# 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, 2005

or

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

For the transition period from

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.)

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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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

⊠ Yes o No

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

o Yes 🗵 No

The number of outstanding shares of the registrant's Common Stock, \$0.001 par value, was 83,421,780 as of October 26, 2005.

#### INCYTE CORPORATION

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### PART I: FINANCIAL INFORMATION

#### Item 1. Financial Statements

### **INCYTE CORPORATION Condensed Consolidated Balance Sheets**

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(in thousands)

(in thousands)				
	Se	September 30, 2005		December 31, 2004*
ASSETS	(	(unaudited)		
Current assets:				
Cash and cash equivalents	\$	49,197	\$	132,180
Marketable securities—available-for-sale	Ф	314,841	Þ	
Accounts receivable, net		1,045		337,584 2,143
Prepaid expenses and other current assets		5,738		7,142
Assets of discontinued operation  Total current assets		270.021		2,264
Total current assets		370,821		481,313
Property and equipment, net		8,119		9,959
Long-term investments (1)		7,386		11,427
Intangible and other assets, net		11,783		14,220
Total assets	\$	398,109	\$	516,919
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	4,372	\$	2,321
Accrued compensation	Ψ	6,210	Ψ	7,876
Interest payable		1,935		6,217
Accrued and other current liabilities		8,764		4,838
Deferred revenue		742		1,807
Accrued restructuring and acquisition costs		5,261		5,873
Liabilities of discontinued operation		5,201		2,549
Total current liabilities		27,284	-	31,481
Total current nationics		27,204		31,401
Convertible subordinated notes		341,919		378,766
Other liabilities		25,391		28,155
Total liabilities		394,594		438,402
Stockholders' equity:				
Preferred stock		_		
Common stock, \$0.001 par value; 200,000,000 shares authorized; 83,421,780 and 83,022,414 shares				
issued and outstanding as of September 30, 2005 and December 31, 2004, respectively		83		83
Additional paid-in capital		818,103		817,150
Deferred stock-based compensation		(34)		(186)
Accumulated other comprehensive loss		(2,846)		(2,226)
Accumulated deficit		(811,791)		(736,304)

Total stockholders' equity	3,515	 78,517
Total liabilities and stockholders' equity	\$ 398,109	\$ 516,919

<sup>\*</sup> The condensed consolidated balance sheet at December 31, 2004 has been derived from the audited financial statements at that date.

(1) Includes investments in companies considered related parties under SFAS 57 of \$7.3 million and \$11.3 million at September 30, 2005 and December 31, 2004, respectively.

See accompanying notes.

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# INCYTE CORPORATION Condensed Consolidated Statements of Operations

(in thousands, except per share amounts) (unaudited)

		Three Months Ended September 30,			Nine Months Ended September 30,		
		2005		2004	2005	2004	
Revenues	\$	1,228	\$	2,332 \$	6,818 \$	11,821	
Costs and expenses:							
Research and development		27,356		17,648	71,676	67,210	
Selling, general and administrative		2,710		4,898	8,244	15,979	
Other expenses		299		(132)	1,088	42,538	
Total costs and expenses		30,365		22,414	81,008	125,727	
Loss from operations		(29,137)		(20,082)	(74,190)	(113,906)	
Interest and other income (expense), net (1)		2,656		(571)	10,228	1,403	
Interest expense		(3,810)		(4,623)	(12,257)	(13,011)	
Gain (loss) on repurchase of convertible subordinated notes		85		(226)	506	(226)	
Loss on certain derivative financial instruments, net		(1)		(216)	(89)	(470)	
Loss from continuing operations before income taxes		(30,207)		(25,718)	(75,802)	(126,210)	
Provision (benefit) for income taxes					(156)	182	
Loss from continuing operations	\$	(30,207)	\$	(25,718) \$	(75,646)\$	(126,392)	
Income (loss) from discontinued operation, net of tax		(3)		(258)	159	(899)	
Net loss	<u> </u>	(30,210)		(25,976)	(75,487)	(127,291)	
Basic and diluted net loss per share:							
Continuing operations	\$	(0.36)	\$	(0.35)\$	(0.91)\$	(1.73)	
Discontinued operations				· —		(0.01)	
	\$	(0.36)	\$	(0.35) \$	(0.91)	(1.74)	
Shares used in computing basic and diluted net loss per share		83,414		73,323	83,213	72,966	

<sup>(1)</sup> Includes a gain on sale of securities of \$2.8 million for the nine months ended September 30, 2005 and a loss on long-term investments in companies considered related parties under SFAS 57 of \$1.9 million for the nine months ended September 30, 2004.

See accompanying notes.

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### INCYTE CORPORATION

#### **Condensed Consolidated Statements of Comprehensive Loss**

(in thousands) (unaudited)

	Three Months I September 3		Nine Months E September 3	
	 2005	2004	2005	2004
Net loss	\$ (30,210) \$	(25,976) \$	(75,487) \$	(127,291)

Other comprehensive loss:

Unrealized losses on marketable securities	(159)	2,839	(612)	(686)
Foreign currency translation adjustments	 (4)	7	(8)	64
Other comprehensive loss	 (163)	2,846	(620)	(622)
Comprehensive loss	\$ (30,373) \$	(23,130) \$	(76,107) \$	(127,913)

See accompanying notes.

