

INCYTE CORP  
Form 10-Q  
November 02, 2006

## UNITED STATES

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

### FORM 10-Q

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

For the quarterly period ended September 30, 2006

or

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

For the transition period from      to

Commission File Number: 0-27488

## INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**94-3136539**  
(IRS Employer  
Identification No.)

Edgar Filing: INCYTE CORP - Form 10-Q

**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.

Yes     No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. Check one:

Large Accelerated Filer

Accelerated Filer

Non-accelerated Filer

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

Yes     No

The number of outstanding shares of the registrant's Common Stock, \$0.001 par value, was 83,855,064 as of October 27, 2006.

---

INCYTE CORPORATION  
INDEX

**PART I: FINANCIAL INFORMATION**

<b><u>Item 1.</u></b>	<u>Financial Statements</u>	3
	<u>Condensed Consolidated Balance Sheets</u>	3
	<u>Condensed Consolidated Statements of Operations</u>	4
	<u>Condensed Consolidated Statements of Comprehensive Loss</u>	5
	<u>Condensed Consolidated Statements of Cash Flows</u>	6
	<u>Notes to Condensed Consolidated Financial Statements</u>	7
<b><u>Item 2.</u></b>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<b><u>Item 3.</u></b>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	22
<b><u>Item 4.</u></b>	<u>Controls and Procedures</u>	22

**PART II: OTHER INFORMATION**

<b><u>Item 1.</u></b>	<u>Legal Proceedings</u>	23
<b><u>Item 1A.</u></b>	<u>Risk Factors</u>	24
<b><u>Item 2.</u></b>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
<b><u>Item 6.</u></b>	<u>Exhibits</u>	34
	<u>Signatures</u>	35
	<u>Exhibit Index</u>	36

**PART I: FINANCIAL INFORMATION****Item 1. Financial Statements**

**INCYTE CORPORATION**  
**Condensed Consolidated Balance Sheets**  
(in thousands, except share amounts)

	September 30, 2006 (unaudited)	December 31, 2005*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 115,921	\$ 11,494
Marketable securities available-for-sale	310,380	333,477
Accounts receivable, net	1,390	1,423
Prepaid expenses and other current assets	4,310	7,582
Total current assets	432,001	353,976
Marketable securities available-for-sale	17,790	
Property and equipment, net	5,741	7,667
Long-term investments (1)		1,312
Intangible and other assets, net	9,354	11,153
Total assets	\$ 464,886	\$ 374,108
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 3,704	\$ 3,573
Accrued compensation	6,132	7,590
Interest payable	2,009	5,382
Convertible subordinated notes	91,690	
Accrued and other current liabilities	5,255	5,124
Deferred revenue	22,935	604
Accrued restructuring and acquisition costs	5,068	5,584
Total current liabilities	136,793	27,857
Convertible senior notes	112,018	
Convertible subordinated notes	257,024	341,862
Deferred revenue	5,938	
Other liabilities	19,263	23,786
Total liabilities	531,036	393,505
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock		
Common stock, \$0.001 par value; 200,000,000 shares authorized; 83,854,139 and 83,597,080 shares issued and outstanding as of September 30, 2006 and December 31, 2005, respectively	84	84
Additional paid-in capital	826,255	818,638
Accumulated other comprehensive income	521	1,228
Accumulated deficit	(893,010)	(839,347)
Total stockholders' deficit	(66,150)	(19,397)
Total liabilities and stockholders' deficit	\$ 464,886	\$ 374,108

\* The condensed consolidated balance sheet at December 31, 2005 has been derived from the audited financial statements at that date.

(1) Includes investments in companies considered related parties under SFAS 57 of \$1.3 million at December 31, 2005.

Edgar Filing: INCYTE CORP - Form 10-Q

See accompanying notes.

3

---

**INCYTE CORPORATION**  
**Condensed Consolidated Statements of Operations**  
(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended September 30, 2006		2005		Nine Months Ended September 30, 2006		2005	
<b>Revenues:</b>								
Contract revenues	\$	6,249	\$		\$	18,069	\$	
License and royalty revenues		1,019		1,228		2,518		6,818
Total revenues		7,268		1,228		20,587		6,818
<b>Costs and expenses:</b>								
Research and development		19,558		27,356		64,037		71,676
Selling, general and administrative		3,454		2,710		10,750		8,244
Other expenses		13		299		3,105		1,088
Total costs and expenses		23,025		30,365		77,892		81,008
Loss from operations		(15,757)	)	(29,137)	)	(57,305)	)	(74,190)
Interest and other income, net (1)		3,996		2,656		15,470		10,228
Interest expense		(4,077)	)	(3,810)	)	(11,828)	)	(12,257)
Gain on repurchase of convertible subordinated notes				85				506
Loss on certain derivative financial instruments, net				(1)	)			(89)
Loss from continuing operations before income taxes		(15,838)	)	(30,207)	)	(53,663)	)	(75,802)
Provision for income taxes								(156)
Loss from continuing operations	\$	(15,838)	)	\$	(30,207)	)	\$	(53,663)
								\$
								(75,646)
Income (loss) from discontinued operation, net of tax				(3)	)			159
Net loss		(15,838)	)	(30,210)	)	(53,663)	)	(75,487)
<b>Basic and diluted net loss per share:</b>								
Continuing operations	\$	(0.19)	)	\$	(0.36)	)	\$	(0.64)
Discontinued operations								\$
		(0.19)	)		(0.36)	)		\$
								(0.91)
Shares used in computing basic and diluted net loss per share		83,852		83,414		83,755		83,213

(1) Includes an impairment charge of \$1.3 million on a privately-held investment for the nine months ended September 30, 2006, a gain on sale of securities of \$5.5 million for the nine months ended September 30, 2006, and a gain on sale of securities of \$2.8 million for nine months ended September 30, 2005. The aforementioned transactions were all considered related party transactions under SFAS 57.

See accompanying notes.



**INCYTE CORPORATION**  
**Condensed Consolidated Statements of Comprehensive Loss**  
(in thousands)  
(unaudited)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Net loss	\$ (15,838 )	\$ (30,210 )	\$ (53,663 )	\$ (75,487 )
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	2,330	(159 )	(707 )	(612 )
Foreign currency translation adjustments		(4 )		(8 )
Other comprehensive gain (loss)	2,330	(163 )	(707 )	(620 )
Comprehensive loss	\$ (13,508 )	\$ (30,373 )	\$ (54,370 )	\$ (76,107 )

See accompanying notes.



**INCYTE CORPORATION**  
**Condensed Consolidated Statements of Cash Flows**  
(in thousands)  
(unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (53,663 )	\$ (75,487 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Income from discontinued operations		(159 )
Non-cash restructuring (credits) charges	(299 )	1,088
Depreciation and amortization	4,140	6,516
Compensation expense on executive loans	18	18
Stock-based compensation	6,640	152
Loss on derivative financial instruments, net		89
Gain on repurchase of convertible subordinated notes		(506 )
Realized gain on long-term investments	(5,459 )	(2,791 )
Impairment of long term investments	1,312	
Changes in operating assets and liabilities:		
Accounts receivable	33	1,097
Prepaid expenses and other assets	3,367	1,812
Accounts payable	131	2,051
Accrued and other current liabilities	(9,441 )	(6,486 )
Deferred revenue	25,036	(1,065 )
Net cash used in continuing operating activities	(28,185 )	(73,671 )
Net cash used in discontinued activities		(182 )
Net cash used in operating activities	(28,185 )	(73,853 )
<b>Cash flows from investing activities:</b>		
Capital expenditures	(569 )	(1,179 )
Net proceeds from sale of Proteome facility and equipment		59
Purchases of marketable securities	(498,213 )	(290,764 )
Sales and maturities of marketable securities	508,510	317,647
Net cash provided by investing activities	9,728	25,763
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock under stock plans	977	953
Repurchase of convertible subordinated notes		(35,838 )
Proceeds from issuance of convertible senior notes and convertible subordinated notes	121,907	
Net cash provided by (used in) financing activities	122,884	(34,885 )
Effect of exchange rate on cash and cash equivalents		(8 )
Net increase (decrease) in cash and cash equivalents	104,427	(82,983 )
Cash and cash equivalents at beginning of period	11,494	132,180
Cash and cash equivalents at end of period	\$ 115,921	\$ 49,197

See accompanying notes.

**INCYTE CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2006**  
(Unaudited)

**1. Organization and business**

Incyte Corporation ( Incyte, we, us, or our ) is focused on the discovery and development of novel drugs to treat major medical conditions. Our core therapeutic areas are oncology and inflammation, and we have additional programs in diabetes and human immunodeficiency virus, or HIV. We have assembled a team of scientists with core competencies in the areas of medicinal chemistry and molecular, cellular and in vivo biology.

