MEDAREX INC
Form 10-Q
November 13, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2003

OR

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

For the transition period from _____ to _____ .

Commission File No. 0-19312

MEDAREX, INC.

(Exact Name of Registrant as Specified in Its Charter.)

New Jersey	22-2822175
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
707 State Road, Princeton, New Jersey	**08540**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s Telephone Number, Including Area Code: (609) 430-2880

Indicate by check x whether registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

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

Yes x No ¨

The number of shares of common stock, $.01 par value, outstanding as of October 31, 2003 was 78,809,708 shares.

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31, 2002	September 30, 2003
		(Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,812	$ 122,817
Marketable securities	288,234	259,020
Segregated cash		5,603
Prepaid expenses and other current assets	10,143	7,496
Total current assets	360,189	394,936
Property, buildings and equipment:		
Land	6,624	6,624
Buildings and leasehold improvements	71,277	74,342
Machinery and equipment	31,821	35,297
Furniture and fixtures	3,963	4,041
Construction in progress	2,148	3,825
	115,833	124,129
Less accumulated depreciation and amortization	(18,522)	(28,237)
	97,311	95,892
Investments in Genmab	21,206	13,987
Investments in IDM	48,199	48,199
Investments in, and advances to, other affiliates and partners	11,982	12,582
Segregated cash	1,300	11,535
Other assets	8,864	10,753
Total assets	$ 549,051	$ 587,884
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Trade accounts payable	$ 2,686	$ 1,700
Accrued liabilities	15,377	13,440
Deferred contract revenue current	2,646	3,967
Total current liabilities	20,709	19,107
Deferred contract revenue long-term	1,152	714
Other long-term obligations	47	2,452
Convertible senior notes		125,000
Convertible subordinated notes	175,000	175,000
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $1.00 par value, 2,000,000 shares authorized; none issued and outstanding		
Common stock, $.01 par value; 200,000,000 shares authorized; 77,725,376 shares issued and 76,929,984 outstanding at December 31, 2002 and 78,466,141 shares issued and 77,897,156 shares outstanding at September 30, 2003	777	785
Capital in excess of par value	630,279	633,064

Treasury stock, at cost 795,392 shares in 2002 and 568,985 shares in 2003	(2,001)	(1,431)
Deferred compensation	1,311	1,127
Accumulated other comprehensive income	5,380	7,687
Accumulated deficit	(283,603)	(375,621)
Total shareholders' equity	352,143	265,611
Total liabilities and shareholders' equity	$ 549,051	$ 587,884

See notes to these unaudited consolidated financial statements.

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2003	2002	2003
Sales	$	$	$ 176	$ 25
Contract and license revenues	7,640	943	22,020	4,593
Sales, contract and license revenues from Genmab (includes sales of $6,555 and $9,363 to Genmab in 2002)	6,989	1,317	11,288	3,857
Total revenues	14,629	2,260	33,484	8,475
Costs and expenses:				
Cost of sales ($3,923 and $5,678 from sales to Genmab in 2002)	3,923		5,729	3
Research and development	20,902	24,742	56,517	72,018
General and administrative	5,826	5,322	17,022	16,204
Write-off of facility costs	28		11,294	
Acquisition of in-process technology			16,312	
Total costs and expenses	30,679	30,064	106,874	88,225
Operating loss	(16,050)	(27,804)	(73,390)	(79,750)
Equity in net loss of affiliate	(35,024)	(4,652)	(42,289)	(11,593)
Interest and dividend income	4,593	2,584	14,290	8,299
Impairment loss on investments in partners	(3,880)		(7,971)	
Additional payments related to asset acquisition	(1,419)		(1,700)	(86)
Interest expense	(2,263)	(3,395)	(6,790)	(8,013)
Pre tax loss	(54,043)	(33,267)	(117,850)	(91,143)
Provision for income taxes	75	3	75	45
Loss before cumulative effect of change in accounting principle	(54,118)	(33,270)	(117,925)	(91,188)
Cumulative effect of change in accounting principle				(830)
Net loss	$ (54,118)	$ (33,270)	$ (117,925)	$ (92,018)
Basic and diluted net loss per share:				
Loss before cumulative effect of change in accounting principle	($ 0.72)	($ 0.43)	($ 1.58)	($ 1.17)
Cumulative effect of change in accounting principle				(0.01)
Net loss	($ 0.72)	($ 0.43)	($ 1.58)	($ 1.18)
Weighted average number of common shares outstanding basic and diluted	75,491	78,088	74,612	78,046

See notes to these unaudited consolidated financial statements.