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# INCYTE CORPORATION Condensed Consolidated Statements of Cash Flows

(in thousands) (unaudited)

		Nine Months Ended September 30,		
		2005	2004	
Cash flows from operating activities:	<b>*</b>	(55.405) A	(127.221)	
Net loss	\$	(75,487) \$	(127,291)	
Adjustments to reconcile net loss to net cash used in operating activities:		(4.50)	000	
(Income) loss from discontinued operations		(159)	899	
Non-cash restructuring charges and impairment of long-lived assets		1,088	25,176	
Depreciation and amortization		6,516	10,573	
Compensation expense on executive loans		18	56	
Stock-based compensation		152	368	
Loss on derivative financial instruments, net		89	470	
Impairment of long-term investments		_	5,247	
Loss (gain) on repurchase of convertible subordinated notes		(506)	226	
Realized gain on long term investments		(2,791)	(123)	
Changes in operating assets and liabilities:				
Accounts receivable		1,097	3,557	
Prepaid expenses and other assets		1,812	5,034	
Accounts payable		2,051	(3,523)	
Accrued and other current liabilities		(6,486)	(4,280)	
Deferred revenue		(1,065)	(2,527)	
Net cash used in continuing operating activities		(73,671)	(86,138)	
Net cash used in discontinued activities		(182)	(1,040)	
Net cash used in operating activities		(73,853)	(87,178)	
Cash flows from investing activities:				
Capital expenditures		(1,179)	(705)	
Net proceeds from sale of Proteome facility and equipment		59	_	
Net proceeds from sale of equipment		_	1,491	
Purchases of marketable securities		(290,764)	(619,173)	
Proceeds from sale of long term investments			123	
Sales and maturities of marketable securities		317,647	546,509	
Investing activities of discontinued operation			(117)	
Net cash provided by (used in) investing activities		25,763	(71,872)	
Cash flows from financing activities:		<u> </u>		
Proceeds from issuance of common stock under stock plans		953	3,924	
Net proceeds from issuance of convertible subordinated notes		_	242,500	
Repurchase of convertible subordinated notes		(35,838)	(38,412)	
Net cash (used in) provided by financing activities		(34,885)	208,012	
Effect of exchange rate on cash and cash equivalents		(8)	64	
Net increase (decrease) in cash and cash equivalents	- <u>-</u> -	(82,983)	49,026	
Cash and cash equivalents at beginning of period		132.180	29,698	
Cash and cash equivalents at beginning of period  Cash and cash equivalents at end of period	\$	49,197 \$	78,724	
Cubit and Cubit equivalents at one of period	Φ	77,171 Ø	10,124	

See accompanying notes.

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# INCYTE CORPORATION NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2005

(Unaudited)

Incyte Corporation ("Incyte," "we," "us," or "our") is focused on the discovery and development of novel, small molecule drugs to treat major medical conditions, including infection with human immunodeficiency virus, or HIV, inflammatory disorders, cancer and diabetes. We have assembled a team of scientists with core competencies in the area of medicinal chemistry, and molecular, cellular and in vivo biology.

In January 2005, we sold certain assets and liabilities related to our Proteome facility based in Beverly, Massachusetts ("Proteome"). The condensed consolidated financial statements for the three months and nine months ended September 30, 2004 have been restated to present the operations of our Proteome facility as a discontinued operation.

#### 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, 2005, condensed consolidated statements of operations for the three and nine months ended September 30, 2005 and 2004, condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2005 and 2004 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2005 and 2004 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, 2004 has been derived from audited financial statements.

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

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2004.

#### Stock-based compensation

In accordance with the provisions of FASB Statement No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), we have elected to continue applying the provisions of APB Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25"), as amended by FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation ("FIN 44"), in accounting for our stock-based compensation plans. Accordingly, we do not recognize compensation expense for stock options granted to employees and directors when the stock option price at the grant date is equal to or greater than the fair market value of the stock at that date. We also record, and amortize over the related vesting periods, deferred compensation representing the difference between the price per share of stock issued or the exercise price of stock options granted and the fair value of our common stock at the time of issuance or grant.

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The fair value of each option and employee purchase right was estimated at the date of grant using a Black-Scholes option-pricing model, assuming no expected dividends and the following weighted average assumptions:

	Employee Stock Options			Employee Stock Purchase Plan				
	For the		For the	e	For the		For the	•
	Three		Nine		Three		Nine	
	Months		Month		Months		Month	
	Ended Ended					Ended		
		September 3	- /		September 30,			
	2005	2004	2005	2004	2005	2004	2005	2004
Average risk-free interest rates	3.98%	2.74%	3.93%	2.34%	3.95%	1.55%	3.95%	1.54%
Average expected life (in years)	3.43	2.44	3.28	3.28	.50	1.43	.50	1.15
Volatility	86%	88%	86%	89%	97%	90%	97%	90%

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of our employee stock options.

For purposes of disclosures pursuant to SFAS 123, as amended by FASB Statement No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure* ("SFAS 148"), the estimated fair value of options is amortized over the options' vesting period. The following illustrates the pro forma effect on net loss and net loss per share as if we had applied the fair value recognition provisions of SFAS 123.

		For the Three Months Ended September 30 ,		For the Nine Months September 30,		
		2005	2004	2005	2004	
	(in thousands, except per share amounts)					
Net loss, as reported	¢	(30,210) \$	(25,976) \$	(75,487)\$	(127,291)	
Add: Stock-based employee compensation	Ψ	51	121	152	416	
Deduct: Total stock-based employee compensation determined						
under the fair value-based method for all awards		(2,686)	(2,098)	(7,496)	(4,106)	

Pro forma net loss	\$ (32,845) \$	(27,953) \$	(82,831) \$	(130,981)
Net loss per share:				
Basic and diluted net loss per share-as reported	\$ (0.36) \$	(0.35)\$	(0.91)\$	(1.74)
Basic and diluted net loss per share-as SFAS 123 adjusted	\$ (0.39) \$	(0.38) \$	(1.00) \$	(1.80)

#### Recent Accounting Pronouncements

In November 2003, the Emerging Issues Task Force ("EITF") of the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, ("EITF 03-1"), which provides additional guidance for evaluating whether an investment is other-than-temporarily impaired and requires additional disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under FASB Statements No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and No. 124, *Accounting for Certain Investments Held by Not-for-Profit Organizations*. The guidance in EITF 03-1 for evaluating other-than-temporary impairments is effective for evaluations made in reporting periods beginning after June 15, 2004 and the disclosure requirements are effective in annual financial statements for fiscal years ending after December 15, 2003, for investments accounted for under FASB Statements 115 and 124. For all other investments within the scope of EITF 03-1, the disclosure requirements are effective in annual financial statements for fiscal years ending after June 15, 2004. The additional disclosures for cost method investments are effective for fiscal years ending after June 15, 2004. On September 30, 2004, the FASB issued Staff Position No. EITF Issue 03-1-1, under which the effective date for the measurement and recognition guidance of EITF 03-1 has been delayed pending further consideration of whether application

