.

4. Revenues

For the three and nine months ended September 30, 2009, one customer contributed 44% and 45%, respectively, of revenues. For the three and nine months ended September 30, 2008, one customer contributed 42% and 30%, respectively, of revenues.

Three customers comprised 89% of the accounts receivable balance at September 30, 2009. Three customers comprised 78% of the accounts receivable balance at December 31, 2008.

5. Stock compensation

Under FASB accounting guidance for stock compensation, we recorded $2.2 million and $8.1 million of stock compensation expense on our unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2009, respectively. We recorded $3.9 million and $11.1 million of stock compensation expense on our unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 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				Employee Stock Purchase Plan			
	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2009	2008	2009	2008	2009	2008	2009	2008
Average risk-free interest rates	1.26%	2.68%	1.05%	2.08%	0.92%	2.21%	0.92%	2.21%
Average expected life (in years)	2.93	2.95	2.95	2.92	0.50	0.50	0.50	0.50
Volatility	72%	67%	72%	65%	87%	66%	87%	66%
Weighted-average fair value (in dollars)	2.34	3.81	1.46	5.07	0.84	1.75	0.84	1.75

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

Table of Contents

expected life of the options. A dividend yield of zero is assumed based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

Based on our historical experience, we have assumed an annualized forfeiture rate of 5% for our options. We will record additional expense if the actual forfeiture rate is lower than we estimated, and will record a recovery of prior expense if the actual forfeiture is higher than we estimated.

Total compensation cost of options granted but not yet vested, as of September 30, 2009, was $5.0 million, which is expected to be recognized over the weighted average period of 2.98 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
Additional authorized	1,200,000		
Options granted	(3,140,000)	3,140,000	3.12
Options exercised		(55,397)	5.08
Options cancelled	116,866	(116,866)	7.07
Balance at September 30, 2009	3,567,333	17,950,213	$ 7.72
Exercisable, September 30, 2009		12,451,299	$ 8.52

6. Common stock offering

On September 30, 2009, we completed a public offering of 20,700,000 shares of our authorized but unissued common stock at a price to the public of $6.75 per share pursuant to an effective shelf registration statement, which resulted in net proceeds of approximately $132.7 million. Entities affiliated with Julian C. Baker, one of our directors and principal stockholders (the Baker Entities), purchased an aggregate of 2,000,000 shares of our common stock in this offering.

7. Debt

On September 30, 2009, we completed the sale, in a private placement, of $400.0 million aggregate principal amount of our 4.75% Senior Notes, which resulted in net proceeds of approximately $388.0 million. The Baker Entities purchased $160.0 million aggregate principal amount of 4.75% Senior Notes in this private placement.

The 4.75% Senior Notes bear interest at the rate of 4.75% per year, payable semi-annually on April 1 and October 1, and are due October 1, 2015. The 4.75% Senior Notes are pari passu in right of payment with our 3½% convertible senior notes due 2011 (the 3½% Senior Notes) and senior in right of payment to our 3½% convertible subordinated notes due 2011 (the 3½% Subordinated Notes) and convertible subordinated notes issued to Pfizer Inc. (the Pfizer Notes). The Indenture governing the 4.75% Senior Notes (the Indenture) contains a covenant that, among other things, limits our ability and the ability of any of our subsidiaries to incur additional indebtedness, create liens, or sell, lease, license, transfer or otherwise dispose of certain of our or their assets. This covenant is subject to a number of exceptions, limitations and qualifications set forth in the Indenture. We may not redeem the 4.75% Senior Notes prior to their scheduled maturity date. If we undergo a fundamental change, as defined in the Indenture, subject to certain conditions, holders may require us to repurchase their 4.75% Senior Notes at a purchase price equal to 100% of the principal amount being purchased, plus accrued and unpaid interest, up to the date of purchase.

The 4.75% Senior Notes are convertible into shares of our common stock at an initial conversion rate of 113.9601 shares per $1,000 principal amount of the 4.75% Senior Notes, equivalent to an initial conversion price of approximately $8.78 per share. We currently do not have a sufficient number of shares of our common stock reserved for issuance upon conversion for all of the 4.75% Senior Notes. Until we have reserved sufficient shares of our common stock for issuance upon conversion of all the 4.75% Senior Notes, we will issue a combination of shares of our common stock and our series A preferred stock in lieu of shares of common stock based on an initial ratio of 1.1 shares of series A preferred stock for every 1,000 shares of common stock otherwise issuable, subject to certain adjustments. Series A preferred stock is convertible into shares of common stock at a rate of 1,000 shares of common stock for each 1.1 shares of series A preferred stock, subject to certain adjustments, contingent upon the reservation of sufficient shares of common stock. We have agreed to use reasonable efforts to obtain stockholder approval to increase the number of shares of common stock we are authorized to issue to an amount sufficient for conversion of all 4.75% Senior Notes. If we have not established a sufficient reserve of shares of our common stock by January 1, 2010, the 4.75% Senior Notes will accrue additional interest at the rate of 5.25% per annum (for a total interest rate of 10% per annum) from and after January 1, 2010. If we have not established a sufficient reserve of shares of our common stock by June 30, 2010, the additional interest accruing on the 4.75% Senior Notes will increase from the rate of 5.25% per annum to the rate of 10.25% per annum (for a total interest rate of 15% per annum) from and after June 30, 2010,

Table of Contents

and such additional interest will increase by an additional 5% per annum on each June 30 thereafter. In each case, such additional interest will accrue until a reserve of shares of our common stock sufficient for conversion of all outstanding 4.75% Senior Notes has been established. Once the number of shares of common stock we are authorized to issue is increased to an amount sufficient for conversion of all 4.75% Senior Notes, we will no longer (and will cease to have the ability to) issue shares of our series A preferred stock in lieu of, or in combination with, shares of our common stock upon conversion of the 4.75% Senior Notes.