**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, 2006, condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2006 and 2005, and condensed consolidated statements of cash flows for the nine months ended September 30, 2006 and 2005 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, 2005 has been derived from audited financial statements.

Although we believe that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information and footnote information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission. Certain amounts reported in previous years have been reclassified to conform to the 2006 financial statement presentation.

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, 2005.

***Recent Accounting Pronouncements***

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, ( FIN 48 ). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on our consolidated financial statements.

In November 2005, the FASB issued staff position FAS 115-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments* ( FSP 115-1 ). FSP 115-1 address the determination as to when an investment is considered impaired, whether that impairment is other than temporary and the measurement of an impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in FSP 115-1 amends FASB Statements No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and Accounting Principles Board ( APB ) Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*.

FSP 115-1 replaces the impairment evaluation guidance of Emerging Issues Task Force ( EITF ) Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* ( EITF 03-1 ), with references to existing other-than-temporary impairment guidance. EITF 03-1 's disclosure requirements remain in effect, and are applicable for year-end reporting and for interim periods if there are significant changes from the previous year-end. FSP 115-1 also supersedes EITF Topic No. D-44, *Recognition of Other-Than-Temporary Impairment upon the Planned Sale of a Security Whose Cost Exceeds Fair Value*, and clarifies that an investor should recognize an impairment loss no later than when the impairment is deemed other-than-temporary, even if a decision to sell an impaired security has not been made. FSP 115-1 applies to reporting periods beginning after December 15, 2005.



FSP 115-1 did not have a material impact on our results of operations, or cash flows for the three and nine months ended September 30, 2006.

We adopted Statement of Financial Accounting Standards ( SFAS ) No. 123 (revised 2004), *Share-Based Payment*, ( SFAS 123R ) effective January 1, 2006. SFAS 123R is a new complex accounting standard, the application of which requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility, expected option lives, and expected option forfeiture rates, to value equity-based compensation. SFAS 123R requires the recognition of the fair value of stock compensation in the statement of operations. Refer to Note 6 Stock compensation in our notes to our unaudited condensed consolidated financial statements included elsewhere in this quarterly report on Form 10-Q for more discussion of our adoption of SFAS 123R.

### **3. Long-term investments and marketable securities**

Marketable securities consist of investments in corporate debt securities, mortgage 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 activity in our long-term investments, in any given quarter, may result in gains or losses on sales or impairment charges. Amounts realized upon disposition of these investments may be different from their carrying value.

In June 2006, we recorded an impairment charge of \$1.3 million to reduce the carrying value of our investment in a privately-held investee because the investee had less than six months of cash and we believed that the likelihood of obtaining future debt or equity financing that would not result in an impairment was remote.

In March 2006, we sold a portion of our investment in a publicly-held company accounted for under FASB Statement No.115, *Accounting for Certain Investments in Debt and Equity Securities*, for \$11.5 million, which resulted in a realized gain of \$5.5 million during the nine months ended September 30, 2006. In October 2006, we sold the remaining portion of this investment for \$5.8 million, which will result in a realized gain of \$0.8 million in the three months ended December 31, 2006.

### **4. Concentration of credit risk**

One customer represented 86% and 88%, respectively, of total revenues for the three and nine months ended September 30, 2006.

Two customers comprised 82% of the accounts receivable balance at September 30, 2006. Three customers comprised 67% of the accounts receivable balance at December 31, 2005.

### **5. Collaborative research and license agreement**

In November 2005, we entered into a collaborative research and license agreement with Pfizer Inc. ( Pfizer ), which became effective in January 2006. Pfizer gained worldwide development and commercialization rights to our portfolio of CCR2 antagonist compounds. Pfizer's rights extend to the full scope of potential indications, with the exception of multiple sclerosis and one other undisclosed indication, where we retained worldwide rights, along with certain compounds. We do not have obligations to Pfizer on pre-clinical development candidates we select for pursuit in these indications.

We received an upfront nonrefundable payment of \$40.0 million in January 2006 and are eligible to receive additional future development and milestone payments of up to \$743.0 million for the successful development and commercialization of CCR2 antagonists in multiple indications, as well as royalties on worldwide sales. The \$40.0 million upfront fee was recorded as deferred revenue and is being recognized on a straight-line basis over two years, our estimated performance period under the agreement. Contract revenues related thereto of approximately \$5.2 million and \$15.2 million, respectively, were recognized for the three and nine months ended September 30, 2006. Future development and milestone payments will be recognized as earned.

We also recognized contract revenues of approximately \$0.7 million and \$1.8 million, respectively, for the three and nine months ended September 30, 2006 in connection with research services provided to Pfizer. At September 30, 2006 approximately \$0.8 million was receivable from Pfizer for reimbursement of expenses incurred by us pursuant to the agreement.

**6. Stock compensation**

We adopted SFAS 123R on January 1, 2006. SFAS 123R requires the recognition of the fair value of stock compensation in the statement of operations. We recognize the stock compensation expense over the requisite service period of the individual grants, which generally equals the vesting period. Prior to January 1, 2006, we followed APB Opinion 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for our stock compensation.

8

---

Edgar Filing: INCYTE CORP - Form 10-Q

We elected the modified prospective method in adopting SFAS 123R. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption is recognized in net income in the periods after the date of adoption using the same valuation method (Black-Scholes) and assumptions determined under the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*, as disclosed in our previous filings.

Under the provisions of SFAS 123R, we recorded \$2.1 million and \$6.6 million, respectively, of stock compensation expense on our unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2006. As a result of adopting SFAS 123R, our net loss for the three and nine months ended September 30, 2006, is \$2.1 million and \$6.6 million, higher, respectively, than if we had continued to account for share-based compensation under APB Opinion 25. Basic and diluted net loss per share for the three and nine months ended September 30, 2006 are \$0.03 and \$0.08 higher, respectively, than if we had continued to account for share-based compensation under APB Opinion 25. For the three and nine months ended September 30, 2005 we recorded no stock compensation expense on our unaudited condensed consolidated statement of operations as SFAS 123R had not been adopted. 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, 2006		For the Nine Months Ended September 30, 2005		For the Three Months Ended September 30, 2006		For the Nine Months Ended September 30, 2005	
Average risk-free interest rates	5.03 %	3.98 %	4.42 %	3.93 %	4.80 %	3.95 %	4.80 %	3.95 %
Average expected life (in years)	3.15	3.43	3.17	3.28	.50	.50	.50	.50
Volatility	76 %	86 %	76 %	86 %	72 %	97 %	72 %	97 %
Weighted-average fair value (in dollars)	2.32	4.90	2.79	5.03	1.38	2.81	1.38	2.81

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

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

SFAS 123R requires us to present pro forma information for the comparative period prior to the adoption as if we had accounted for all our stock options under the fair value method of the original SFAS 123. The following table illustrates the effect on net loss and loss per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation in the prior-year period (dollars in thousands, except per-share data).

	For the Three Months Ended September 30, 2005	For the Nine Months Ended September 30, 2005
Net loss, as reported	\$ (30,210 )	\$ (75,487 )
Add: Stock-based employee compensation	51	152
Deduct: Total stock-based employee compensation determined under the fair value-based method for all awards	(2,686 )	(7,496 )
Pro forma net loss	\$ (32,845 )	\$ (82,831 )
Net loss per share:		
Basic and diluted net loss per share-as reported	\$ (0.36 )	\$ (0.91 )

Edgar Filing: INCYTE CORP - Form 10-Q

Basic and diluted net loss per share-as SFAS 123 adjusted	\$	(0.39	)	\$	(1.00	)
---	----	-------	---	----	-------	---

9

---

The amortization of stock compensation under SFAS 123R for the period after its adoption, and under APB Opinion 25 or SFAS 123 (pro forma disclosure) for the period prior to its adoption was calculated in accordance with FASB Interpretation ( FIN ) No. 28. Total compensation cost of options granted but not yet vested, as of September 30, 2006, was \$8.8 million, which is expected to be recognized over the weighted average period of 3.17 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, 2005	6,148,158	7,798,401	\$ 8.99
Options granted	(2,736,227 )	2,736,227	5.28
Options exercised		(54,995 )	4.74
Options cancelled	319,455	(319,455 )	8.87
Balance at September 30, 2006	3,731,386	10,160,178	\$ 8.02
Exercisable, September 30, 2006		5,387,261	\$ 9.35

## 7. Segment reporting

Our operations are treated as one operating segment, drug discovery and development, in accordance with FASB Statement No. 131 *Disclosures about Segments of an Enterprise and Related Information* ( SFAS 131 ). For the three and nine months ended September 30, 2006, we recorded revenue from customers throughout the United States, Canada, Sweden, and Germany. Sales to international customers for the three and nine months ended September 30, 2006 were \$0.4 million and \$0.6 million, respectively, and \$0.4 million and \$2.7 million, respectively, in the corresponding periods of 2005.