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guidance is necessary. We do not expect EITF 03-1 will have an impact on our financial position, results of operations, or cash flows.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" (SFAS No. 123R), which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim period after June 15, 2005, with early adoption encouraged. In April 2005, the Securities and Exchange Commission delayed the implementation date of SFAS No. 123R for calendar-year-end companies to January 1, 2006. Under SFAS No. 123R, the pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The permitted transition methods include either retrospective or prospective adoption. Under the retrospective option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options at the beginning of the first quarter of adoption of SFAS No. 123R, while the retrospective methods would record compensation expense for all unvested stock options beginning with the first period presented. We are currently evaluating the requirements of SFAS No. 123R and expect that adoption of SFAS No. 123R will have a material impact on our consolidated financial position and consolidated results of operations. We have not yet determined the method of adoption or the effect of adopting SFAS No. 123R, nor have we determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.

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

During the nine months ended September 30, 2005 we sold our investment in a publicly-held company accounted for under FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, for \$5.7 million, resulting in a realized gain of \$2.8 million. At September 30, 2005, the carrying value of our long-term investments consisted of equity investments in two privately-held companies accounted for under the cost method and the fair value of warrants to purchase common stock of one public company accounted for under FASB Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities*.

During the three and nine months ended September 30, 2004, we recorded impairment charges of \$2.5 million and \$5.2 million, respectively, to reduce the carrying value of our investments in three privately-held investees by \$2.5 million, \$1.9 million and \$0.8 million, respectively, because the investees had less than six months of cash and the likelihood of future debt or equity financing by the investees was remote. There were no such impairment charges during the three and nine months ended September 30, 2005.

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.

#### 4. Revenues

Revenues recognized from transactions in which there was originally a concurrent commitment entered into by us to purchase goods and services was \$0 for the three and nine months ended September 30, 2005 and \$0.0 million and \$1.5 million, respectively, for the corresponding periods in 2004. No new transactions in which there was a concurrent commitment by us to purchase goods or services were entered into during the nine months ended September 30, 2005

For the three and nine months ended September 30, 2005, four and eight customers, respectively, contributed 91% and 75%, respectively, of total revenues. For the three and nine months ended September 30, 2004, two and seven customers, respectively, contributed 27% and 36%, respectively, of total revenues.

Four customers comprised 79% of the accounts receivable balance at September 30, 2005. Three customers comprised 46% of the accounts receivable balance at December 31, 2004.

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 subordinated 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:

	Septembe	er 30,
	2005	2004
Outstanding stock options	7,941,497	6,746,632
Common shares issuable upon conversion of 3½% Notes	22,284,625	22,284,625
Common shares issuable upon conversion of 5.5% Notes	1,470,109	1,911,105
Total potential common shares excluded from diluted net loss per share computation	31,696,231	30,942,362

#### 6. 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, 2005, we recorded revenue from customers throughout the United States and in Canada, Switzerland, Germany, Japan, United Kingdom and Sweden. Sales to international customers for the three and nine months ended September 30, 2005 were \$0.4 million and \$2.7 million, respectively, and \$1.7 million and \$6.4 million, respectively, in the corresponding periods of 2004.

#### 7. Debt

During the nine months ended September 30, 2005, through various transactions, we repurchased \$36.5 million in face value of our 5.5% convertible subordinated notes due 2007 ("the 5.5% Notes") on the open market. One such transaction involved the repurchase, at a purchase price of 98.25% of face value, of \$5.0 million in face value of such notes from a limited partnership of which Julian C. Baker, a director of the Company, is a controlling member of the general partner of the general partner and may have a pecuniary interest. Mr. Baker did not participate in the Company's decision to engage in such a repurchase transaction. The price paid by the Company in such repurchase transaction was equal to the price paid by the Company to an independent third party in a comparable transaction negotiated on an arms'-length basis a short time prior to such repurchase transaction.

At September 30, 2005 the carrying value of our 3½% convertible subordinated notes due 2011 (the "3½% Notes") was \$250.0 million while the fair market value was approximately \$189.0 million. The carrying value of our 5.5% Notes approximated fair market value at September 30, 2005.

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#### 8. 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, 2005. 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

	inal Charge corded in 2004	Accrual Balance at December 31, 2004		2005 Charges to Operations		2005 Charges Utilized	Accrual Balance at September 30, 2005
Restructuring expenses:				(in thousands)			
C 1			_				
Workforce reduction	\$ 6,745	\$	2	\$ (2)	\$	_ 9	<u> </u>
Lease commitment and related							
costs	20,207		15,497	539		(2,004)	14,032
Other costs	671		_	227		(227)	_
Subtotal	27,623		15,499	 764		(2,231)	14,032
Impairment of tenant improvements, equipment and	11.272						
other items	11,363		_	_			
Impairment of gene and genomics-							
related patent costs	12,099		_	_			<u> </u>
Total other expenses	\$ 51,085	\$	15,499	\$ 764	\$	(2,231)	14,032

#### 2002 Restructuring

	Original Charge Recorded in 2002			Accrual Balance at December 31, 2004	2005 Charges to Operations	2005 Charges Utilized	Accrual Balance at September 30, 2005		
						(in thousands)			
Restructuring expenses:									
Workforce reduction	\$	7,325	\$	_	\$	_	\$ _	\$	_
Equipment and other assets		8,662		_		_	_		_
Lease commitments and other									
restructuring charges		17,924		16,155		170	(1,874)		14,451
Other expenses	¢	33 011	2	16 155	\$	170	\$ (1.874)	\$	14 451

#### Maxia Acquisition Costs

Below is a summary of activity related to accrued acquisition costs related to our 2003 acquisition of Maxia Pharmaceuticals, Inc. for the nine months ended September 30, 2005. The estimates below have been made based upon management's best estimate of the amounts and timing of certain events 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 this accrual at the point that the differences become determinable.