If, before there are sufficient shares of our common stock reserved for conversion of the 4.75% Senior Notes, a person or group acquires in a tender or exchange offer beneficial ownership of more than 50% of the voting power of our common equity (a Qualifying Tender Offer), then the 4.75% Senior Notes will accrue additional interest at a rate equal to the higher of the rate then in effect, as described in the preceding paragraph, or 10.25% per annum (for a total interest rate of 15% per annum), and such additional interest will increase by an additional 5% per annum on each anniversary of such Qualifying Tender Offer thereafter. Such additional interest will accrue until a reserve of shares of our common stock sufficient for conversion of all outstanding 4.75% Senior Notes has been established.

In addition, if, and to the extent, a holder elects to convert any 4.75% Senior Notes in connection with a make-whole fundamental change transaction, as defined in the Indenture, we will, under certain circumstances, increase the applicable conversion rate by a number of additional shares of our common stock.

In connection with the private placement of the 4.75% Senior Notes, we entered into a Pledge and Escrow Agreement, pursuant to which an aggregate of approximately $56.3 million was placed into an escrow account. Funds in the escrow account will be invested in Permitted Securities (as defined in the Pledge and Escrow Agreement), and a portion of the Permitted Securities may be redeemed or sold for cash to make each of the first six scheduled semi-annual interest payments on the 4.75% Senior Notes. Pursuant to the Pledge and Escrow Agreement, we have pledged our interest in the escrow account to the Trustee under the Indenture as security for these interest payments. The amounts held in escrow, totaling $56.2 million as of September 30, 2009, are included within restricted cash (short and long-term) in the consolidated balance sheet.

During the three months ended September 30, 2009, through various privately negotiated transactions, we repurchased $86.3 million in face value of our 3½% Senior Notes and $99.0 million in face value of our 3½% Subordinated Notes. Among these transactions were the repurchases from the Baker Entities of $38.3 million in face value of our 3½% Senior Notes at a purchase price equal to 98.74% of face value and $59.1 million in face value of our 3½% Subordinated Notes at a purchase price equal to 97.88% of face value. The prices paid by us in the repurchase transactions with the Baker Entities were equal to the weighted average prices paid by us to independent third parties in comparable transactions for the balance of the notes repurchased during this period.

Due to the variable mix of common stock and series A preferred stock that would be issued to satisfy the conversion of the 4.75% Senior Notes, until we have reserved sufficient shares of our common stock, the embedded conversion feature is not considered indexed to our stock. As a result, the embedded conversion feature is not eligible for equity classification and is required to be bifurcated from the underlying debt instrument. Accordingly, the fair value of the embedded conversion feature on September 30, 2009 of $148.1 million was recorded as a derivative liability and the carrying value of the 4.75% Senior Notes was reduced to reflect a debt discount equal to the fair value of the embedded conversion feature. The derivative liability is classified as the embedded derivative liability on 4.75% Senior Notes in the accompanying balance sheet. The derivative liability related to the conversion feature will be revalued on a quarterly basis with changes in fair market value recorded through earnings until we have reserved sufficient shares of our common stock. Once we have reserved sufficient shares of our common stock to satisfy the conversion provisions of the 4.75% Senior Notes, we expect the conversion feature to be considered indexed to our stock at which point the fair value of the conversion feature will be reclassified from a liability into stockholders deficit. The debt discount related to the derivative liability will be amortized to interest expense over the six year term of the 4.75% Senior Notes using the effective interest method. We valued the embedded conversion feature using a single factor binomial lattice model, with the assistance of a

valuation consultant. This model incorporates inputs such as stock price, historical volatility, risk free interest rate, equivalent bond yield, as well as assumptions about fundamental change and note holder behavior.

There are circumstances under which we may be required to pay a higher rate of interest, including those disclosed above that are triggered when we have not established a sufficient reserve of our common stock. While these contingent interest rate provisions are considered derivatives, their fair value at September 30, 2009 was de minimis. The fair value of the contingent interest rate provisions will be revalued on a quarterly basis with changes in fair market value recorded through earnings.

Table of Contents

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

	September 30, 2009		December 31, 2008	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
3½% Senior Notes	$ 59,551	65,110	$ 130,969	$ 81,972
3½% Subordinated Notes	150,070	144,067	250,000	139,583
Pfizer Note due 2013	8,303	8,303	7,963	7,963
Pfizer Note due 2014	7,543	7,543	7,235	7,235
4.75% Senior Notes	251,952	400,000		
	477,419	625,023	$ 396,167	$ 236,753

8. Preferred stock

We are authorized to issue 5,000,000 shares of preferred stock, none of which was outstanding as of September 30, 2009. The Board of Directors may determine the rights, preferences and privileges of any preferred stock issued in the future. We have reserved 100,000 shares of preferred stock designated as series A preferred stock for issuance in connection with our 4.75% Senior Notes, as described in Note 7 above.

Except as required by law and as to matters that would adversely affect the rights of the series A preferred stock relative to common stock, the series A preferred stock does not have any voting rights. Each share of series A preferred stock is generally entitled to receive a proportional amount of dividends declared on our common stock. If a Qualifying Tender Offer occurs, then holders of the series A preferred stock will be entitled to receive, when, as and if declared by our board of directors, cumulative dividends, payable quarterly in cash, at the rate per annum equal to the then applicable interest rate per annum payable on the 4.75% Senior Notes, including additional interest that accrues upon a Qualifying Tender Offer. The series A preferred stock is not convertible at the election of the holder of any series A preferred stock. Once the number of shares of common stock authorized and reserved is an amount sufficient for conversion of all 4.75% Senior Notes into shares of common stock, each 1.1 shares of series A preferred stock will convert into shares of our common stock at a rate of 1,000 shares of common stock, subject to adjustment (the Common Conversion Number). The series A preferred stock is not redeemable. In the event of a liquidation, dissolution or winding up, holders of the series A preferred stock will be entitled to receive, before any payment or distribution is made to holders of common stock, accumulated and unpaid dividends on the series A preferred stock. In addition, holders of the series A preferred stock will be entitled to receive, upon a liquidation, dissolution or winding up, an amount per share equal to the Common Conversion Number multiplied by the amount to be distributed per share of common stock. In the event of a merger or consolidation in which shares of common stock are exchanged for other securities, cash or property, each share of series A preferred stock will be exchanged for the Common Conversion Number multiplied by the consideration received per share of common stock.