## 8. Debt

In September 2006, we received proceeds of \$111.9 million from the sale of \$151.8 million aggregate principal amount of the 3½% convertible senior notes due 2011 (the 3½% Senior Notes ). The 3½% Senior Notes bear interest at the rate of 3.5% per year, payable semi-annually on February 15 and August 15, and are due February 15, 2011. The 3½% Senior Notes are convertible into shares of Incyte common stock at an initial conversion rate of 89.1385 shares per \$1,000 principal amount of the 3½% Senior Notes, equivalent to an initial conversion price of approximately \$11.22 per share. The 3½% Senior Notes are senior in right of payment to Incyte's outstanding 3½% convertible subordinated notes (the 3½% Subordinated Notes ) and the Pfizer Note (defined below). Incyte may redeem the 3½% Senior Notes beginning on February 20, 2007. The 3½% Senior Notes were issued at a discount to par of approximately \$39.9 million. The 3½% Senior Notes will accrete up to their face value over the 53 month term of the notes by recording interest expense under the effective interest method.

In connection with the collaborative research and license agreement, Pfizer purchased a \$10.0 million convertible subordinated note (the Pfizer Note ) in February 2006 and may purchase an additional \$10.0 million note at Incyte's option after Incyte files an Investigational New Drug Application in a retained Incyte indication. The Pfizer Note purchased in February 2006 bears no interest, is due seven years from the date of issuance and is convertible into our common stock at an initial conversion price of \$6.8423 per share, subject to adjustments. The Pfizer Note is subordinated to the 3½% Senior Notes and any other senior indebtedness and pari passu in right of payment with our 3½% Subordinated Notes and our 5.5% convertible subordinated notes due 2007 (the 5.5% Notes ). We may, at our option, repay the Pfizer Note beginning February 3, 2009. Pfizer may require us to repay the Pfizer Note upon a change of control, as defined. As the Pfizer Note is non interest bearing, it has been discounted to its net present value of \$6.8 million by imputing interest at a rate of 4.5%, which represented market conditions in place at the time the note was issued. The carrying value of the Pfizer Note is \$7.0 million at September 30, 2006. We will accrete the Pfizer Note up to its face value over its term of seven years by recording interest expense under the effective interest method. The difference between the cash received and the present value of the Pfizer Note, which equals the face value less the non interest bearing portion and beneficial conversion feature, represents additional consideration from Pfizer under the agreement. We have accounted for this additional consideration as deferred revenue and will recognize it over two years, our estimated performance period under the agreement. Contract revenues related thereto of





approximately \$0.4 million and \$1.1 million, respectively, were recognized for the three and nine months ended September 30, 2006.

At September 30, 2006 the carrying value of our 3½% Senior Notes was \$112.0 million, which approximated fair market value. The carrying value of our 3½% Subordinated Notes was \$250.0 million while the fair market value was approximately \$188.4 million. The \$91.6 million carrying value of our 5.5% Notes approximated fair market value at September 30, 2006. In October 2006, all of the outstanding 5.5% Notes were redeemed for 100% of their principal amount plus accrued and unpaid interest to the redemption date, which will result in a \$0.1 million charge in the three months ended December 31, 2006 as a result of the write-off of the remaining deferred financing costs related to the 5.5% Notes.

## 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 our 3½% Senior Notes, 3½% Subordinated Notes and 5.5% 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:

	September 30, 2006	2005
Outstanding stock options	10,160,178	7,941,497
Common shares issuable upon conversion of the Pfizer Note	1,461,496	
Common shares issuable upon conversion of 3½% Senior Notes	13,531,224	
Common shares issuable upon conversion of 3½% Subordinated Notes	22,284,625	22,284,625
Common shares issuable upon conversion of 5.5% Notes (1)	1,358,865	1,470,109
Total potential common shares excluded from diluted net loss per share computation	48,796,388	31,696,231

(1) All of the outstanding 5.5% Notes were redeemed on October 16, 2006.

## 10. Other expenses

Below is a summary of the activity related to other expenses recorded for the periods in which activity related to our restructuring programs has taken place through the nine months ended September 30, 2006. 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.

### 2004 Restructuring

	Original Charge Recorded in 2004 (in thousands)	Accrual Balance at December 31, 2005	2006 Charges to Operations	2006 Accrual Utilized	Accrual Balance at September 30, 2006
Restructuring expenses:					
Lease commitment and related costs	20,207	13,545	745	2,262	12,028
Other costs			93	93	
Restructuring expenses	\$ 20,207	\$ 13,545	\$ 838	\$ 2,355	\$ 12,028

### 2002 Restructuring

	Original Charge Recorded in 2002 (in thousands)	Accrual Balance at December 31, 2005	2006 Credit to Operations	2006 Accrual Utilized	Accrual Balance at September 30, 2006
--	--	--	------------------------------	--------------------------	---

Edgar Filing: INCYTE CORP - Form 10-Q

Restructuring expenses:

Lease commitments and other

restructuring charges	17,924	13,700	(1,116)	)	1,760	10,824
Restructuring expenses	\$ 17,924	\$ 13,700	\$ (1,116)	)	\$ 1,760	\$ 10,824

11

---

**Maxia Acquisition Costs**

	Original Accrual (in thousands)	Accrual Balance at December 31, 2005	2006 Credit to Operations	2006 Accrual Utilized	Accrual Balance at September 30, 2006
Accrued acquisition costs:					
Lease commitments and other restructuring fees	2,016	2,069	(20 )	570	1,479
Accrued acquisition costs	\$ 2,016	\$ 2,069	\$ (20 )	\$ 570	\$ 1,479

**11. Litigation****Invitrogen**

In October 2001, Invitrogen Corporation ( Invitrogen ) filed an action against us in the federal court for the District of Delaware, alleging infringement of three patents. The complaint sought unspecified money damages and injunctive relief. In November 2001, we filed our answer to Invitrogen's patent infringement claims, and asserted seven counterclaims against Invitrogen, seeking declaratory relief with respect to the patents at issue, implied license, estoppel, laches and patent misuse. We also sought our fees, costs and expenses. Invitrogen filed its answer to our counterclaims in January 2002. In February 2003, we added a counterclaim for unfair business practices. In February 2004, the federal court for the District of Delaware ordered a stay of all proceedings pending disposition of the appeal in a related case of a judgment invalidating the same patents that are asserted in this case. On November 18, 2005, the Court of Appeals for the Federal Circuit issued its opinion vacating the judgment invalidating these patents and remanding for further proceedings in that related case. On January 25, 2006, the federal court for the District of Delaware lifted the stay of proceedings in this case with respect to discovery related to our license defense.

On June 15, 2006 we entered into a settlement agreement with Invitrogen pursuant to which we agreed to pay Invitrogen \$3.4 million as a settlement fee. This amount was paid on June 20, 2006 and is included in other expenses in the accompanying condensed consolidated statements of operations for the nine months ended September 30, 2006. Pursuant to stipulation, the federal court for the District of Delaware ordered the action dismissed with prejudice on June 26, 2006.

In addition to the matter described above, from time to time we have been involved in certain legal actions arising in the ordinary course of business. In management's opinion, the outcome of such actions will not have a material adverse effect on our financial position, results of operations, or liquidity.

**12. Subsequent event**

In October 2006, all of the outstanding 5.5% Notes were redeemed for 100% of their principal amount plus accrued and unpaid interest to the redemption date, which will result in a \$0.1 million charge in the three months ended December 31, 2006 as a result of the write-off of the remaining deferred financing costs related to the 5.5% Notes.