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	For the Nine Months Ended September 30,	
	2002	**2003**
Operating activities:		
Net loss	$ (117,925)	$ (92,018)
Adjustments to reconcile net loss to net cash used in operating activities:		
Cumulative effect of change in accounting principle		830
Depreciation	5,299	7,811
Amortization	2,062	2,560
Stock options and awards to employees	456	718
Stock options and warrants to non-employees	(8)	
Non cash revenue IDM	(14,332)	
Non cash revenue Genmab		(333)
Write-off of facility costs	11,294	
Write-off of in-process technology	14,157	
Equity in net loss of Genmab	11,318	11,593
Impairment loss on investment in Genmab	30,971	
Impairment loss on investments	7,971	
Gain on exchange of Eos Stock		(393)
Changes in operating assets and liabilities		
Other current assets	386	3,414
Trade accounts payable	108	(986)
Accrued liabilities	(5,376)	(876)
Deferred contract revenue	(2,373)	(782)
Net cash used in operating activities	(55,992)	(68,462)
Investing activities:		
Purchase of property and equipment	(32,412)	(6,170)
Proceeds from sale of equipment	640	
Decrease in other assets	1	
Increase in investments and advances to affiliates and partners		(1,000)
Increase in segregated cash	(600)	(15,838)
Purchase of marketable securities	(2,500)	(121,260)
Sales of marketable securities	128,473	151,299
Net cash provided by investing activities	93,602	7,031
Financing activities:		
Cash received from sales of securities, net	198	1,461
Proceeds received from senior convertible notes, net		121,260
Principal payments under debt obligations		(285)
Net cash provided by financing activities	198	122,436
Net increase in cash and cash equivalents	37,808	61,005

Cash and cash equivalents at beginning of period	31,269	61,812
Cash and cash equivalents at end of period	$ 69,077	$ 122,817
Non-cash investing and financing activities:		
Issuance of common stock for intangible assets	$ 5,094	$
Supplemental disclosures of cash flow information		
Cash paid during period for:		
Interest	$ 7,985	$ 7,900

See notes to these unaudited consolidated financial statements.

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(Dollars in thousands, unless otherwise indicated, except per share data)

1. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared from the books and records of Medarex, Inc. and Subsidiaries (the Company) 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. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Interim results are not necessarily indicative of the results that may be expected for the year. The balance sheet at December 31, 2002 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required for complete financial statements. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2002.

Net Loss per Share

Basic and diluted net loss per share are calculated in accordance with the Financial Accounting Standards Board (FASB) SFAS No. 128, *Earnings per Share*. Basic net loss per share is based upon the number of weighted average shares of common stock outstanding. Diluted net loss per share is based upon the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding. Potential shares of common stock result from the assumed exercise of outstanding stock options, which are included under the treasury stock method. For the three and nine month periods ended September 30, 2002 and 2003, all potentially dilutive securities have been excluded from the computation of diluted net loss per share, as their effect is antidilutive.

Marketable Securities

Marketable securities consist of fixed income investments with a maturity of greater than three months and other highly liquid investments that can be readily purchased or sold using established markets. Under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, these investments are classified as available-for-sale and are reported at fair value on the Company s consolidated balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive income as a separate component of shareholders equity. Under the Company s accounting policy, a decline in the fair value of marketable securities is deemed to be other than temporary and such marketable securities are generally considered to be impaired if their fair value is less than the Company s cost basis for more than six months, or some other period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of a marketable security below the Company s cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value and the amount of the write-down is included in earnings as an impairment charge.