9. Net loss per share

For all periods presented, both basic and diluted net loss per common share are computed by dividing the net loss by the number of weighted average common shares outstanding during the period. Stock options and potential common shares issuable upon conversion of the 4.75% Senior Notes, the 3½% Senior Notes, the 3½% 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:

	2009	2008
Outstanding stock options	17,950,213	15,272,256
Common shares issuable upon conversion of 4.75% Senior Notes	45,584,040	
Common shares issuable upon conversion of 3½% Senior Notes	5,840,265	13,531,224
Common shares issuable upon conversion of 3½% Subordinated Notes	13,433,172	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	85,294,827	53,575,242

Table of Contents

10. Segment reporting

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

11. Other expenses

Below is a summary of the activity related to our restructuring programs for the nine months ended September 30, 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 September 30, 2009
			(in thousands)		
Lease commitment and related costs	$ 15,497	$ 5,788	$ 216	$ (2,006)	$ 3,998
Other costs			103	(103)	
Restructuring expenses	$ 15,497	$ 5,788	$ 319	$ (2,109)	$ 3,998

2002 Restructuring

	Original Charge Recorded in 2002	Accrual Balance at December 31, 2008	2009 Charges to Operations	2009 Charges Utilized	Accrual Balance at September 30, 2009
			(in thousands)		
Lease commitment and related costs	$ 16,155	$ 5,931	$ 1,725	$ (2,553)	$ 5,103

Maxia Acquisition Costs

	Original	Accrual	2009	2009	Accrual

	Charge	Balance at December 31, 2008	Charges to Operations	Charges Utilized	Balance at September 30, 2009
			(in thousands)		
Lease commitment and related costs	$ 2,373	$ 15	$ (4)	$ (11)	$

12. Subsequent event

From October 1, 2009 to November 5, 2009, we repurchased, and retired, $31.1 million principal amount of our 3½% Subordinated Notes.

Table of Contents

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

The following discussion of our financial condition and results of operations as of and for the three and nine months ended September 30, 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 relationship 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;*

Table of Contents

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

- *our patent prosecution and maintenance efforts; and*

- *our indebtedness, and debt service obligations.*

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

- *our ability to 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 substantial leverage and limitations on our ability to incur additional indebtedness and incur liens on our assets*

Table of Contents

imposed by our debt obligations;

- *our ability to obtain additional capital when needed;*
- *fluctuations in net cash used by investing activities;*
- *our history of operating losses; and*
- *the risks set forth under Risk Factors.*

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

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

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

Table of Contents

Overview

Incyte is a drug discovery and development company focused on developing 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 III
		Polycythemia Vera/Essential Thrombocythemia	Phase II
	INCB18424 (Topical)	Psoriasis	Phase IIb
	INCB28050	Rheumatoid Arthritis	Phase II
HSD1			
	INCB13739	Type 2 Diabetes	Phase IIb
Sheddase			
	INCB7839	Breast Cancer	Phase II
Programs pending additional funding or seeking collaborative partner			
c-MET			
	INCB28060	Solid Cancers	IND Cleared
IDO			
	INCB24360	Oncology	IND Cleared
HM74a			
	INCB19602	Type 2 Diabetes	Phase IIa
CCR5			
	INCB9471	Human Immunodeficiency Virus (HIV)	Phase II
	INCB15050	HIV	Phase I

Since the beginning of 2009, we have focused our efforts on clinical programs that we believe have the greatest likelihood of creating near-term value and on compounds that we believe a company of our size can effectively develop and commercialize on its own, or that we can further develop and commercialize through strategic relationships. Currently, our highest priority program involves our JAK inhibitors. Our JAK inhibitor program includes an oral formulation of INCB18424 as a treatment for myeloproliferative disorders (myelofibrosis, polycythemia vera and essential thrombocythemia) and certain other oncology indications, a topical formulation of INCB18424 for psoriasis, and an oral formulation of INCB28050 for rheumatoid arthritis and other chronic inflammatory conditions.

We intend to retain rights in the United States for INCB18424 for myeloproliferative disorders and other oncology indications, as we believe this is a market where a company of our size can effectively compete. For markets outside of the United States, we are currently evaluating strategic relationships. We may progress topical INCB18424 for psoriasis on our own, or we may seek to partner INCB18424 for this indication. For INCB28050 for rheumatoid arthritis and other chronic inflammatory conditions, we are evaluating a number of broad global alliances which may allow us to participate in the commercialization of INCB28050 and retain rights in certain indications. We are evaluating strategic relationships with respect to several of our programs and may enter into an agreement with respect to one or more of these programs in the near future. However, these arrangements and negotiations are complex and time consuming and there can be no assurance that we will reach agreement with a strategic partner with respect to any of these programs in the near future or at all.

We have several other oncology programs, including our sheddase inhibitor, INCB7839, that is under development as a treatment for breast cancer. We have two earlier stage oncology programs involving an oral c-MET inhibitor, INCB28060, and an indoleamine dioxygenase, or IDO, inhibitor, INCB24360. We do not intend to initiate clinical trials for either of these programs until we have either secured additional capital or found a strategic partner for these programs.

Table of Contents

We have several other clinical programs that target either large primary care indications or require lengthy and expensive clinical development programs. These include: our 11ßHSD1 inhibitors, INCB13739 and INCB20817, for which we have shown positive results for the lead compound in a three-month Phase IIb trial in patients with type 2 diabetes; our HM74a agonist, INCB19602, also for type 2 diabetes; and our CCR5 receptor antagonists, INCB9471 and INCB15050, for HIV. Because these therapeutic areas require greater financial and commercial resources than we currently possess, we are seeking strategic relationships or collaborative partners for these programs.