**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 should be read in conjunction with the financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q as of September 30, 2006 and our audited financial statements for the year-ended December 31, 2005 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;*
- the increase in our drug discovery and development efforts;*
- the expected timing, progress, results and other information regarding our preclinical testing, clinical trials and drug development programs;*
- conducting clinical trials internally, with collaborators, or with contract research organizations;*
- our collaboration and strategic alliance efforts; anticipated benefits and disadvantages of entering into collaboration agreements;*
- the regulatory approval process, including determinations to seek U.S. Food and Drug Administration, or FDA, 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; 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 of or payments to collaborators resulting from milestones or royalties; the decrease in revenues from our information product-related activities;*
- expected expenses and expenditure levels; expected revenues and sources of revenues;*
- expected losses; fluctuation of losses;*
- our profitability; the adequacy of our capital resources;*
- the need to raise additional capital; the costs associated with resolving matters in litigation; our expectations regarding competition; our investments, including anticipated expenditures, losses and expenses;*
- costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights;*

- *our ability to obtain, maintain or increase coverage of product liability and other insurance;*
- *adequacy of our product liability insurance; and*
- *our indebtedness;*

*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 contract 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;*
- *our ability to in-license a potential drug compound or drug candidate;*
- *the cost of accessing, licensing or acquiring potential drug compounds or drug candidates developed by other companies;*
- *the costs of terminating any licensing or access arrangement for third party drug compounds or drug candidates;*
- *the risk that our product candidates may not obtain regulatory approval;*
- *the impact of technological advances and competition;*
- *the ability to compete against third parties with greater resources than ours;*
- *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 results of businesses in which we have made investments;*
- *our ability to obtain additional capital when needed;*
- *our history of operating losses; and*
- *the risks set forth under Risk Factors.*

## Edgar Filing: INCYTE CORP - Form 10-Q

*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 or our 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 Form 10-Q.*

14

---



### **Overview**

Incyte Corporation is focused on the discovery and development of novel drugs to treat major medical conditions. Our core therapeutic areas are oncology and inflammation, and we have additional programs in diabetes and human immunodeficiency virus, or HIV. We have assembled a team of scientists with core competencies in the areas of medicinal chemistry and molecular, cellular and *in vivo* biology.

We have several internal drug development programs underway. Our most advanced oncology program involves inhibitors of an enzyme activity known as sheddase. We believe these compounds may have application in the treatment of breast cancer and other tumor types. Based on results from single and multiple-dose-escalation Phase I clinical trials of our lead candidate from this program in healthy volunteers, we have initiated a Phase Ib/IIa dose-escalation clinical trial in cancer patients.

We have developed a series of novel proprietary small molecule inhibitors of 11-beta hydroxysteroid dehydrogenase type 1 ( 11βHSD1 ). 11 HSD1 inhibitors have the potential to treat Type 2 diabetes. We initiated a Phase I clinical trial of INCB13739, our lead 11 HSD1 inhibitor compound, in healthy volunteers in the second quarter of 2006 and completed the single-dose-escalation portion of that trial in the third quarter of 2006.

We also have an oral CCR5 antagonist program. We believe CCR5 antagonists may represent a new class of HIV drugs. We initiated a Phase I clinical trial in healthy volunteers in the second quarter of 2006 with our lead CCR5 antagonist compound, INCB9471. This trial was completed in the third quarter of 2006 and we have initiated a 14-day Phase IIa trial in HIV patients.

One of our inflammation programs is focused on developing antagonists to a key chemokine receptor involved in inflammation called CCR2. We believe that CCR2 receptor antagonists may represent a new class of compounds to treat various inflammation-driven diseases, including rheumatoid arthritis, multiple sclerosis, diabetes, and atherosclerosis. We have entered into a collaborative research and license agreement with Pfizer Inc. ( Pfizer ), described below. We have retained rights to certain CCR2 antagonist compounds for multiple sclerosis and expect to file an Investigational New Drug Application, or IND, in the fourth quarter of 2006 for our lead compound for multiple sclerosis.

Earlier stage programs, directed against distinct targets, have generated novel compounds with potential applications in oncology and inflammation.

In April 2006, we announced that we were discontinuing the development of our then most advanced clinical candidate, dextelvucitabine or DFC (formerly known as Reverset), a nucleoside analog reverse transcriptase inhibitor, or NRTI, that was being developed as a treatment for patients with HIV infections.

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.

### ***Collaborative Research and License Agreement with Pfizer***

In November 2005, we entered a collaborative research and license agreement with Pfizer for the pursuit of our CCR2 antagonist program, which became effective in January 2006. As part of this agreement, we may receive up to \$803.0 million in milestone and other payments, including \$40.0 million that was received as an upfront payment in January 2006 and \$10.0 million that was received through the purchase of a convertible subordinated note (the Pfizer Note ) in February 2006. Pfizer gained worldwide development and commercialization rights to our portfolio of CCR2 antagonist compounds, the most advanced of which was in Phase IIa clinical trials in rheumatoid arthritis and insulin-resistant obese patients. Pfizer's rights extend to the full scope of potential indications, with the exception of multiple sclerosis and one other undisclosed indication, for which we retained worldwide rights, along with certain compounds. We do not have obligations to Pfizer on pre-clinical development candidates we select for pursuit in these indications. After we file an IND for our CCR2 antagonist candidate for multiple sclerosis and, at our option, Pfizer may purchase from us an additional \$10.0 million convertible subordinated note.

### **Critical Accounting Policies and Significant Estimates**

## Edgar Filing: INCYTE CORP - Form 10-Q

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

15

---

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:

- Revenue recognition;
- Research and development costs;
- Valuation of long-lived assets;
- Accounting for long-term investments;
- Restructuring charges; and
- Stock compensation.

**Revenue Recognition.** Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. We have entered into various types of agreements for access to our information databases and use of our intellectual property. Revenues are deferred for fees received before earned or until no further obligations exist. We exercise judgment in determining that collectibility is reasonably assured or that services have been delivered in accordance with the arrangement. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectibility based primarily on the customer's payment history and on the creditworthiness of the customer.

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

Certain of our contractual arrangements with customers involve multiple deliverables or elements. Under these arrangements, the multiple elements generally consist only of access to our information databases, use of our intellectual property, and sales of our custom products and services. Revenues recognized from multiple element contracts are allocated to each element of the arrangement based on the fair values of the elements. 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.

In connection with our collaborative research and license agreement with Pfizer, we received an upfront non-refundable payment of \$40.0 million in January 2006. The \$40.0 million upfront fee was recorded as deferred revenue and is being recognized on a straight-line basis over two years, our estimated performance period under the agreement. Pfizer also purchased the Pfizer Note for \$10.0 million from us in February 2006. As the Pfizer Note is non-interest bearing, it has been discounted to its net present value. The difference between the cash received and the present value of the Pfizer Note represents additional consideration from Pfizer under the agreement. We have accounted for this additional consideration as deferred revenue and will recognize it over two years, our estimated performance period under the agreement.

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

These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. In the event that we prepay CRO fees for future milestones, 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. Because these fees are incurred at various times during the contract term and they are used throughout the contract term, we record a monthly expense allocation to recognize the fees during the contract period. Fees incurred to set up the clinical trial are expensed during the setup period.

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

- Significant changes in the strategy of our overall business;
- Significant underperformance relative to expected historical or projected future operating results;
- Significant changes in the manner of use of the acquired assets;
- Significant negative industry or economic trends;
- Significant decline in our stock price for a sustained period; and
- Our market capitalization relative to net book value.

When we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, in accordance with Financial Accounting Standards Board ( FASB ) Statement No. 144, *Accounting for the Impairment or Disposal of Long Lived Assets* ( SFAS 144 ), 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.

**Accounting for Long-Term Investments.** Our long-term investments have historically consisted of investments in both privately and publicly-held companies in which we have owned less than 20% of the outstanding voting stock and have not had the ability to exert significant influence over the investees. Accordingly, our long-term investments in privately-held companies have been accounted for under the cost method and our investments in publicly-held companies have been accounted for in accordance with FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Our investments in publicly-held companies are classified as available-for-sale and are adjusted to their fair value each period based on their quoted market price with any adjustments being recorded in accumulated other comprehensive income (loss) as a separate component of stockholders equity (deficit).

We periodically evaluate the carrying value of our ownership interests in privately-held cost method investees by reviewing conditions that might indicate an other-than temporary decline in fair value, including the following:

- Financial performance of the investee;
- Achievement of business plan objectives and milestones including the hiring of key employees, obtaining key business partnerships, and progress related to research and development activities;
- Available cash; and
- Completion of debt and equity financings.

If our review of these factors indicates that an other-than-temporary decline in the fair value of the investee has occurred, we estimate the fair value of the investee. When the carrying value of our investments is materially greater than our pro-rata share of the estimated fair value of the investee, we record an impairment charge to reduce our carrying value. Impairment charges are recorded in the period when the related triggering condition becomes known to management. We use the best information available in performing our periodic evaluations; however, the information available may be limited. These evaluations involve significant management judgment, and the actual amounts realized for a specific investment may differ from the carrying value. For our available-for-sale investments in publicly-held investees, we monitor all unrealized losses to determine whether a decline in fair value below carrying value is other-than-temporary. Generally, when fair value is materially less than carrying value for six consecutive months, we consider the decline to be other-than-temporary. When we conclude that a decline is other-than-temporary, we adjust the carrying value of our long-term investments in publicly-held investees so that our carrying value per share is equal to the quoted market price per share. Future adverse changes in market conditions or poor operating results of underlying investments could result in additional impairment charges.