	Original Accrual		Accrual Balance at becember 31, 2004	2005 Additions			2005 Accrual Utilized	Accrual Balance at eptember 30, 2005
				(in	thousands)			
Accrued acquisition costs:								
Workforce reduction	\$ 845	\$	_	\$	_	\$	_	\$ _
Lease commitments and other restructuring fees	2,016		2,373		154		(440)	2,087
Transaction fees	1,450		_		_		_	_
Accrued acquisition costs	\$ 4,311	\$	2,373	\$	154	\$	(440)	\$ 2,087
		1	1					

#### 9. Litigation

#### Invitrogen

In October 2001, Invitrogen Corporation ("Invitrogen") filed an action against us in federal court, alleging infringement of three patents. The complaint seeks 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 are also seeking 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. On February 9, 2004, the Court 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.

We believe we have meritorious defenses and intend to defend the suit brought by Invitrogen vigorously if Invitrogen prevails on appeal and the stay is lifted. However, our defenses may be unsuccessful. At this time, we cannot reasonably estimate the possible range of any loss or damages resulting from these suits and counterclaims due to uncertainty regarding the ultimate outcome. In addition, if the case goes forward, we expect that the litigation will result in future costs to us, regardless of the outcome, which could be substantial.

#### Iconix Pharmaceuticals, Inc.

In May 2001, we entered into a Development and License Agreement with Iconix Pharmaceuticals, Inc. ("Iconix"). Pursuant to the terms of the Agreement, the parties agreed to collaborate on the development and commercialization of a chemical genomic database (the "Database"), currently called DrugMatrix. The Database was to be designed by Iconix to contain data, information and annotations related to gene expression, chemicals, pharmacology and toxicology, and related informatics tools and software. On November 10, 2003, Iconix filed a demand for arbitration against us. An arbitration panel was selected and hearings were scheduled in two phases to address the parties' claims and counterclaims. The first hearing was held in October 2004 and the second hearing was scheduled for the first quarter of 2005. In the first phase of the hearing, Iconix alleged that we were obligated to make payments to it in the aggregate amount of \$28.25 million and that the payments presently due to Iconix, discounted to a present day value, amount to \$22.6 million. On December 10, 2004 an award was issued in the first phase. The arbitration panel considered and denied all first phase claims and concluded that we are not obligated to make any payments related to such claims to Iconix. On January 14, 2005, the parties reached a written agreement to settle all remaining claims raised in the arbitration. The settlement agreement had no material impact on our financial position or results of operations.

In addition to the matters 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.

#### 10. Subsequent Event

In connection with the completion of its initial public offering, Genomic Health, Inc. ("Genomic Health") exercised an election under which we were required to acquire \$5.0 million of Genomic Health common stock on October 4, 2005. Our investment in Genomic Health will be accounted for as an available-forsale marketable security under FASB Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities".

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

The following discussion of our financial condition and results of operations 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, 2005 and our audited financial statements for the year-ended December 31, 2004 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; 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 licenses to products, compounds or technology, or other intellectual property rights; the receipt of or payments to collaborators resulting from milestones or royalties; difficulties resulting from the discontinuation of certain of our information product-related activities, including the amendment, termination or transition of customer contracts; expected expenses and expenditure levels; expected revenues and sources of revenues; expected losses; our profitability; the adequacy of our capital resources; the need to raise additional capital; the costs associated with resolving matters currently in litigation; our expectations regarding competition; our long-term investments, including anticipated expenditures, losses and expenses; costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights; the adequacy of our current facilities; 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 and contract research organizations; continuing trends with respect to reduced pharmaceutical and biotechnology research spending; risks relating to the development of new products and their use by us and our potential collaborators; 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 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; uncertainties relating to the continuing access and use of our Delaware headquarters; 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 "Factors That May Affect Results." 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 the section of this report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Results," all references to "Incyte," "we," "us," or "our" mean Incyte Corporation and our subsidiaries.

Incyte is our registered trademark. We also refer to trademarks of other corporations and organizations in this document.

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#### Overview

Incyte is focused on the discovery and development of novel, small molecule drugs to treat major medical conditions, including infection with human immunodeficiency virus, or HIV, inflammatory disorders, cancer and diabetes. We are using our expertise in medicinal chemistry, and molecular, cellular and in vivo biology to discover and develop novel drugs. Our most advanced product candidate, dexelvucitabine or DFC (formerly known as Reverset TM), is a nucleoside analog reverse transcriptase inhibitor, or NRTI, that is being developed as a once-a-day oral therapy for use in combination with other antiviral drugs for patients with HIV infections. DFC is currently in Phase IIb development to treat patients infected with HIV.

On September 27, 2005, we met with representatives from the Food and Drug Administration ("FDA") regarding the development of DFC. The purpose of the meeting was to discuss the results of a recently completed Phase IIb clinical trial, which were presented in July 2005 at the International AIDS Society meeting, and our plans to move DFC into two Phase III pivotal trials. At the meeting, the FDA did not approve of our moving into Phase III clinical trials. The agency requested that we conduct another Phase IIb clinical trial to provide additional data to support the efficacy and safety demonstrated in the original Phase IIb clinical trial. We expect this to result in a delay of 12 to 18 months in our DFC program.

In addition to our DFC development program, we have several internal drug discovery programs underway. The most advanced of these programs is focused on developing antagonists to a key chemokine receptor involved in inflammation called CCR2. The CCR2 lead candidate is currently in a Phase IIa clinical trial in patients with rheumatoid arthritis and in a Phase IIa clinical trial in obese insulin-resistant subjects. 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. Our next most-advanced internal program involves novel sheddase inhibitors that we believe may have application in the treatment of breast cancer and other tumor types. Based on results from single-dose-rising and multiple-dose-rising Phase I clinical trials of our sheddase inhibitor lead candidate in healthy volunteers, we have initiated a double-blind placebo-controlled Phase I/II dose-ranging clinical trial in cancer patients. We have also selected an oral CCR5 antagonist compound for clinical development. We expect to complete the IND for this compound and initiate a Phase I clinical trial in the first half of 2006. Earlier stage programs have generated other compounds with potential for applications in cancer, diabetes, inflammation and HIV.

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. We do not expect to generate revenues 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.