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;

- Stock compensation; and

- Convertible debt and derivative accounting

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

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

Table of Contents

products or services to third parties by the licensee or other agreed upon terms. We estimate royalty revenues based on previous period royalties received and information provided by the third party licensee. We exercise judgment in determining whether the information provided by licensees is sufficiently reliable for us to base our royalty revenue recognition thereon.

Under agreements involving multiple products, services and/or rights to use assets, the multiple elements are divided into separate units of accounting when certain criteria are met, including whether the delivered items have stand alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. When separate units of accounting exist, consideration is allocated among the separate elements based on their respective fair values. The determination of fair value of each element is based on objective evidence from historical sales of the individual elements by us to other customers. If such evidence of fair value for each undelivered element of the arrangement does not exist, all revenue from the arrangement is deferred until such time that evidence of fair value for each undelivered element does exist or until all elements of the arrangement are delivered. When elements are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligation tied to the element is completed. When revenues for an element are not specifically tied to a separate earnings process, they are recognized ratably over the term of the agreement.

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

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

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

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, 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, including costs resulting from the acquisition of Maxia Pharmaceuticals, Inc. (Maxia), 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 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

Table of Contents

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. 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. Financial Accounting Standards Board (FASB) accounting guidance for stock compensation requires all share-based payment transactions with employees, including grants of employee stock options, to be recognized as compensation expense over the requisite service period based on their fair values. The accounting guidance also requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value equity-based compensation and requires the recognition of the fair value of stock compensation in the statement of operations. We recorded $2.2 million and $8.1 million of stock compensation expense for the three and nine months ended September 30, 2009, respectively, and $3.9 million and $11.1 million for the three and nine months ended September 30, 2008, respectively.

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

Due to the variable mix of common stock and series A preferred stock that would be issued to satisfy the conversion of our 4.75% convertible senior notes due 2015 (the 4.75% Senior Notes), until we have reserved sufficient shares of our common stock for issuance upon conversion of all of the 4.75% Senior Notes, the embedded conversion feature is not considered indexed to our stock. As a result, the embedded conversion feature is not eligible for equity classification and is required to be bifurcated from the underlying debt instrument. Accordingly, the fair value of the embedded conversion feature on September 30, 2009 of $148.1 million was recorded as a derivative liability and the carrying value of the 4.75% Senior Notes was reduced to reflect a debt discount equal to the fair value of the embedded conversion feature. The derivative liability is classified as the embedded derivative liability on 4.75% convertible senior notes in our balance sheet. The derivative liability related to the conversion feature will be revalued on a quarterly basis with changes in fair market value recorded through earnings until we have reserved sufficient shares of our common stock. Once we have reserved sufficient shares of our common stock to satisfy the conversion provisions of the 4.75% Senior Notes, we expect the conversion feature to be considered indexed to our stock at which point the fair value of the conversion feature will be reclassified from a liability into stockholders deficit. The debt discount related to the derivative liability will be amortized to interest expense over the six year term of the 4.75% Senior Notes using the effective interest method. We valued the embedded conversion feature using a single factor binomial lattice model, with the assistance of a valuation consultant. This model incorporates inputs such as stock price, historical volatility, risk free interest rate, equivalent bond yield, as well as assumptions about fundamental change and note holder behavior.

Results of Operations

We recorded net losses of $43.4 million and $123.4 million and basic and diluted net losses per share of $0.44 and $1.26 per share for the three and nine months ended September 30, 2009, respectively, as compared to net losses of $44.8 million and $130.5 million and basic and diluted net losses per share of $0.48 and $1.50 per share in the corresponding periods in 2008.

Revenues.

	For the three months ended, September 30,		For the nine months ended, September 30,	
	2009	2008	2009	2008
	(in millions)		(in millions)	
Contract revenues	$	$	$	$ 0.7
License and royalty revenues	0.9	1.1	2.4	2.3
Total revenues	$ 0.9	$ 1.1	$ 2.4	$ 3.0

Table of Contents

Our contract revenues for the three and nine months ended September 30, 2009 decreased from the three and nine months ended September 30, 2008, as we had fully recognized contract revenues associated with the $40.0 million upfront fee under our collaborative research and license agreement with Pfizer Inc. (Pfizer), the debt discount and beneficial conversion feature related to the convertible subordinated notes issued to Pfizer (the Pfizer Notes) and the reimbursement of certain expenses by Pfizer for research and development expenses pursuant to the collaborative research and license agreement.

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 be steady or decline as we focus on our drug discovery and development programs.

Operating Expenses.

Research and development expenses.

	For the three months ended, September 30,		For the nine months ended, September 30,	
	2009	2008	2009	2008
	(in millions)		(in millions)	
Salary and benefits related	$ 8.9	$ 8.7	$ 27.2	$ 26.6
Stock compensation	1.5	2.8	5.8	8.1
Clinical research and outside services	12.0	20.9	40.5	60.8
Occupancy and all other costs	4.1	4.5	11.7	12.5
Total research and development expenses	$ 26.5	$ 36.9	$ 85.2	$ 108.0

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 and nine months ended September 30, 2008 to the three and nine months ended September 30, 2009 was primarily the result of increased headcount to sustain our development pipeline. Stock compensation decreased for the three and nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 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 calculate equity-based compensation. For clinical research and outside services, the decrease from the three and nine months ended September 30, 2008 to the three and nine months ended September 30, 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 and nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008 was due to a decrease in depreciation and professional service 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, September 30,		For the nine months ended, September 30,	
	2009	2008	2009	2008
	(in millions)		(in millions)	
Salary and benefits related	$ 1.9	$ 1.5	$ 5.6	$ 4.6
Stock compensation	0.7	1.1	2.3	3.0
Other contract service and outside costs	2.2	1.4	5.8	4.9
Total selling, general and administrative expenses	$ 4.8	$ 4.0	$ 13.7	$ 12.5

For salary and benefit related costs, the increase from the three and nine months ended September 30, 2008 to the three and nine months ended September 30, 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 decreased for the three and nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 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 calculate equity-based

Table of Contents

compensation. For other contract service and outside costs, the increase from the three and nine months ended September 30, 2008 to the three and nine months ended September 30, 2009 was primarily the result of initial marketing preparations for the potential commercialization of INCB18424 for myeloproliferative disorders.