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

determined based on the estimated severance and fringe benefit charge for identified employees. In calculating the cost to exit the facilities, we estimate for each location the amount to be paid in lease termination payments, the future lease and operating costs to be paid until the lease is terminated, the amount, if any, of sublease receipts and real estate broker fees. This requires us to estimate the timing and costs of each lease to be terminated, the amount of operating costs, and the timing and rate at which we might be able to sublease the site. To form our estimates for these costs, we perform an assessment of the affected facilities and considered the current market conditions for each site. We also estimate our credit adjusted risk free interest rate in order to discount our projected lease payments in accordance with SFAS 146. Estimates are also used in our calculation of the estimated realizable value on equipment that is being held for sale. These estimates are formed based on recent history of sales of similar equipment and market conditions. Our assumptions on either the lease termination payments, operating costs until terminated, the offsetting sublease receipts and estimated realizable value of fixed assets held for sale may turn out to be incorrect and our actual cost may be materially different from our estimates. Our estimates of future liabilities may change, requiring us to record additional restructuring charges or reduce the amount of liabilities recorded.

At the end of each reporting period, we evaluate the remaining accrued balances to ensure their adequacy, that no excess accruals are retained and the utilization of the provisions are for their intended purposes in accordance with developed exit plans. We periodically evaluate current available information and adjust our restructuring reserve as necessary. We also make adjustments related to accrued professional fees to adjust estimated amounts to actual. For the period ended September 30, 2006, such adjustments were made for the 2002 restructuring program, 2004 restructuring program, and the acquisition of Maxia.

**Stock Compensation.** Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004) ( SFAS 123R ), *Share-Based Payment*, which revised Statement of Financial Accounting Standards 123 ( SFAS 123 ), *Accounting for Stock-Based Compensation*. SFAS 123R requires all share-based payment transactions with employees, including grants of employee stock options, to be recognized as compensation expense over the requisite service period based on their relative fair values. SFAS 123R is a new complex accounting standard, the application of which requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value equity-based compensation. SFAS 123R requires the recognition of the fair value of stock compensation in the statement of operations. Prior to the adoption of SFAS 123R, stock-based compensation expense related to employee stock options was not recognized in the statement of operations. Prior to January 1, 2006, we had adopted the disclosure-only provisions under SFAS 123. For the three and nine months ended September 30, 2006, stock-compensation expense of approximately \$2.1 million and \$6.6 million, respectively, was recorded in the condensed consolidated statement of operations in connection with adoption of SFAS 123R. As a result of adopting SFAS 123R, our net loss for the three and nine months ended September 30, 2006, is \$2.1 million and \$6.6 million, higher, respectively, than if we had continued to account for share-based compensation under Accounting Principles Board ( APB ) Opinion 25. Basic and diluted net loss per share for the three and nine months ended September 30, 2006 are \$0.03 and \$0.08 higher, respectively, than if we had continued to account for share-based compensation under APB Opinion 25. There was no cumulative effect of adoption. Refer to Note 6 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this report for further information.

## Results of Operations

We recorded a net loss of \$15.8 million and \$53.7 million and basic and diluted net loss per share of \$0.19 and \$0.64 per share for the three and nine months ended September 30, 2006, respectively, as compared to a net loss of \$30.2 million and \$75.5 million and basic and diluted net loss per share of \$0.36 and \$0.91 per share in the corresponding periods in 2005. The decline in net loss is primarily attributable to higher revenue related to the Pfizer collaboration and lower research and development expenses related to the timing of our clinical trial activities.

## Revenues.

	For the three months ended, September 30, 2006		For the nine months ended, September 30, 2006	
	2006	2005	2006	2005
	(in millions)		(in millions)	
Contract revenues	\$ 6.3	\$	\$ 18.1	\$

Edgar Filing: INCYTE CORP - Form 10-Q

License and royalty revenues	1.0	1.2	2.5	6.8
Total revenues	\$ 7.3	\$ 1.2	\$ 20.6	\$ 6.8

Our contract revenues for the three and nine months ended September 30, 2006 increased to \$6.3 million and \$18.1 million, respectively, from \$0.0 million for the three and nine months ended September 30, 2005. Contract revenues were derived from recognition of revenue associated with the Pfizer \$40.0 million upfront fee, recognition of revenue associated with the debt discount and beneficial conversion feature related to the Pfizer Note, and research services provided to Pfizer.

18

---



## Edgar Filing: INCYTE CORP - Form 10-Q

Our license and royalty revenues for the three and nine months ended September 30, 2006 decreased to \$1.0 million and \$2.5 million, respectively, from \$1.2 million and \$6.8 million, respectively, for the three and nine months ended September 30, 2005. License and royalty revenues were derived from database subscriptions and licensing of our gene- and genomic-related intellectual property. The decrease in license and royalty revenues from 2005 to 2006 is attributable to our decision to discontinue offering information products. We expect that revenues generated from information products, including licensing of gene- and genomic-related intellectual property, will continue to decline as we focus on our drug discovery and development programs.

### *Operating Expenses.*

#### *Research and development expenses.*

	<b>For the three months ended, September 30, 2006</b>		<b>For the nine months ended, September 30, 2006</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
	<b>(in millions)</b>		<b>(in millions)</b>	
Salary and benefits related	\$ 6.3	\$ 6.3	\$ 19.0	\$ 19.0
Stock compensation	1.4		4.2	
Collaboration and outside services	7.6	16.4	27.7	37.4
Occupancy and all other costs	4.3	4.7	13.1	15.3
<b>Total research and development expenses</b>	<b>\$ 19.6</b>	<b>\$ 27.4</b>	<b>\$ 64.0</b>	<b>\$ 71.7</b>

We currently track research and development costs by natural expense line and not by project. Stock compensation costs for the three and nine months ended September 30, 2006 was the result of our adoption of SFAS 123R which required the recognition of stock compensation expense in our consolidated statement of operations. For collaboration and outside services, the decrease from the three and nine months ended September 30, 2005 to the three and nine months ended September 30, 2006 was primarily the result of decreased drug discovery and development costs due to our collaborative research and license agreement with Pfizer and the decision in April 2006 to discontinue the development of our DFC program. For occupancy and all other costs, the decrease from the three and nine months ended September 30, 2005 to the three and nine months ended September 30, 2006 was primarily the result of increased efficiency in our use of laboratory and reagent supplies.

We expect that research and development expenditures related to drug discovery and development will decrease during 2006 due to our collaborative research and license agreement with Pfizer and the discontinuation of development of DFC. 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 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.*

	<b>For the three months ended, September 30, 2006</b>		<b>For the nine months ended, September 30, 2006</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
	<b>(in millions)</b>		<b>(in millions)</b>	
Salary and benefits related	\$ 1.6	\$ 1.6	\$ 4.9	\$ 4.5
Stock compensation	0.7		2.4	0.2
Other contract service and outside costs	1.2	1.1	3.5	3.5
<b>Total selling, general and administrative expenses</b>	<b>\$ 3.5</b>	<b>\$ 2.7</b>	<b>\$ 10.8</b>	<b>\$ 8.2</b>

The increase from the three and nine months ended September 30, 2005 to the three and nine months ended September 30, 2006 was primarily the result of our adoption of SFAS 123R which required the recognition of stock compensation expense in our consolidated statement of operations. We expect our total selling, general and administrative expenses to increase in 2006 due to the impact of SFAS 123R adoption.

*Other expenses.* Total other expenses for the three and nine months ended September 30, 2006 was \$0.0 million and \$3.1 million, respectively, compared to \$0.3 million and \$1.1 million, respectively, for the corresponding periods in 2005. The change for the nine

19

---

months ended September 30, 2006 is due primarily to the settlement agreement with Invitrogen pursuant to which we paid Invitrogen \$3.4 million as a settlement fee in June 2006. The three and nine months ended September 30, 2006 and 2005 also include charges recorded in connection with the previously announced restructuring programs.

**Interest and Other Income, net.** Interest and other income, net, for the three and nine months ended September 30, 2006 was \$4.0 million and \$15.5 million, respectively, compared to \$2.7 million and \$10.2 million, respectively, for the corresponding periods in 2005. The change for the three months ended September 30, 2006 is due to higher interest rates and a higher average cash balance in 2006. The change for the nine months ended September 30, 2006 is primarily attributable to the \$5.5 million realized gain recorded from the sale of a portion of our investment in a publicly-held company in March 2006 offset by an impairment charge of \$1.3 million recorded in June 2006 to reduce the carrying value of our investment in a privately-held investee.