In addition, the Company has investments in several of its partners whose securities are not publicly traded. Because these securities are not publicly traded, the Company values these investments by using information acquired from industry trends, the management of these companies, financial statements, and several other external sources. Based on the information acquired through these sources, the Company records

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

an investment impairment charge when it believes an investment has experienced a decline in value that is considered to be other than temporary.

Stock Based Compensation

The Company accounts for its stock option plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees,* and related Interpretations. No stock-based employee compensation cost is reflected in net loss, as all options granted under the Company s stock option plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	Three Months Ended September 30		Nine Months Ended September 30	
	2002	2003	2002	2003
Net loss, as reported	$ (54,118)	$ (33,270)	$ (117,925)	$ (92,018)
Add: Total stock-based employee compensation expense determined under fair value method	(717)	(2,703)	(2,153)	(7,452)
Pro forma net loss	$ (54,835)	$ (35,973)	$ (120,078)	$ (99,470)
Loss per share:				
Basic and diluted, as reported	$ (0.72)	$ (0.43)	$ (1.58)	$ (1.18)
Basic and diluted, pro forma	$ (0.73)	$ (0.46)	$ (1.61)	$ (1.27)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30		Nine Months Ended September 30	
	2002	2003	2002	2003

Expected stock price volatility	120.1%	76.7%	120.1%	76.7%
Risk-free interest rate	4.0%	3.5%	4.0%	3.5%
Expected life of options	5 years	5 years	5 years	5 years
Expected dividend yield	0%	0%	0%	0%

Recently Issued Accounting Pronouncements

In November 2002, the FASB issued Interpretation No. 45 (or FIN 45), *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual values guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and initial measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 31, 2002. Adoption of FIN 45 did not have a material impact on the Company s results of operations or financial position.

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In January 2003, the FASB issued Interpretation No. 46 (or FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 requires a variable interest entity to be consolidated by a company if that company absorbs a majority of the entity s expected losses, receives a majority of the entity s expected residual returns, or both, as a result of ownership, contractual or other financial interests in the entity. Currently, entities are generally consolidated by a company when it has controlling financial interest through ownership of a majority voting interest in the entity. The Company will adopt FIN 46 in the quarter ended December 31, 2003. The Company is in the process of evaluating the impact of FIN 46 on its non-consolidated entities.

2. Investments in Genmab

As a result of a series of transactions, including an initial public offering by Genmab A/S, a Danish biotechnology company (Genmab), of its ordinary shares in October 2000, the Company owned approximately 32.6% interest in Genmab as of December 31, 2001. In June 2002, the Company s ownership percentage was reduced to approximately 31.2% as a result of the issuance by Genmab of new shares to a corporate partner in connection with an antibody collaboration.

In September 2002, Genmab issued a press release in which it announced that its HuMax-CD4 product, a fully human antibody that targets the CD4 receptor on cells known as T-cells, was found not to be effective in combination with methotrexate in a Phase II study of 155 patients with active rheumatoid arthritis. Following Genmab s September 2002 press release, the market value of Genmab s stock decreased by approximately 60%, and accordingly, the Company recorded an impairment charge of approximately $31.0 million in the third quarter of 2002. If the Company deems this investment to be further impaired at the end of any future period, the Company may incur an additional impairment charge on this investment.

In July 2003, the Company received 246,914 shares of Genmab stock valued at $2.0 million representing payment for the fourth of five annual payments under an August 2000 binding memorandum of understanding between the Company and Genmab. The Company s ownership percentage in Genmab increased to approximately 32.0% as a result of the receipt of the 246,914 shares of Genmab stock.