Other expenses. Total other expenses for the three and nine months ended September 30, 2009 was $1.1 million and $2.0 million, respectively compared to $(0.1) million and $(0.9) million, respectively for the corresponding periods in 2008, and represent charges recorded in connection with previously announced restructuring programs.

Interest and Other Income (Expense), Net. Interest income for the three and nine months ended September 30, 2009 was $0.2 million and $1.0 million, respectively, as compared to $1.3 million and $4.7 million, respectively, for the corresponding periods in 2008. The decrease is due to a lower average cash balance and a lower yield for the three and nine months ended September 30, 2009 as compared to the corresponding periods in 2008. Included in interest and other income (expense), net for the nine months ended September 30, 2009 is a $1.3 million non-cash other-than-temporary impairment charge. There was no such other-than-temporary impairment charge recorded in the corresponding periods in 2008.

Interest Expense. Interest expense for the three and nine months ended September 30, 2009 was $6.5 million and $19.3 million, respectively, compared to $6.3 million and $18.6 million, respectively, for the corresponding periods in 2008.

Loss on Debt Repurchase. During the three and nine months ended September 30, 2009, we repurchased $86.3 million of our 3½% convertible senior notes due 2011 (the 3½% Senior Notes) and $99.0 million of our 3½% convertible subordinated notes due 2011 (the 3½% Subordinated Notes). These repurchases resulted in a loss of $5.4 million primarily related the pro rata share of the unamortized debt discount from the 3½% Senior Notes we repurchased during the three and nine months ended September 30, 2009.

As described above, we have recorded an embedded derivative liability in connection with our 4.75% Senior Notes. The derivative liability related to the conversion feature will be revalued on a quarterly basis with changes in fair market value recorded through earnings until we have reserved sufficient shares of our common stock. Once we have reserved sufficient shares of our common stock to satisfy the conversion provisions of the 4.75% Senior Notes, we expect the conversion feature to be considered indexed to our stock at which point the fair value of the conversion feature will be reclassified from a liability into stockholders deficit. We have called a special meeting of stockholders on November 24, 2009 to obtain such stockholder approval and to increase the shares of common stock reserved to a level sufficient for conversion of all our of our 4.75% Senior Notes. If stockholder approval is obtained at that meeting, we will record in our statement of operations for the quarter ending December 31, 2009 the difference between the fair value of the conversion feature as of the date we have reserved sufficient shares and the amount of the embedded derivative liability at September 30, 2009. Additionally, we expect to record non-cash charges related to the amortization of the debt discount and debt issuance costs of the 4.75% Senior Notes of approximately $5.2 million for the quarter ending December 31, 2009 using the effective interest method. We expect to record non-cash charges related to the amortization of the debt discount and debt issuance costs of approximately $21.9 million, $23.8 million, $26.0 million, $28.2 million, $30.8 million and $24.9 million for the years ended December 31, 2010, 2011, 2012, 2013, 2014 and 2015, respectively.

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 September 30, 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 September 30, 2009, approximately $6.9 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 September 30, 2009, we had available cash, cash equivalents, and short-term and long-term marketable securities of $395.2 million. Our cash and marketable securities balances are held in a variety of interest- bearing instruments including money market accounts, obligations of U.S. government agencies, high-grade corporate bonds, and asset backed and mortgage backed securities. Available cash is invested in accordance with our investment policy s primary objectives of liquidity, safety of principal and diversity of investments. Recent distress in the financial markets has had an adverse impact on financial market activities including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. We have assessed the implications of these factors on our current business and determined that there had not been a significant impact to our financial position, results of operations or liquidity for the period ended September 30, 2009.

Net cash used in operating activities was $106.2 million for the nine months ended September 30, 2009, compared to $108.6 million for the nine months ended September 30, 2008. The $2.4 million decrease was due primarily to changes in working capital, as well as a lower net loss for the nine months ended September 30, 2009 compared to the corresponding period in 2008.

Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures. Net cash used in investing activities was $13.0 million for the nine months ended September 30, 2009, which represented primarily sales and maturities of marketable securities of $13.3 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of capital expenditures, maturities/sales and purchases of marketable securities, and acquisitions, including possible earn-out payments to former stockholders of Maxia.

Table of Contents

Net cash provided by financing activities was $281.9 million and $104.3 million for the nine months ended September 30, 2009 and 2008, respectively. For the nine months ended September 30, 2009 and 2008, we received $1.2 million and $2.6 million, respectively, from issuance of common stock under our stock plans and employee stock purchase plan. For the nine months ended September 30, 2009, we received $388.0 million of net proceeds from the sale of $400.0 million aggregate principal amount of our 4.75% Senior Notes and net proceeds of $132.7 million from our public offering of 20,700,000 shares of common stock. Also for the nine months ended September 30, 2009, we paid $183.8 million in connection with repurchases of our 3½% Senior Notes and 3½% Subordinated Notes and funded a restricted cash escrow account of $56.2 million associated with the first six semi-annual interest payments on our 4.75% Senior Notes. For the nine months ended September 30, 2008, we received $101.7 million of net proceeds from the issuance of common stock in a public offering.