In January 2005 we sold certain assets and liabilities related to our Proteome facility in Beverly, Massachusetts. The condensed consolidated financial statements for the three and nine months ended September 30, 2004 have been restated to present the operations of our Proteome facility as a discontinued operation.

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

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making

judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our consolidated financial statements:

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

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**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. 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, based on 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.

When contracts include non-monetary payments, the value of the non-monetary transaction is determined using the fair value of the products and services involved, as applicable. For non-monetary payments involving the receipt of equity in a public entity, the fair value is based on the traded stock price on the date revenue is earned. For non-monetary payments involving the receipt of equity in a privately-held company, fair value is determined either based on a current or recent arm's length financing by the issuer or upon an independent valuation of the issuer.

In November 2002, the EITF issued EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"), which addresses certain aspects of the accounting for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. Under EITF 00-21, revenue arrangements with multiple deliverables should be divided into separate units of accounting if the deliverables meet certain criteria, including whether the delivered items have stand alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. In addition, the consideration should be allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria should be considered separately for each of the separate units of accounting. EITF 00-21 became effective for revenue arrangements we entered into after June 30, 2003.

**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 ("CRO's") 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 based on the percentage of completion. 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 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 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.

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 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 Maxia Pharmaceuticals, Inc. ("Maxia") acquisition 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 professional fees due to actual amounts being lower than originally estimated.

#### **Results of Operations**

We recorded 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 for the three and nine months ended September 30, 2005, respectively, as compared to a net loss of \$26.0 million and \$127.3 million and basic and diluted net loss per share of \$0.35 and \$1.74 per share in the corresponding periods in 2004.

**Revenues.** Our revenues for the three and nine months ended September 30, 2005 declined to \$1.2 million and \$6.8 million, respectively, from \$2.3 million and \$11.8 million for the three and nine months ended September 30, 2004. Revenues were derived exclusively from our information products, which include database subscriptions, licensing of our gene- and genomic-related intellectual property, and partner programs. The decline in revenues from 2004 to 2005 is attributable to the 2004 closure of our Palo Alto, California facility and the decision to discontinue offering information products. We expect that revenues generated from information products, including licensing of gene and gene-technology related intellectual property, will continue to decline as we focus on our drug discovery and development programs.

Revenues recognized from transactions in which there was originally a concurrent commitment entered into by us to purchase goods and services were \$0 for the three and nine months ended September 30, 2005 and \$0.0 million and \$1.5 million, respectively, for the corresponding periods in 2004. No new transactions in which there was a concurrent commitment by us to purchase goods for services were entered into during the nine months ended September 30, 2005.

Operating Expenses. Total costs and expenses for the three and nine months ended September 30, 2005 were \$30.4 million and \$81.0 million, respectively, compared to \$22.4 million and \$125.7 million for the corresponding periods in 2004. In conjunction with our restructuring programs, we recorded \$0.3 million and \$1.1 million, respectively, during the three and nine months ended September 30, 2005, compared to a \$0.1 million (gain) and \$42.5 million for the corresponding periods in 2004, which is included in other expense in the accompanying condensed consolidated statements of operations. These restructuring charges include charges related to the closure of our Palo Alto facilities, previously capitalized equipment, a workforce reduction and other items

Research and development expenses.

	For the three months September 30		For the nine m Septeml	
	2005	2004	2005	2004
	(in millions)		(in mil	lions)
Salary and benefits related	\$ 6.2 \$	4.4	\$ 18	.6 \$ 18.8
Collaboration and outside services	16.4	6.2	37	.4 22.5
Occupancy and all other costs	4.8	7.0	15	.7 25.9
Total research and development expenses	\$ 27.4	\$ 17.6	\$ 71	.7 \$ 67.2

We currently track research and development costs by natural expense line and not costs by project. These costs are exclusive of all charges related to the purchase of in-process research and development projects. For salary and benefits related costs, the increase from the three months ended September 30, 2005 was primarily the result of increased costs associated with our drug discovery and development initiatives. For collaboration and outside services, the increase from the three and nine months ended September 30, 2005 was primarily the result of increased drug discovery and development costs. For occupancy and all other costs, the decrease from the three months ended September 30, 2004 to the three months ended September 30, 2005 is a result of our previously announced restructuring programs.

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We expect that research and development expenditures related to drug discovery and development will increase during 2005 and subsequent years due to the continuation and expansion of clinical trials for our small molecule programs, the initiation of clinical trials for other potential indications and additional study expenditures for potential pharmaceutical candidates. 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. We expect there will be no further research and development expenditures related to our information business.

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.

	F	For the three months er September 30,	For the nine months ended, September 30,			
		2005	2005		2004	
	<u></u>	(in millions)				
Salary and benefits related	\$	1.7 \$	1.7	\$ 5	.1 \$	6.2
Other contract service and outside costs		1.0	3.2	3	.1	9.8
Total selling, general and administrative expenses	\$	2.7 \$	4.9	\$ 8	.2 \$	16.0

The decrease from the three and nine months ended September 30, 2004 to the three and nine months ended September 30, 2005 was primarily the result of expenses eliminated through the restructuring programs, reduced legal expenses related to patent infringement litigation, arbitration, prosecution and maintenance, and a reduction in outside services related to transitioning our corporate headquarters functions from Palo Alto to Delaware. Regardless of the

outcome, we expect our ongoing patent litigation to result in future costs to us, which could be substantial. We expect our total selling, general and administrative expenses to decline in 2005 due to the impact of our 2004 restructuring program.

Other expenses. Total other expenses for the three and nine months ended September 30, 2005 were \$0.3 million and \$1.1 million, respectively, compared to \$0.1 million (gain) and \$42.5 million, respectively, for the corresponding periods in 2004, and represent charges recorded in connection with previously announced restructuring programs. The three and nine months ended September 30, 2004 included charges recorded in connection with the shutdown of our Palo Alto operations.

Interest and Other Income (Expense), net. Interest and other income, net, for the three and nine months ended September 30, 2005 was \$2.7 million and \$10.2 million, respectively, compared to \$0.6 million (expense) and \$1.4 million, respectively, for the corresponding periods in 2004. The change is primarily attributable to \$2.8 million realized gain related to the sale of securities in the nine months ended September 30, 2005 and prior year impairment charges related to long term investments of \$5.2 million in the nine months ended September 30, 2004.