**Interest Expense.** Interest expense for the three and nine months ended September 30, 2006 were \$4.1 million and \$11.8 million, respectively, compared to \$3.8 million and \$12.3 million, respectively, for the corresponding periods in 2005. The decrease for the nine months ended September 30, 2006 is due to a lower average outstanding balance of our 5.5% convertible subordinated notes due 2007 ( the 5.5% Notes ).

**Gain on Repurchase of Convertible Subordinated Notes.** In 2005 we repurchased \$36.5 million in face value of the 5.5% Notes on the open market. The repurchase resulted in a gain of \$0.1 million and \$0.5 million, respectively, for the three and nine months ended September 30, 2005.

**Loss on Certain Derivative Financial Instruments, net.** The loss on derivative financial instruments in the three and nine months ended September 30, 2006 and 2005 represents the change in the fair value of certain long-term investments, specifically warrants held in other companies, in accordance with FASB Statement No. 133 ( SFAS 133 ).

**Income From Discontinued Operations, net.** Income from discontinued operations of \$0.2 million for the nine months ended September 30, 2005 represents the gain on the sale from the Proteome facility based in Beverly, Massachusetts, net of the loss from its operations through the January 17, 2005 disposal of the facility. There was no such income related to Proteome for the nine months ended September 30, 2006.

#### **Recent Accounting Pronouncements**

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, ( FIN 48 ). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on our consolidated financial statements.

In November 2005, the FASB issued staff position FAS 115-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments* ( FSP 115-1 ). FSP 115-1 address the determination as to when an investment is considered impaired, whether that impairment is other than temporary and the measurement of an impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in FSP 115-1 amends FASB Statements No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*.

FSP 115-1 replaces the impairment evaluation guidance of EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* ( EITF 03-1 ), with references to existing other-than-temporary impairment guidance. EITF 03-1 s disclosure requirements remain in effect, and are applicable for year-end reporting and for interim periods if there are significant changes from the previous year-end. FSP 115-1 also supersedes EITF Topic No. D-44, *Recognition of Other-Than-Temporary Impairment upon the Planned Sale of a Security Whose Cost Exceeds Fair Value*, and clarifies that an investor should recognize an impairment loss no later than when the impairment is deemed other-than-temporary, even if a decision to sell an impaired security has not been made. FSP 115-1 applies to reporting periods beginning after December 15, 2005. FSP 115-1 did not have a material impact on our results of operations, or cash flows for the three and nine months ended September 30, 2006.

## Edgar Filing: INCYTE CORP - Form 10-Q

We adopted SFAS 123R on January 1, 2006. SFAS 123R is a new complex accounting standard, the application of which requires significant judgment and the use of estimates, particularly surrounding Black-Scholes assumptions such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value equity-based compensation. SFAS 123R requires the recognition of the fair value of stock compensation in the statement of operations. Refer to Note 6 of notes to our unaudited condensed consolidated financial statements included elsewhere in this quarterly report on Form 10-Q for more discussion of our adoption of SFAS 123R.

20

---

## Liquidity and Capital Resources

In September 2006, we received proceeds of \$111.9 million from the sale of \$151.8 million aggregate principal of the 3½% convertible senior notes due 2011 (the 3½% Senior Notes ).

As of September 30, 2006, we had \$444.1 million in cash, cash equivalents and short-term and long-term marketable securities, compared with \$345.0 million as of December 31, 2005. In October 2006, we used \$92.7 million to redeem the \$91.6 million aggregate principal amount of our existing 5.5% Notes and accrued interest thereon. We have historically financed our operations primarily through the sale of equity securities, the issuance of convertible subordinated notes and cash received from our customers and collaborative partners. As of September 30, 2006, approximately \$17.8 million of marketable securities are classified as long-term assets on the condensed consolidated balance sheet as they have been in an unrealized loss position for longer than six months and we have the ability to hold them until the carrying value recovers, which may be longer than one year. Available cash is invested in accordance with the primary objectives of our investment policy, including liquidity, safety of principal and diversity of investments.

Net cash used in operating activities was \$28.2 million for the nine months ended September 30, 2006 and net cash used in operating activities was \$73.9 million for the nine months ended September 30, 2005. The \$45.7 million decrease was due primarily to the \$40.0 million upfront fee received from Pfizer in January 2006.

Our investing activities, other than purchases, sales and maturities of marketable securities, have consisted predominantly of capital expenditures and sales and purchases of long-term investments. Net cash provided by investing activities was \$9.7 million for the nine months ended September 30, 2006, which represented primarily sales and maturities of marketable securities of \$508.5 million, offset by purchases of marketable securities of \$498.2 million. In the future, net cash used by investing activities may fluctuate significantly from period to period due to the timing of strategic equity investments, acquisitions, including possible earn-out payments to former Maxia stockholders, capital expenditures and maturities/sales and purchases of marketable securities.

Net cash provided by financing activities was \$122.9 million for the nine months ended September 30, 2006 and net cash used in financing activities was \$34.9 million for the nine months ended September 30, 2005. During 2006, we received proceeds of \$121.9 million in connection with the 3½% Senior Notes and the Pfizer Note, and \$1.0 million of proceeds from issuance of common stock under our stock plans and employee stock purchase plan.

The following summarizes our significant contractual obligations as of September 30, 2006 and the effect those obligations are expected to have on our liquidity and cash flow in future periods:

	Total (in millions)	Less Than 1 Year	Years 1 3	Years 4 5	Over 5 Years
<b>Contractual Obligations:</b>					
Principal on convertible subordinated debt	\$ 351.6	\$ 91.6	* \$	\$ 250.0	\$ 10.0
Principal on convertible senior debt	151.8			151.8	
Interest on convertible subordinated debt	40.4	9.8	17.5	13.1	
Interest on convertible senior debt	23.3	4.7	10.6	8.0	
Non-cancelable operating lease obligations:					
Related to current operations	8.0	4.6	3.4		
Related to vacated space	35.8	8.2	16.3	11.3	
<b>Total contractual obligations</b>	<b>\$ 610.9</b>	<b>\$ 118.9</b>	<b>\$ 47.8</b>	<b>\$ 434.2</b>	<b>\$ 10.0</b>

\* In October 2006, we redeemed the \$91.6 million aggregate principal amount of our existing 5.5% Notes and accrued interest thereon.

The amounts and timing of payments related to vacated facilities may vary based on negotiated timing of lease terminations. We have entered into sublease agreements for our vacated space with scheduled payments to us of \$2.7 million (less than 1 year), \$4.1 million (years 1-3), \$2.4 million (years 4-5), and \$0.0 million (over 5 years); 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.

## Edgar Filing: INCYTE CORP - Form 10-Q

Additional 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

21

---

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 have been achieved as of September 30, 2006.

We have entered into and intend to continue to seek to license additional rights relating to compounds or 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 alliances, license agreements and acquisitions of and investments in complementary products, technologies and businesses; expenditures in connection with potential repayments of our 3½% Senior Notes, 3½% Subordinated Notes, and the Pfizer Note; expenditures in connection with our drug discovery and development programs; expenditures in connection with litigation; competing technological and market developments; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and costs associated with the integration of new operations assumed through mergers and acquisitions. Changes in our research and development plans or other changes affecting our operating expenses may result in changes in the timing and amount of expenditures of our capital resources. We expect that future revenues generated from information products, including licensing of intellectual property, will continue to decline as we focus on drug discovery and development programs, and in 2006, will not represent a significant source of cash inflow for us.

#### **Off Balance Sheet Arrangements**

We have no material 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 and mortgage and asset-backed securities, 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 interest rates increase. Our marketable securities also included our investment in the common stock of Genomic Health, Inc. At September 30, 2006, the fair market value of our investment in Genomic Health, Inc. was \$6.0 million. In October 2006, we sold this investment, which will result in a realized gain of \$0.8 million in the three months ended December 31, 2006. As of September 30, 2006, cash, cash equivalents and marketable securities were \$444.1 million. 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, 2006, 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.

## Edgar Filing: INCYTE CORP - Form 10-Q

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.