The following summarizes our significant contractual obligations as of September 30, 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
			(in millions)		
Contractual Obligations:					
Principal on convertible subordinated debt	$ 170.1	$	$ 150.1	$ 20.0	$
Principal on convertible senior debt	465.5		65.5		400.0
Interest on convertible subordinated debt	7.9	5.3	2.6		
Interest on convertible senior debt	117.4	11.8	39.1	38.0	28.5
Non-cancelable operating lease obligations:					
Related to current operations	4.0	4.0			
Related to vacated space	11.3	8.1	3.2		
Total contractual obligations	$ 776.2	$ 29.2	$ 260.5	$ 58.0	$ 428.5

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 $2.4 million (less than 1 year) and $1.0 million (years 1-3); these scheduled payments are not reflected in the above table. In addition, we have funded an escrow account of $56.2 million for the first six semi-annual interest payments on the 4.75% Senior Notes; 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 September 30, 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 3½% Senior Notes, 3½% Subordinated Notes, 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 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 strategic relationships 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 or remain steady 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 repurchase or otherwise retire our outstanding convertible notes that mature in February 2011. Repurchases might occur through open market transactions, privately negotiated transactions or otherwise. Such repurchases, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors.

Table of Contents

The amounts involved in any such transactions, individually or in the aggregate, may be material.

Until we can generate a sufficient amount of product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The sale of equity or additional convertible debt securities in the future may be dilutive to our stockholders, and may provide for rights, preferences or privileges senior to those of our holders of common stock. Debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to incur further indebtedness. The indenture under which our 4.75% Senior Notes are issued contains a covenant that, among other things, limits our ability and the ability of any of our subsidiaries to incur additional indebtedness, create liens, or sell, lease, license, transfer or otherwise dispose of certain of our or their assets. We do not know whether additional funding will be available on acceptable terms, if at all. The credit markets and the financial services industry recently experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events generally made equity and debt financing difficult to obtain since their occurence. 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 September 30, 2009, cash, cash equivalents and short-term and long-term marketable securities were $451.4 million, including a funded restricted cash escrow account of $56.2 million associated with the first six semi-annual interest payments on our 4.75% Senior Notes. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of September 30, 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.

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.

Table of Contents

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.

All but one of our drug candidates in clinical trials are in Phase I and Phase II trials. Our other drug candidates are still undergoing preclinical testing. 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. 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.

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 is 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 are evaluating strategic relationships with respect to several of our programs and may enter into an agreement with respect to one or more of these programs in the near future. However, these arrangements and negotiations are complex and time consuming and there can be no assurance that we will reach agreement with a strategic partner with respect to any of these programs in the near future or at all.

Although we may conduct initial clinical trials on our drug candidates, we may need to seek collaborators for our drug candidates such as our 11ßHSD1 inhibitors because of the expense, effort and expertise required to continue additional clinical trials and further develop those drug candidates. We are seeking 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. We are also currently evaluating strategic relationships for INCB18424 for myeloproliferative disorders and other oncology indications for markets outside the United States. Because collaboration arrangements are complex to negotiate, we may not be successful in our attempts to establish these arrangements. Also, we may not have drug compounds that are desirable to other parties, or we may be unwilling to license a drug compound because the party

Table of Contents

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, do not devote adequate resources to the program, or do not agree with our approach to development or manufacturing of the potential product, the relationship 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.

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

We have obtained a special protocol assessment, or SPA, for the registration trial for our JAK inhibitor for the treatment of myelofibrosis in the United States. The SPA process allows for Food and Drug Administration, or FDA, evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application, or NDA, and provides a product sponsor with an agreement confirming that the design and size of the trial will be appropriate to form the primary basis of an efficacy claim for an NDA if the trial is performed according to the SPA. An SPA is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, the trial will be adequate to demonstrate safety and efficacy, or otherwise be sufficient to support regulatory approval. There can be no assurance that the terms of an SPA will ultimately be binding on the FDA, and the FDA is not obligated to approve an NDA, if any, even if the clinical outcome is positive. The FDA retains significant latitude and discretion in interpreting the terms of an SPA and the data and results from a clinical trial, and can require trial design changes if issues arise essential to determining safety or efficacy. In addition, data may subsequently become available that causes the FDA to reconsider the previously agreed upon scope of review and the FDA may have subsequent safety or 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 amendment and, even if they agree, they may request other amendments to the trial design that could require additional cost and time, as well as increase the degree of difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to support an efficacy claim and product approval.

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

We have invested significant resources in the development of our most advanced product candidates. We have one drug candidate, INCB18424, in Phase III clinical trials. We have a number of drug candidates in Phase I and Phase II clinical trials. Our ability to generate product revenues will depend on the successful development and eventual commercialization of our most advanced product candidates. We 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 or because third parties such as insurance companies or Medicare have not approved it for substantial reimbursement. In addition, we may decide not to continue to commercialize a product if another product comes on the market that is as effective but has fewer side effects. There is also a risk that competitors may develop similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

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

Table of Contents

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

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

- the willingness and ability of patients and the healthcare community to use our products;

- the ability to manufacture our drug products in sufficient quantities with acceptable quality and to offer our drug products for sale at competitive prices;

- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of our drug products compared to those of competing products or therapies;

- the label and promotional claims allowed by the FDA;

- the pricing and reimbursement of our drug products relative to existing treatments; and

- marketing and distribution support for our drug products.

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.

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

Table of Contents

testing (animal testing) and clinical trials (human testing). Preclinical testing and clinical development are long, expensive and uncertain processes, and we do not know whether the FDA will allow us to undertake clinical trials of any potential drug products in addition to our compounds currently in clinical trials.

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

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

Data obtained from clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier clinical trials. In addition, regulatory authorities may refuse or delay approval as a result of other factors, such as changes in regulatory policy during the period of product development and regulatory agency review. For example, the FDA has in the past required and could in the future require that we conduct additional trials of any of our product candidates, which would result in delays.

Due, in part, to the early stage of our drug candidate research and development process, we cannot predict whether regulatory approval will be obtained for any product we develop. All but one of 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 requirements needed to receive marketing approval. If regulatory approval of a product is granted, this approval will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective. Failure to obtain regulatory approval would delay or prevent us from commercializing products.