*Interest Expense.* Interest expense for the three and nine months ended September 30, 2005 was \$3.8 million and \$12.3 million, respectively, compared to \$4.6 million and \$13.0 million, respectively, for the corresponding periods in 2004. The decrease for the three and nine months ended September 30, 2005 is due to a lower average outstanding balance related to the 5.5% convertible subordinated notes due 2007 ("the 5.5% Notes"), of which a portion were repurchased in the nine months ended September 30, 2005.

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 \$0.5 million for nine months ended September 30, 2005 compared to \$0.2 million loss for the corresponding period in 2004.

Loss on Certain Derivative Financial Instruments, net. The loss on derivative financial instruments in the three and nine months ended September 30, 2005 and 2004 represent 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").

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**Provision for Income Taxes.** Due to our net loss in the three and nine months ended September 30, 2005 and in 2004, we have a minimal effective annual income tax rate.

*Income (Loss) From Discontinued Operations, net.* The income from discontinued operations of \$0.2 million for the nine months ended September 30, 2005 represents the gain on the disposal of our Proteome facility based in Beverly, Massachusetts, net of the loss from its operations through the January 17, 2005 disposal of the facility. The \$0.3 million and \$0.9 million losses, respectively, for the three and nine months ended September 30, 2004 represents only the loss from operations for Proteome.

### **Recent Accounting Pronouncements**

In November 2003, the Emerging Issues Task Force ("EITF") of the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* ("EITF 03-1"), which provides additional guidance for evaluating whether an investment is other-than-temporarily impaired and requires additional disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under FASB Statements No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and No. 124, *Accounting for Certain Investments Held by Not-for-Profit Organizations*. The guidance in EITF 03-1 for evaluating other-than-temporary impairments is effective for evaluations made in reporting periods beginning after June 15, 2004 and the disclosure requirements are effective in annual financial statements for fiscal years ending after December 15, 2003, for investments accounted for under FASB Statements 115 and 124. For all other investments within the scope of EITF 03-1, the disclosure requirements are effective in annual financial statements for fiscal years ending after June 15, 2004. On September 30, 2004, the FASB issued Staff Position No. EITF Issue 03-1-1, under which the effective date for the measurement and recognition guidance of EITF 03-1 has been delayed pending further consideration of whether application guidance is necessary. We do not expect EITF 03-1 will have an impact on our financial position, results of operations, or cash flows.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" (SFAS No. 123R), which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim period after June 15, 2005, with early adoption encouraged. In April 2005, the Securities and Exchange Commission delayed the implementation date of SFAS No. 123R for calendar-year-end companies to January 1, 2006. Under SFAS No. 123R, the pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The permitted transition methods include either retrospective or prospective adoption. Under the retrospective option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options at the beginning of the first quarter of adoption of SFAS No. 123R, while the retrospective methods would record compensation expense for all unvested stock options beginning with the first period presented. We are currently evaluating the requirements of SFAS No. 123R and expect that adoption of SFAS No. 123R will have a material impact on our consolidated financial position and consolidated results of operations. We have not yet determined the method of adoption or the effect of adopting SFAS No. 123R, nor have we determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123. See Stock-Based Compensation in Note 2 to the condensed consolidated financial statements.

#### **Liquidity and Capital Resources**

As of September 30, 2005, we had \$364.0 million in cash, cash equivalents and marketable securities, compared with \$469.8 million as of December 31, 2004. 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. We have classified all of our marketable securities as short-term, as we may choose not to hold our marketable securities until maturity. 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 \$73.9 million and \$87.2 million for the nine months ended September 30, 2005 and 2004, respectively. The \$13.3 million decrease was due primarily to a \$0.9 million increase in cash used to fund operating expenses and a \$17.4 million decline in cash used for

restructuring activities. These items were partially offset by a \$6.0 million decrease in cash received from customer sales and changes in tax expense, interest income, interest expense, other income, and discontinued operations of \$2.8 million.

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 used in investing activities of \$25.8 million for the nine months ended September 30, 2005 represented primarily purchases of marketable securities of \$290.8 million, offset by sales

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and maturities of marketable securities of \$317.6 million. Sales and maturities of marketable securities include \$5.7 million of proceeds from the sale of our investment in a publicly-held company. 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 used in financing activities was \$34.9 million and provided by financing activities was \$208.0 million for the nine months ended September 30, 2005 and 2004, respectively. During the first quarter of 2004, we issued a total of \$250.0 million of the 3½% convertible subordinated notes due 2011 ("the 3½% Notes"), which resulted in net proceeds of approximately \$242.5 million. During 2005, we paid \$35.8 million in connection with repurchases of our 5.5% Notes, offset partially by \$0.9 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, 2005 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in millions):

	 Total	Less Than 1 Year		Years 1—3	Years 4—5	Over Years
Contractual Obligations		(	(in m	illions)		
Contractual Obligations:						
Principal on convertible subordinated debt	\$ 341.6	\$ _	\$	91.6	\$ _	\$ 250.0
Interest on convertible subordinated debt	55.7	13.8		20.0	17.5	4.4
Non-cancelable operating lease obligations:						
Related to current operations	12.6	4.4		8.2	_	_
Related to vacated space	43.8	8.0		16.5	16.1	3.2
Total contractual obligations	\$ 453.7	\$ 26.2	\$	136.3	\$ 33.6	\$ 257.6

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 \$2.5 million (less than 1 year), \$3.8 million (years 1-3), \$3.3 million (years 4-5), and \$0.8 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.

In connection with the completion of its initial public offering, Genomic Health, Inc. ("Genomic Health") exercised an election under which we were required to acquire \$5.0 million of Genomic Health common stock on October 4, 2005. Our investment in Genomic Health will be accounted for as an available-forsale marketable security under FASB Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities".