During the three and nine month periods ended September 30, 2002, the value of the Company s investment in Genmab was adjusted to reflect the Company s share of Genmab s net loss ($4.0 million) and ($11.3 million), respectively, and an unrealized loss of $0.7 million and an unrealized gain of $6.8 million, respectively, related to foreign exchange translation. During the three and nine month periods ended September 30, 2003, the value of the Company s investment in Genmab was further adjusted to reflect the Company s share of Genmab s net loss ($4.7 million) and ($11.6 million), respectively, and an unrealized loss of $14 thousand and an unrealized gain of $2.4 million, respectively, related to foreign exchange translation. Such foreign exchange translation adjustments are included within accumulated other comprehensive income in the Company s consolidated balance sheets. The Company s share of Genmab s net loss for the nine month period ended September 30, 2003, reflects a reconciliation of revenue recognition between the accounting principles generally accepted in the United States used by the Company and the international financial reporting standards used by Genmab in its published financial results. The net loss reported by the Company for the nine month period ended September 30, 2003 is greater than would have been reported if the Company had used the same reporting standards as Genmab.

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Summary financial information for Genmab is as follows:

	As of and for the Nine Months Ended September 30	
	2002	**2003**
Current assets	$ 199,320	$ 186,193
Non current assets	26,788	20,652
Current liabilities	11,969	13,228
Non current liabilities	1,802	2,104
Revenue		500
Gross profit		500
Net loss	(35,400)	(36,972)

3. Convertible Senior Notes

On July 23, 2003, the Company completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended, of $125 million of 4.25% Convertible Senior Notes due August 15, 2010 to qualified institutional investors. The notes are initially convertible into shares of the Company s common stock at the rate of 148.8261 per each $1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately $6.72 per share, subject to anti-dilution adjustments.

The Company will pay interest on these notes on February 15 and August 15 of each year beginning on February 15, 2004. The Company received net proceeds from the private placement of approximately $121.3 million (after deducting the initial purchasers discounts and offering expenses). Approximately $15.8 million of the net proceeds have been used to purchase U.S. Treasury security strips to collateralize the notes in an amount sufficient to pay the initial six interest payments on the notes. Such amount has been classified as segregated cash in the Company s September 30, 2003 consolidated balance sheet and is comprised of the current portion of approximately $5.6 million and the non-current portion of approximately $10.2 million.

Prior to August 15, 2006, the Company may redeem some or all of the notes at any time at a redemption price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest to the redemption date and the make-whole payment described below, if the closing price of the Company s common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days ending on the trading day before the date of mailing of the provisional redemption notice. Upon any such provisional redemption, the Company will make an additional make-whole payment equal to $130.10 per $1,000 principal amount of notes redeemed, less the amount of any interest actually paid and any interest accrued and unpaid on these notes before the provisional redemption date. The Company may make such additional payment, at its option, in cash or shares or a combination thereof. Payments made in shares of the Company s common stock will be valued at 95% of the average of the closing sale prices of the Company s common stock for the five consecutive trading days ending on the third trading day immediately prior to the provisional redemption date. Noteholders have the option, subject to certain conditions, to require the Company to repurchase the notes in the event of a change in control at a price equal to 100% of the principal amount of the notes plus accrued and unpaid interest to the date of repurchase.

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MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Contingencies

The Company has a contingent commitment to pay $1.0 million to Essex Chemical Corporation (Essex) without interest in installments equal to 20% of net after tax earnings of the Company in future years. The Company s contingent commitment, as amended, to pay up to $1.0 million out of future earnings may be satisfied, at the Company s option, through the payment of cash or shares of the Company s common stock having a fair market value equal to the amount owed, provided that such shares are registered with the Securities and Exchange Commission. The Company accrued $0.7 million related to this liability during 2000, and such amount remains accrued at September 30, 2003.

In May 2002, the Company entered into an Asset Purchase Agreement with Corixa Corporation, Coulter Pharmaceutical, Inc., a wholly owned subsidiary of Corixa Corporation, and Corixa Belgium S.A., a subsidiary of Corixa Corporation (collectively referred to as Corixa). Under the terms of the Asset Purchase Agreement, the Company acquired certain selected assets and business operations of Corixa, including certain preclinical product candidates and programs related to the research and development of therapeutic products for the treatment of autoimmune diseases, cancer and infectious diseases, for $21.0 million (excluding transaction costs of $0.4 million). As part of this transaction, Corixa had the right to receive up to an additional $6.0 million in future consideration in cash or, at the Company s election, in shares of common stock, based upon certain contingencies, including the renegotiation of an existing license agreement with respect to the Ultra-Potent Toxin technology originally between Kyowa Hakko Kogyo Co., Ltd., or Kyowa, and Corixa, which license agreement the Company acquired as part of the Asset Purchase Agreement with Corixa. See Note 9 Subsequent Events.