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

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

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

Table of Contents

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

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates. We currently rely on third parties for the manufacture of both the active pharmaceutical ingredient, or API, and finished drug product of our drug candidates for clinical trials. In addition, we expect to continue to rely on third parties for the manufacture of commercial supplies of API and finished drug product for any drugs that we successfully develop. For most of our drug candidates, including our lead drug candidate INCB18424, we rely on one third party to manufacture the API, another to make finished drug product and a third to package and label the finished product. The FDA requires that the API and finished product for each of our drug products be manufactured according to its current Good Manufacturing Practices, or cGMP, regulations and regulatory authorities in other countries have similar requirements. There are only a limited number of manufacturers that comply with these requirements. If the third parties that manufacture our drug candidates are not compliant with the applicable regulatory requirements, the FDA or a foreign regulatory authority may require us to halt ongoing clinical trials or not approve our application to market our drug products. Failure to comply with cGMP and the applicable regulatory requirements of other countries in the manufacture of our products could result in the FDA or foreign regulatory authority halting our clinical trials, withdrawing or denying regulatory approval of our drug product, enforcing product recalls or other enforcement actions, which could have a material adverse effect on our business.

We may not be able to obtain sufficient quantities of our drug candidates or any drug products we may develop if our designated manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. In addition, we may not be able to arrange for our drug candidates or any drug products that we may develop to be manufactured by one of these parties on reasonable terms, if at all. Also, raw materials that may be required to manufacture any products we develop may only be available from a limited number of suppliers. Generally, we have only a single source that is qualified to supply the API and finished product of our drug candidates. If any of these single source suppliers were to become unable or unwilling to supply us with API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials or interruption of commercial supply which could have a material adverse effect on our business. We are currently seeking to qualify a second source of supply for certain of our drug candidates, including a second source of supply for the API for INCB18424, however, there is no assurance that we will be able to identify and qualify a second source of supply for any of our drug candidates or drug products on a timely basis. If we have promised delivery of a new product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs would be delayed, and we may have to expend additional sums in order to ensure that manufacturing capacity is available when we need it even if we do not use all of the manufacturing capacity. This expense would adversely affect our operating results.

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

In order to obtain approval of our products, including INCB18424, by the FDA and foreign regulatory agencies, we need to complete testing on both the API and on the finished product in the packaging we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, we will be required to consistently produce the API in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation. With respect to INCB18424, although we have manufactured the product at commercial scale, we have started, but not yet completed, this process validation requirement. If the required testing or process validation is delayed or produces unfavorable results, we may not obtain approval to launch the product or product launch may be delayed.

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

for manufacturing and may also include additional risks.

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 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

Table of Contents

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 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 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

Table of Contents

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 $1.3 billion as of September 30, 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.

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 and to repay our indebtedness. Additional factors that may

Table of Contents

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.

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

As of September 30, 2009, the aggregate principal amount of our total consolidated debt was $635.6 million and our stockholders deficit was $199.4 million. Our substantial leverage could have significant negative consequences for our future operations, including:

- increasing our vulnerability to general adverse economic and industry conditions;

- limiting our ability to obtain additional financing for working capital, capital and research and development expenditures, and general corporate purposes;

- requiring the dedication of a substantial portion of our expected cash flow or our existing cash to service our indebtedness, thereby reducing the amount of our cash available for other purposes, including working capital, capital expenditures and research and development expenditures;

- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; or

- placing us at a possible competitive disadvantage compared to less leveraged competitors and competitors that have better access to capital resources;

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 obligations with respect to our outstanding convertible senior notes and convertible subordinated notes. As of September 30, 2009, $65.5 million aggregate principal amount of our 3½% convertible senior notes due 2011 was outstanding and due in February 2011. Our annual interest payments for the 3½% convertible senior notes due 2011 through 2010, based on the aggregate principal amount outstanding as of September 30, 2009 and assuming none of these notes are converted, redeemed, repurchased or exchanged, are $2.3 million, and an additional $1.1 million in interest is payable in 2011. As of September 30, 2009, $150.1 million aggregate principal amount of our 3½% convertible subordinated notes due 2011 was outstanding and is due in February 2011. Our annual interest payments for the 3½% convertible subordinated notes due 2011 through 2010, based on the aggregate principal amount outstanding as of September 30, 2009 and 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

Table of Contents

in 2011. As of September 30, 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. As of September 30, 2009, $400.0 million aggregate principal amount of our 4.75% convertible senior notes due 2015 was outstanding and due in October 2015. Our annual interest payments for the 4.75% convertible senior notes due 2015 through 2015, assuming that none of these notes are converted, redeemed, repurchased or exchanged, are $19.0 million.

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 otherwise retire our outstanding debt, including our convertible notes that mature in February 2011. Repurchases might occur through open market transactions, privately negotiated transactions or otherwise. Such repurchases, if any, will depend on prevailing market conditions, our cash position, our liquidity requirements, contractual restrictions and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material.

The indenture governing our 4.75% convertible senior notes due 2015 includes limitations on our ability to incur additional indebtedness, issue certain preferred stock, and incur liens on our assets, including on intellectual property concerning our JAK inhibitor program. These limitations could interfere with our ability to raise additional capital in the future or engage in activities that may be in our long-term best interest.

Because we do not now and may never have enough shares of common stock authorized to accommodate the full conversion of our 4.75% convertible senior notes due 2015, we may be required to issue shares of a new series of preferred stock upon conversion of the notes instead of common stock and pay additional interest on the notes.