Additional commitments related to Maxia and Pharmasset, Inc. ("Pharmasset") are also considered contingent commitments as future events must occur to cause these commitments to be enforceable. In February 2003, we completed our acquisition of Maxia. Under the merger agreement, former Maxia stockholders have the right to receive certain earn-out amounts of up to a potential aggregate amount of \$14.0 million upon the occurrence of certain research and development milestones set forth in the merger agreement. Twenty percent of each earn out payment, if earned, will be paid in cash and the remaining eighty percent will be paid in shares of our common stock such that an aggregate of \$2.8 million in cash and \$11.2 million in our common stock (based upon the then fair value) could potentially be paid pursuant to the earn out milestones. The milestones are set to occur as Maxia products enter various stages of human clinical trials and may be earned at any time prior to the tenth anniversary of the consummation of the merger. In any event, no more than 13,531,138 shares of our common stock may be issued to former Maxia stockholders in the aggregate pursuant to the merger agreement. None of these milestones have been achieved as of September 30, 2005.

Under the terms of our collaborative licensing agreement with Pharmasset, we agreed to pay Pharmasset certain future performance milestone payments and future royalties on net sales.

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.

2.0

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 5.5% Notes and 3½% Notes; 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 2005, 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.

#### FACTORS THAT MAY AFFECT RESULTS

#### 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.

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, DFC, our lead CCR2 antagonist, and our lead sheddase inhibitor in Phase IIb, Phase IIa, and Phase I/II clinical trials, respectively. Our other internal drug discovery programs are focused on compounds with potential for applications in HIV, diabetes and cancer. 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.

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The success of our drug discovery and development efforts may depend on our ability to find suitable collaborators to fully exploit our capabilities. If we are unable to establish collaborations or if these future collaborations are unsuccessful, 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 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 in order to obtain regulatory approvals and formulation, marketing and manufacturing capabilities. As a result of these resources, our competitors may develop drug products that render our products obsolete or noncompetitive by developing more effective drugs or by developing their products more efficiently. Our ability to develop competitive products would be limited if our competitors succeeded in obtaining regulatory approvals for drug candidates more rapidly than we were able to or in obtaining patent protection or other intellectual property rights that limited our drug development efforts. Any drugs resulting from our research and development efforts, or from our joint efforts with collaborators or licensees, might not be able to compete successfully with our competitors' existing and future products, or obtain regulatory approval in the United States or elsewhere.

#### Our ability to develop and commercialize DFC may be adversely affected if a dispute arose with Pharmasset.

We are developing DFC under a collaborative licensing agreement with Pharmasset entered into in September 2003. If a dispute arose with Pharmasset over the terms of the collaborative license agreement, including the alleged breach of any provision, our development, commercialization and marketing of DFC may be adversely affected.

If conflicts arise between our collaborators, 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 Pharmasset, 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

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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 in-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. 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 CROs to perform preclinical testing and clinical trials for drug candidates that we choose to develop without a collaborator. 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 clinical 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 whether the FDA will allow us to undertake clinical trials of any potential drug products in addition to DFC, our lead compound from our CCR2 antagonist program and our lead sheddase inhibitor compound.

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

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- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- poor or unanticipated effectiveness of products during the clinical trials;
- government or regulatory agencies may reach different conclusions as to clinical trial designs or results; 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. In September 2005, the FDA requested that we conduct another Phase IIb clinical trial for DFC to support the efficacy and safety demonstrated in the original Phase IIb clinical trial. We expect this to result in a delay of 12 to 18 months in our DFC program.

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, DFC, our lead CCR2 antagonist, and our lead sheddase inhibitor in Phase IIb, Phase IIa, and Phase I/II clinical trials, respectively. Our other drug candidates are still undergoing preclinical testing. 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 the manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. Also, raw materials that may be required to manufacture any products we develop may only be available from a limited number of suppliers. If we have promised delivery of a new product and are unable to meet the delivery requirement due to manufacturing difficulties, our development programs would be delayed, and we may have to expend additional sums in order to ensure that manufacturing capacity is available when we need it even if we do not use all of the manufacturing capacity. This expense would adversely affect our operating results. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. 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.

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

We do not have experience marketing drug products. If the FDA approves one of our drug products to go to market, 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.

DFC, our lead CCR2 antagonist and our lead sheddase inhibitor are our only three drug candidates in clinical trials. 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. 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 DFC, or another 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. Actions of governmental authorities and other groups could result in lower prices for certain drugs, including drugs that address HIV infection. 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 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.

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#### 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 victims and legal costs, or we may be required to limit commercialization of our products. Although we currently carry a product liability insurance policy that provides coverage for liabilities arising from our clinical trials, it 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.

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#### 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 the quarter ended September 30, 2005. Because of those losses, we had an accumulated deficit of \$811.8 million as of September 30, 2005. 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 2005 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 commercialize 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 DFC, our leading drug candidate, or another drug, 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 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 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.

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

#### Our long-term investments may decline in value and our losses may increase.

We have made and may in the future make long-term 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 volatility of the equity markets and the uncertainty of the biotechnology industry may result in fluctuations in the value of our investments in public companies. 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. As of September 30, 2005, the total aggregate value of our long-term investments was \$7.3 million.

# 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, 2005, we had total consolidated debt of \$341.9 million and stockholders' equity of \$3.5 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

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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 subordinated notes. As of September 30, 2005, \$91.6 million aggregate principal amount of our 5.5% convertible subordinated notes due 2007 were outstanding. Our annual interest payments for the 5.5% notes through 2006, assuming none of these notes are converted, redeemed, repurchased or exchanged, are \$5.0 million, and an additional \$2.5 million in interest is payable in 2007. As of September 30, 2005, \$250.0 million aggregate principal amount of our 3 ½% convertible subordinated notes due 2011 were outstanding. Our annual interest payments for the 3 ½% 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. We intend to fulfill our debt service obligations from our existing cash and marketable securities. 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

We are involved in patent litigation, which, if not resolved favorably, could require us to pay damages.

In October 2001, Invitrogen Corporation, or Invitrogen, filed an action against us in federal court, alleging infringement of three patents. The complaint seeks 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 are also seeking 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. On February 9, 2004, the Court 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.