In the ordinary course of business, the Company is at times subject to various legal proceedings. The Company does not believe that any of its current legal proceedings, individually or in the aggregate, will have a material adverse effect on its operations or financial condition.

5. Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes changes in the fair value of the Company s marketable securities and the foreign exchange translation of the Company s equity position in Genmab. The following table sets forth the components of comprehensive income (loss):

	Three Months Ended September 30		Nine Months Ended September 30	
	2002	2003	2002	2003
Net loss	$ (54,118)	$ (33,270)	$ (117,925)	$ (92,018)
Unrealized gain (loss) on securities	590	(873)	(1,138)	(67)
Unrealized gain (loss) on foreign exchange	(697)	(14)	6,783	2,375
Total comprehensive loss	$ (54,225)	$ (34,157)	$ (112,280)	$ (89,710)

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MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Segment Information

The Company is an integrated monoclonal antibody-based company with antibody discovery, development and manufacturing capabilities. The operations of the Company and its wholly owned subsidiaries constitute one business segment.

Revenue from customers representing 10% or more of total revenues is as follows:

	Three Months Ended September 30		Nine Months Ended September 30	
Customer	**2002**	**2003**	**2002**	**2003**
Genmab A/S	48%	58%	34%	46%
Amgen, Inc.	7%	22%	3%	12%
IDM S.A.	29%	%	43%	%

No other single customer accounted for more than 10% of the Company s total revenues for the three and nine months ended September 30, 2002 and 2003, respectively.

7. Asset Retirement Obligations

Effective January 1, 2003, the Company changed its method of accounting for asset retirement obligations in accordance with SFAS No. 143, *Accounting for Asset Retirement Obligations*. Previously, the Company was not required to recognize amounts related to asset retirement obligations. Under SFAS No. 143, the Company now recognizes asset retirement obligations in the period in which they are incurred if a reasonable estimate of a fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset.

The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately $1.4 million, recognition of an asset retirement obligation liability of approximately $2.2 million and a cumulative effect of a change in accounting principle of approximately $0.8 million. Adoption of SFAS No. 143 had no material impact on net loss before the cumulative effect of adoption in the first quarter of 2003 nor would it have had a material impact in the first quarter of 2002 assuming an adoption of SFAS No. 143 effective January 1, 2002.

8. Stock Option Exchange Program

In January 2003, the Company s Board of Directors approved a stock option exchange program. Under this program, eligible employees and eligible officers were given the opportunity to cancel one or more stock options previously granted to them in exchange for new stock options to be granted at least six months and one day from the date the old options are cancelled (the grant date), provided that the individual is still employed by the Company on such date. Eligible employees refers to current Company employees who are not executive officers and who hold options to purchase the Company s stock with an exercise price of $10 or more. Eligible officers refers to executive officers (excluding the President and Chief Executive Officer and the Executive Vice President) who hold options to purchase the Company s stock with an exercise price of $25 or more. Members of the Company s Board of Director s were not eligible to participate in the program. The participation deadline for the program was March 7, 2003. Eligible Employees and Eligible Officers elected

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

to exchange a total of 2,309,401 shares of common stock underlying eligible options. The number of shares subject to the new options was determined based on the old options exercise price. Specifically, if the exercise price of the old options was between $10.00 and $24.99 per share, then the exchange ratio was equal to 0.67 of a share. If the exercise price of the old options was $25.00 per share or higher, then the exchange ratio was equal to 0.50 of a share. The Company issued 1,313,919 replacement options with an exercise price of $6.33 on September 8, 2003.