22

---



**PART II: OTHER INFORMATION**

**Item 1. Legal Proceedings**

*Invitrogen Corporation*

In October 2001, Invitrogen Corporation ( Invitrogen ) filed an action against us in the federal court for the District of Delaware, alleging infringement of three patents. The complaint sought unspecified money damages and injunctive relief. In November 2001, we filed our answer to Invitrogen's patent infringement claims, and asserted seven counterclaims against Invitrogen, seeking declaratory relief with respect to the patents at issue, implied license, estoppel, laches and patent misuse. We also sought our fees, costs and expenses. Invitrogen filed its answer to our counterclaims in January 2002. In February 2003, we added a counterclaim for unfair business practices. In February 2004, the federal court for the District of Delaware ordered a stay of all proceedings pending disposition of the appeal in a related case of a judgment invalidating the same patents that are asserted in this case. On November 18, 2005, the Court of Appeals for the Federal Circuit issued its opinion vacating the judgment invalidating these patents and remanding for further proceedings in that related case. On January 25, 2006, the federal court for the District of Delaware lifted the stay of proceedings in this case with respect to discovery related to our license defense.

On June 15, 2006 we entered into a settlement agreement with Invitrogen pursuant to which we agreed to pay Invitrogen \$3.4 million as a settlement fee. This amount was paid on June 20, 2006. Pursuant to stipulation, the federal court for the District of Delaware ordered the action dismissed with prejudice on June 26, 2006.

In addition to the matter described above, from time to time we have been involved in certain legal actions arising in the ordinary course of business. In management's opinion, the outcome of such actions will not have a material adverse effect on our financial position, results of operations, or liquidity.

**Item 1A. Risk Factors**

**RISKS RELATING TO OUR BUSINESS**

**We are at the early stage of our drug discovery and development efforts and we may be unsuccessful in our efforts.**

We are in the early stage of building our drug discovery and development operations. Our ability to discover, develop, and commercialize pharmaceutical products will depend on our ability to:

- hire and retain key scientific employees;
- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally or license drug candidates from others;
- identify and enroll suitable human subjects, either in the United States or abroad, for our clinical trials;
- complete laboratory testing and clinical trials on humans;
- obtain and maintain necessary intellectual property rights to our products;
- obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;
- enter into arrangements with third parties to provide services or to manufacture our products on our behalf, or develop efficient production facilities meeting all regulatory requirements;
- 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.

**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. Significant research and development efforts will be necessary. For example, in April 2006, we announced the discontinuation of 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 limited experience with the activities listed above and may not be successful in discovering, developing, or commercializing drug products. If we choose to outsource some of these activities, we may be unable to enter into outsourcing or licensing agreements on commercially reasonable terms, if at all. In addition, if we elect to manufacture our products in our own manufacturing facilities, we will require substantial additional capital resources to lease or build and maintain those facilities, including attracting and retaining qualified personnel to lease or build and operate our facilities.**

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

We are currently engaged in a number of different approaches to discover and develop novel drug candidates. At the present time, we have three drug candidates from our active drug discovery and development programs in clinical trials: (1) our lead sheddase inhibitor in Phase Ib/IIa

## Edgar Filing: INCYTE CORP - Form 10-Q

clinical trials; (2) our lead 11 $\beta$ HSD1 inhibitor compound in Phase I clinical trials; and (3) our lead CCR5 antagonist compound in Phase IIa clinical trials. Our other earlier stage internal drug discovery programs are focused on compounds with potential applications in oncology and inflammation. We have also licensed to Pfizer our lead CCR2 antagonist, which was in Phase IIa clinical trials at the time of licensing to Pfizer. We have no control over the further clinical development of any compounds we licensed to Pfizer. Discovery and development of potential drug candidates are expensive and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. If our efforts do not lead to the discovery of a suitable drug candidate, we may be unable to grow our clinical pipeline or we may be unable to enter into agreements with collaborators who are willing to develop our drug candidates.

24

---

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

An important element of our business strategy will be to enter into collaborative or license arrangements with other parties, such as our collaboration with Pfizer, under which we license our drug candidates to those parties for development and commercialization. We expect that while we may initially seek to conduct initial clinical trials on our drug candidates, we will need to seek collaborators for a number of our drug candidates, such as our chemokine receptor antagonists, because of the expense, effort and expertise required to continue additional clinical trials and further develop those drug candidates. 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 interested in it is a competitor. The terms of any such arrangements that we establish may not be favorable to us. Alternatively, potential collaborators may decide against entering into an agreement with us because of our financial, regulatory or intellectual property position or for scientific, commercial or other reasons. If we are not able to establish collaborative agreements, we may not be able to develop and commercialize a drug product, which would adversely affect our business and our revenues.

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

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

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

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

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

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. If Pfizer terminates the license agreement or its rights with respect to certain indications, we may not be able to find a new collaborator to replace Pfizer, and our business could be adversely affected.



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

If conflicts arise between us and our collaborators or licensees, including Pfizer, or our scientific advisors, the other party may act in its self-interest and not in the interest of our stockholders. Conflicts may arise with our collaborators or licensees if they pursue alternative technologies or develop alternative products either on their own or in collaboration with others as a means for developing treatments for the diseases that we have targeted. Competing products, either developed by these future collaborators or licensees or to which these future collaborators or licensees have rights, may result in their withdrawal of support for our product candidates.

Additionally, conflicts may arise if there is a dispute about the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of the relationship. Similarly, the parties to a collaboration or license agreement may disagree as to which party owns newly developed products. Should an agreement be terminated as a result of a dispute and before we have realized the benefits of the collaboration or license, our reputation could be harmed and we may not obtain revenues that we anticipated receiving.

**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 intend to continue to explore opportunities to develop our clinical pipeline by in-licensing drug compounds that fit within our expertise and research and development capabilities. We may be unable to enter into any additional in-licensing agreements because suitable product candidates that are within our expertise may not be available to us on terms that are acceptable to us or because competitors with greater resources seek to in-license the same product candidates. Product candidates that we would like to develop may not be available to us because they are controlled by competitors who are unwilling to license the rights to the drug compound or candidate to us. In addition, we may enter into license agreements that are unsuccessful and our business and operations might be adversely affected by the termination of a drug candidate and termination and winding down of the related license agreement. For example, in April 2006, we announced the discontinuation of development of DFC and we gave notice of termination of our collaborative license agreement with Pharmasset, Inc., which licensed DFC to us. DFC was at the time our most advanced drug candidate. We may also need to license drug delivery or other technology in order to continue to develop our drug candidate pipeline. If we are unable to enter into additional agreements to license drug candidates, drug delivery technology or other technology or if these arrangements are unsuccessful, our research and development efforts could be adversely affected.

**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 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 expenditures. Events such as these may result in delays in our obtaining regulatory approval for our drug candidates or our ability to commercialize our products and could result in increased expenditures that would adversely affect our operating results.

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

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

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

## Edgar Filing: INCYTE CORP - Form 10-Q

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

26

---

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 the 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. At the present time, we have three drug candidates in clinical trials: (1) our lead sheddase inhibitor in Phase Ib/IIa clinical trials; (2) our lead 11 $\beta$ HSD1 inhibitor compound in Phase I clinical trials; and (3) our lead CCR5 antagonist compound in Phase IIa clinical trials. Our other drug candidates are still undergoing preclinical testing. We have also licensed to Pfizer our lead CCR2 antagonist; further clinical development of this compound, which was in Phase IIa clinical trials at the time of licensing, is under Pfizer's control. 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.

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

The FDA requires that drug products be manufactured according to its current Good Manufacturing Practices, or cGMP, regulations and a limited number of manufacturers comply with these requirements. If the other parties that we choose to manufacture our drug products are not compliant with cGMP, the FDA may not approve our application to manufacture our drug products. We may not be able to arrange for our products to be manufactured by one of these parties on reasonable terms, if at all. Failure to comply with cGMP in the manufacture of our products could result in the FDA withdrawing or denying regulatory approval of our drug product or other enforcement actions.

We may not be able to obtain sufficient quantities of our new drug products if our designated manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. Also, raw materials that may be required to manufacture any products we develop may only be available from a limited number of suppliers. If we have promised delivery of a new product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs would be delayed, and we may have to expend additional sums in order to ensure that manufacturing capacity is available when we need it even if we do not use all of the manufacturing capacity. This expense would adversely affect our operating results. Manufacturers of pharmaceutical products often encounter



## Edgar Filing: INCYTE CORP - Form 10-Q

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. The manufacturers we choose may not perform as agreed or 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.