Our defenses against the suit brought by Invitrogen may be unsuccessful. At this time, we cannot reasonably estimate the possible range of any loss or damages resulting from this suit due to uncertainty regarding the ultimate outcome. If the case goes forward, we expect that the Invitrogen litigation will result in future legal and other costs to us, regardless of the outcome, which could be substantial.

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

The technology that we use to make and develop our drug products, the technology that we incorporate in our products, and the products we are developing may be subject to claims that they infringe the patents or proprietary rights of others. The success of our drug discovery and development efforts will also depend on our ability to develop new compounds, drugs and technologies without infringing or misappropriating the proprietary rights of others.

From time to time we may receive notices from third parties 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. Except for Invitrogen, 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. 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.

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 inlicensed to us, the protection of the intellectual property rights may not be in our hands. In the case of DFC, we do not control the intellectual property rights in-licensed to us with respect to the compound and therefore may be unable to protect those rights. If the entity that controls the intellectual property rights related to DFC does not adequately protect those rights, our rights may be impaired, which may impact our ability to develop, market and commercialize DFC

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

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

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

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

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

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

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

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#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to interest rate risk primarily through our investments in short-term marketable securities. Our investment policy calls for investment in short term, low risk, investment-grade instruments. As of September 30, 2005, cash, cash equivalents and marketable securities were \$364.0 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, 2005, the decline in fair value would not be material.

We are exposed to valuation risks related to our portfolio of long-term investments. These investments are primarily in small capitalization stocks of privately-held companies in the pharmaceutical/biotechnology industry sector and are primarily in companies with which we have or had research and development, licensing or other collaborative agreements. As of September 30, 2005, long-term investments were \$7.3 million.

In connection with the completion of its initial public offering, Genomic Health, Inc. ("Genomic Health") exercised an election under which we were required to acquire \$5.0 million of Genomic Health common stock on October 4, 2005. Our investment in Genomic Health will be accounted for as an available-forsale marketable security under FASB Statement No. 115, "Accounting for Certain Investments in Debt and Equity Securities".

#### **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, and management believes that they meet, reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, management, with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, subject to the limitations noted above, our disclosure controls and procedures were effective to ensure that material information relating to us, including our consolidated subsidiaries, is made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

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) identified in connection with the evaluation described above in Item 4 that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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#### PART II: OTHER INFORMATION

#### Item 1. Legal Proceedings

#### **Invitrogen Corporation**

In October 2001, Invitrogen Corporation ("Invitrogen") filed an action against us in federal court, alleging infringement of three patents. The complaint seeks 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 are also seeking 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. On February 9, 2004, the Court 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.

Our defenses against the suit brought by Invitrogen may be unsuccessful. At this time, we cannot reasonably estimate the possible range of any loss or damages resulting from this suit due to uncertainty regarding the ultimate outcome. If the case goes forward, we expect that the Invitrogen litigation will result in future legal and other costs to us, regardless of the outcome, which could be substantial.

#### Iconix Pharmaceuticals, Inc.

In May 2001, we entered into a Development and License Agreement with Iconix Pharmaceuticals, Inc. ("Iconix"). Pursuant to the terms of the Agreement, the parties agreed to collaborate on the development and commercialization of a chemical genomic database (the "Database"), currently called DrugMatrix. The Database was to be designed by Iconix to contain data, information and annotations related to gene expression, chemicals, pharmacology and toxicology, and related informatics tools and software. On November 10, 2003, Iconix filed a demand for arbitration against us. An arbitration panel was selected and hearings were scheduled in two phases to address the parties' claims and counterclaims. The first hearing was held in October 2004 and the second hearing was scheduled for the first quarter of 2005. In the first phase of the hearing, Iconix alleged that we were obligated to make payments to it in the aggregate amount of \$28.25 million and that the payments presently due to Iconix, discounted to a present day value, amount to \$22.6 million. On December 10, 2004 an award was issued in the first phase. The arbitration panel considered and denied all first phase claims and concluded that we are not obligated to make any payments related to such claims to Iconix. On January 14, 2005, the parties reached a written agreement to settle all remaining claims raised in the arbitration. The settlement agreement had no material impact on our financial position or results of operations.

In addition to the matters 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.

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#### Item 6. Exhibits

Exhibit Number	Description of Document						
31.1	Rule 13a — 14(a) Certification of Chief Executive Officer						
31.2	Rule 13a — 14(a) Certification of Chief Financial Officer						
32.1*	Statement of the Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C Section 1350)						
32.2*	Statement of the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)						

<sup>\*</sup> 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.

Dated:	November 1, 2005	By:	/s/ PAUL A. FRIEDMAN PAUL A. FRIEDMAN Chief Executive Officer (Principal Executive Officer)
Dated:	November 1, 2005	By:	/s/ DAVID C. HASTINGS  DAVID C. HASTINGS  Chief Financial Officer (Principal Financial Officer)

#### INCYTE CORPORATION

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#### EXHIBIT INDEX

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#### CERTIFICATION

#### I, Paul A. Friedman, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Incyte Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or cause such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2005

/S/ PAUL A. FRIEDMAN PAUL A. FRIEDMAN

Chief Executive Officer

#### CERTIFICATION

#### I, David C. Hastings, certify that:

- 1. I have reviewed this quarterly report on Form 10-O of Incyte Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or cause such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial data; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2005

/S/ DAVID C. HASTINGS DAVID C. HASTINGS

Chief Financial Officer

#### STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

With reference to the Quarterly Report of Incyte Corporation ("Incyte") on Form 10-Q for the quarter ended September 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul A. Friedman, Chief Executive Officer of Incyte, certify, for the purposes of 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Incyte.

/S/ PAUL A. FRIEDMAN
PAUL A. FRIEDMAN
Chief Executive Officer

November 1, 2005

#### STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

With reference to the Quarterly Report of Incyte Corporation ("Incyte") on Form 10-Q for the quarter ended September 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David C. Hastings, Chief Financial Officer of Incyte, certify, for the purposes of 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Incyte.

/S/ DAVID C. HASTINGS

DAVID C. HASTINGS

Chief Financial Officer

November 1, 2005