The maximum number of shares of common stock into which our 4.75% convertible senior notes due 2015 may be convertible exceeds the number of shares of common stock currently available for us to issue upon conversion of these notes. In order to increase the number of shares of common stock we are authorized to issue, we must obtain the approval of stockholders holding a majority of our outstanding shares of common stock. We have called a special meeting of stockholders on November 24, 2009 to obtain such stockholder approval and to increase the shares of common stock reserved to a level sufficient for conversion of all our of our 4.75% convertible senior notes due 2015. We cannot guarantee that such stockholder approval will be obtained. In the event we have not established a sufficient reserve by January 1, 2010, the interest rate on these notes will increase to 10%. If we have not established a sufficient reserve by June 30, 2010, the interest rate on these notes will increase to 15%. The interest rate on these notes will increase an additional 5% each June 30 thereafter until maturity or until we have established a sufficient reserve.

For so long as we do not have enough shares of common stock authorized and available for issuance upon conversion of these notes, we will issue a combination of shares of our common stock and shares of newly created series A preferred stock upon such conversion. Under the terms of the indenture governing these notes, until we have reserved a sufficient number of shares of our common stock for conversion of all of the notes, we will not be able to raise additional capital through a subsequent sale of common stock or securities convertible into common stock. Until a reserve of common stock sufficient for conversion of all notes is established, our ability to raise additional capital will be severely limited.

Although we will issue shares of series A preferred stock based on a ratio of 1.1 shares of series A preferred stock for every 1,000 shares of common stock otherwise issuable upon conversion of the notes, in the event of any dividends or distributions, any liquidation or dissolution, or in the event of a consolidation, merger, sale or other similar transaction, each whole share of series A preferred stock will have the same economic rights as 1,000 shares of common stock. In addition, if certain tender or exchange offers occur before we establish a sufficient

common stock reserve for the notes, as a result of which a third party or group own beneficially more than 50% of our voting stock, then the interest rate on the notes will increase to 15% (or remain at any higher rate then in effect as a result of our inability to establish a sufficient common stock reserve for the notes as described above), with an additional 5% increase in the interest rate on each anniversary of that occurrence, until we have established a sufficient reserve.

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.

Table of Contents

We derived all of our revenues for the three and nine months ended September 30, 2009 from licensing our intellectual property to others. We are currently evaluating collaboration arrangements for several of our programs, and may be unable to enter into additional collaborative agreements on acceptable terms or at all. 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 to other pharmaceutical and biotechnology companies our know-how and patent rights associated with the information we have generated in the creation of our proprietary databases, for use in the discovery and development of potential pharmaceutical, diagnostic or other products. Any potential product that is the subject of such a license will require several years of further development, clinical trials and regulatory approval before commercialization, all of which is beyond our control, and possibly beyond the control of our licensee. These licensees may not develop the potential product if they do not devote the necessary resources or decide that they do not want to expend the resources to do the clinical trials necessary to obtain the necessary regulatory approvals. Therefore, milestone or royalty payments from these licenses may not contribute to our revenues for several years, if at all. We have decided to discontinue some of our gene and genomics-related patent prosecution and maintenance, and may in the future decide to discontinue additional gene and genomics-related patent prosecution and maintenance, which could limit our ability to receive license-based revenues from our gene and genomics-related patent portfolio.

RISKS RELATING TO INTELLECTUAL PROPERTY AND LEGAL MATTERS

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

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

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

Table of Contents

applications can take several years to issue as patents, there may be pending patent applications of others that may later issue as patents that cover some aspect of our drug candidates. Our existing patents and any future patents we may obtain may not be broad enough to protect our products or all of the potential uses of our products, or otherwise prevent others from developing competing products or technologies. In addition, our patents may be challenged and invalidated or may fail to provide us with any competitive advantages if, for example, others were first to invent or first to file a patent application for the technologies and products covered by our patents.

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

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

- independently develop substantially equivalent proprietary information, products and techniques;
- otherwise gain access to our proprietary information; or
- design around patents issued to us or our other intellectual property.

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

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

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

Table of Contents

Item 6. Exhibits

Exhibit Number	Description of Document
3.1	Certificate of Designation of Series A Preferred Stock of the Company (incorporated by reference to the exhibit of the same number to the Company s Current Report on Form 8-K filed September 30, 2009).
4.1	Indenture dated as of September 30, 2009 between the Company and U.S. Bank National Association, as trustee (including form of 4.75% Convertible Senior Note due 2015) (incorporated by reference to the exhibit of the same number to the Company s Current Report on Form 8-K filed September 30, 2009).
10.1	Pledge and Escrow Agreement, dated as of September 30, 2009, by and among the Company, U.S. Bank National Association, as trustee, and U.S. Bank National Association, as escrow agent (incorporated by reference to the exhibit of the same number to the Company s Current Report on Form 8-K filed September 30, 2009).
10.2	Letter Agreement dated September 24, 2009 among the Company and the entities named therein (incorporated by reference to the exhibit of the same number to the Company s Current Report on Form 8-K filed September 30, 2009).
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.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INCYTE CORPORATION

Dated:	November 5, 2009	By:	/s/ PAUL A. FRIEDMAN PAUL A. FRIEDMAN Chief Executive Officer (Principal Executive Officer)
Dated:	November 5, 2009	By:	/s/ DAVID C. HASTINGS DAVID C. HASTINGS Chief Financial Officer (Principal Financial Officer)

Table of Contents

INCYTE CORPORATION

EXHIBIT INDEX

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4.1	Indenture dated as of September 30, 2009 between the Company and U.S. Bank National Association, as trustee (including form of 4.75% Convertible Senior Note due 2015) (incorporated by reference to the exhibit of the same number to the Company s Current Report on Form 8-K filed September 30, 2009).
10.1	Pledge and Escrow Agreement, dated as of September 30, 2009, by and among the Company, U.S. Bank National Association, as trustee, and U.S. Bank National Association, as escrow agent (incorporated by reference to the exhibit of the same number to the Company s Current Report on Form 8-K filed September 30, 2009).
10.2	Letter Agreement dated September 24, 2009 among the Company and the entities named therein (incorporated by reference to the exhibit of the same number to the Company s Current Report on Form 8-K filed September 30, 2009).
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.