27

---

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

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

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

Our lead sheddase inhibitor, 11βHSD1 inhibitor and CCR5 antagonist compounds are our only drug candidates in clinical trials. We have also licensed to Pfizer our lead CCR2 antagonist, which was in Phase IIa clinical trials at the time of licensing. 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. If a product is developed, but is not marketed, we may have spent significant amounts of time and money on it, which would adversely affect our operating results and financial condition. Even if a drug candidate that we develop receives regulatory approval, we may decide not to commercialize it if we determine that commercialization of that product would require more money and time than we are willing to invest. For example, drugs that receive approval are subject to post-regulatory surveillance and may have to be withdrawn from the market if previously unknown side effects occur. At this point, the regulatory agencies may require additional clinical trials or testing. Once a drug is marketed, if it causes side effects, the drug product may be recalled or may be subject to reformulation, additional studies, changes in labeling, warnings to the public and negative publicity. As a result, we may not continue to commercialize a product even though it has obtained regulatory approval. Further, we may decide not to continue to commercialize a product if the market does not accept the product because it is too expensive and third parties such as insurance companies or Medicare have not approved it for substantial reimbursement. In addition, we may decide not to continue to commercialize a product if another product comes on the market that is as effective but has fewer side effects. There is also a risk that competitors may develop similar or superior products or have proprietary rights that preclude us from ultimately marketing our products.

**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 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

28

---

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, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed. We do not maintain key person insurance on any of our employees.

**We may encounter difficulties in integrating companies we acquire, which may harm our operations and financial results.**

As part of our business strategy, we have in the past and may in the future acquire assets, technologies, compounds and businesses. Our past acquisitions, such as the acquisition of Maxia have involved, and our future acquisitions may involve, risks such as the following:

- we may be exposed to unknown liabilities of acquired companies;
- our acquisition and integration costs may be higher than we anticipated and may cause our quarterly and annual operating results to fluctuate;
- we may experience difficulty and expense in assimilating the operations and personnel of the acquired businesses, disrupting our business and diverting our management's time and attention;
- we may be unable to integrate or complete the development and application of acquired technology, compounds or drug candidates;
- we may experience difficulties in establishing and maintaining uniform standards, controls, procedures and policies;
- our relationships with key customers, suppliers, or collaborative or license partners of acquired businesses may be impaired, due to changes in management and ownership of the acquired businesses;
- we may be unable to retain key employees of the acquired businesses;
- we may incur amortization or impairment expenses if an acquisition results in significant goodwill or other intangible assets; or
- our stockholders may be diluted if we pay for the acquisition with equity securities.

In addition, if we acquire additional businesses that are not located near our new headquarters, we may experience more difficulty integrating and managing the acquired businesses' operations.

**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 2006. Because of those losses, we had an accumulated deficit of \$893.0 million as of September 30, 2006. 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 2006 and in future periods as well.

We anticipate that our drug discovery and development efforts 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 on a going-forward basis.

Additional factors that may affect our future funding requirements include:

- any changes in the breadth of our research and development programs;
- the results of research and development, preclinical testing and clinical trials conducted by us or our future collaborative partners or licensees, if any;
- the acquisition or licensing of businesses, technologies or compounds, 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. 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

## Edgar Filing: INCYTE CORP - Form 10-Q

additional convertible debt securities in the future would 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.

**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.**

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

30

---

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.

**Our investments may decline in value and our losses may increase.**

We have made and may in the future make investments in entities that complement our business. These investments may:

- often be made in securities lacking a public trading market or subject to trading restrictions, either of which increases our risk and reduces the liquidity of our investment;
- require us to record losses and expenses related to our ownership interest;
- require us to record acquisition-related charges, such as in-process research and development;
- require us to record charges related to the impairment in the value of the securities underlying our investment; and
- require us to invest greater amounts than anticipated or to devote substantial management time to the management of research and development relationships or other relationships.

The market values of many of these investments can fluctuate significantly. We evaluate our long-term investments for impairment of their value on a quarterly basis. The value of our investments in private companies can fluctuate significantly. In past periods, market conditions have caused us to write-down the value of our private company investments, sometimes substantially, and market conditions may cause us to write down additional amounts. In addition, we have in the past written down the value of our debt investments in companies experiencing financial difficulties. Impairment could result in future charges to our earnings. Decreases in the value of our strategic investments may cause our losses to increase.

**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, 2006, the aggregate principal amount of total consolidated debt was \$503.4 million and our stockholders' deficit was \$66.2 million. The indentures pursuant to which our outstanding convertible subordinated notes were issued do not limit the issuance of additional indebtedness. Our substantial leverage could have significant negative consequences for our future operations, including:

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

In the past five years, we have had negative cash flow from operations. We likely will not generate sufficient cash flow from our operations in the future to enable us to meet our anticipated fixed charges, including our debt service requirements with respect to our outstanding convertible senior notes and convertible subordinated notes. As of September 30, 2006, \$151.8 million aggregate principal amount of our 3 1/2% Senior



Notes was outstanding. Our annual interest payments, beginning in 2007, for the 3½% Senior Notes through 2010, assuming none of these notes are converted, redeemed, repurchased or exchanged, are \$5.3 million, and an additional \$0.7 million in interest is payable in 2011. As of September 30, 2006, \$91.6 million aggregate principal amount of our 5.5% Notes was outstanding which was subsequently redeemed in October 2006. As of September 30, 2006, \$250.0 million aggregate principal amount of our 3½% Subordinated Notes was outstanding. Our annual interest payments for the 3½% Subordinated Notes through 2010, assuming none of these notes are converted, redeemed, repurchased or exchanged, are \$8.8 million, and an additional \$4.4 million in interest is payable in 2011. As of September 30, 2006, we also had outstanding the \$10.0 million aggregate principal amount of the Pfizer Note, which is due in 2013 but does not bear interest. 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.

**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.**

## Edgar Filing: INCYTE CORP - Form 10-Q

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

31

---

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 certain intellectual property relating to certain drug discovery targets such as CCR5. 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, our ability to commercialize our products could be harmed.

From time to time we may 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. No third party has a current filed patent lawsuit or arbitration against us. If a successful claim were brought against us, we would have to attempt to license the technology from the claimant or to spend time and money to design around the technology. Any such license of the technology may not be available at reasonable terms, or at all.

We may, however, 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 or claims. Regardless of the outcome, litigation can be very costly and can divert management's efforts. For example, we recently settled patent litigation with Invitrogen Corporation. 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 product that we develop. Further, we or our future collaborators or licensees may not be able to obtain any necessary licenses on acceptable terms, if at all.

**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.**

## Edgar Filing: INCYTE CORP - Form 10-Q

Our business and competitive position depend in 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. Any patents issued in connection with our drug discovery efforts may not be broad enough to protect all of the potential uses of the product.

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.**

## Edgar Filing: INCYTE CORP - Form 10-Q

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

32

---

and, in these situations, the patent term will be measured from the date of the earliest priority application. This would shorten our period of patent exclusivity and may decrease the revenues that we might derive from the patents.

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

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

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

(c) On September 26, 2006, we notified the record holders of our 5.5% Notes that we intended to redeem the entire outstanding principal amount of the 5.5% Notes on October 16, 2006 for approximately \$92.7 million, an amount equal to 100% of the principal amount plus accrued and unpaid interest to the redemption date. The redemption was consummated on October 16, 2006.



**Item 6. Exhibits**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
4.1	Indenture related to the 3½% Convertible Senior Notes due 2011, dated as of September 26, 2006, between Incyte Corporation and U.S. Bank National Association, as trustee (including form of 3½% Convertible Senior Note due 2011) (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed September 28, 2006)
4.2	Registration Rights Agreement, dated as of September 26, 2006, by and between the Company and Piper Jaffray & Co. (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed September 28, 2006)
10.1#	1997 Employee Stock Purchase Plan of Incyte Corporation, as amended and restated September 15, 2006 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed September 19, 2006)
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)

# Indicates management contract or compensatory plan or arrangement.

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

**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 2, 2006

By:

/s/ PAUL A. FRIEDMAN  
PAUL A. FRIEDMAN  
Chief Executive Officer  
(Principal Executive Officer)

Dated: November 2, 2006

By:

/s/ DAVID C. HASTINGS  
DAVID C. HASTINGS  
Chief Financial Officer  
(Principal Financial Officer)

INCYTE CORPORATION

EXHIBIT INDEX

Exhibit

Number	Description of Document
4.1	Indenture related to the 3½% Convertible Senior Notes due 2011, dated as of September 26, 2006, between Incyte Corporation and U.S. Bank National Association, as trustee (including form of 3½% Convertible Senior Note due 2011) (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed September 28, 2006)
4.2	Registration Rights Agreement, dated as of September 26, 2006, by and between the Company and Piper Jaffray & Co. (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed September 28, 2006)
10.1#	1997 Employee Stock Purchase Plan of Incyte Corporation, as amended and restated September 15, 2006 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed September 19, 2006)
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)

---

# Indicates management contract or compensatory plan or arrangement.

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