9. Subsequent Events

On October 17, 2003, the Company entered into an Amended and Restated License Agreement with Kyowa, referred to herein as the Kyowa License. Under the terms of the Kyowa License, the Company received certain intellectual property rights relating to the development and commercialization of the Ultra-Potent Toxin technology. As partial consideration for these rights, the Company agreed to pay Kyowa a total of $4.0 million, $3.6 million of which was paid through the issuance of 552,020 shares of its common stock to Kyowa on October 28, 2003 with the balance of $0.4 million paid in cash on the same date, representing applicable withholding taxes. The number of shares of the Company s common stock was determined by dividing $3.6 million by the average of the closing sales prices of the Company s common stock for each of the trading days during the twenty-trading-day period ending two trading days immediately prior to October 17, 2003 (the effective date of the Kyowa License) as publicly reported by NASDAQ. In the event that, during the 60-day period following October 28, 2003, Kyowa sells all of the shares of the Company s common stock delivered as payment under the Kyowa License, and the proceeds of such sale are less than $3.6 million, the Company must pay the difference to Kyowa in cash. If such sale proceeds exceed $3.6 million, Kyowa must pay the Company 50% of any such excess in cash. In the event that, during such 60-day period, Kyowa does not sell all of the shares of the Company s common stock, there will be no such adjustment. Kyowa has agreed not to sell more than 20% of shares issued to them in any five-trading-day period.

Under the terms of the May 2002 Asset Purchase Agreement with Corixa, upon the execution of the Kyowa License, the Company was required to make a final payment to Corixa in the amount of $2.5 million. Such amount was payable, at the Company s option, either in cash or in shares of the Company s common stock. The Company made such payment through the issuance of 353,807 shares of its common stock on October 29, 2003 in satisfaction of this obligation. The number of shares of the Company s common stock was determined by dividing $2.5 million by the average of the closing sales prices of the Company s common stock for each of the trading days during the five-trading-day period ending two trading days immediately prior to October 17, 2003 (the effective date of the Kyowa License) as publicly reported by NASDAQ. The Company has no further obligation to pay additional consideration to Corixa in connection with the Asset Purchase Agreement.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which represent our projections, estimates, expectations or beliefs concerning among other things, financial items that relate to management s future plans or objectives or to our future economic and financial performance. Forward-looking statements involve known and unknown risks and uncertainties and are indicated by words such as anticipates , expects , intends , believes , plans , could , potential and similar words and phrases. These risks and uncertainties include, but limited to, our early stage of product development, history of operating losses and accumulated deficit, additional financing requirements and access to capital funding, dependence on strategic alliances, government regulation of the biopharmaceutical industry and other risks that may be detailed from time to time in our periodic reports and registration statements filed with the Securities and Exchange Commission. All forward-looking statements included in this Quarterly Report are based on information available to us as of the date hereof, and we do not assume any obligation to update any such forward-looking statements. Our actual results may differ materially from the results discussed in the forward-looking statements. Among the factors that could cause actual results to differ materially are the factors detailed in Item 5 below. References to our products, business, financial results or financial condition should be considered to refer to us and our subsidiaries unless the context otherwise requires.

Basis of Financial Statement Presentation

We are a biopharmaceutical company focused on the discovery and development of human antibody-based therapeutic products using our proprietary technology platform, the UltiMAb Human Antibody Development System[SM]. This unique combination of human antibody technologies enables us to rapidly create and develop high affinity, fully human antibodies to a wide range of diseases including cancer, inflammation, auto-immune disease and other life-threatening and debilitating diseases.

Eleven antibodies derived from our UltiMAb human antibody development technology are currently in human clinical trials or have had regulatory applications submitted for such trials for a wide range of diseases, such as cancer (including various lymphomas), rheumatoid arthritis, multiple sclerosis and psoriasis. Three of these products are fully owned by Medarex: MDX-010 (Phase II), MDX-060 (Phase I/II) and MDX-070 (Phase I/II), for the treatment of cancer, lymphoma or HIV. One antibody for autoimmune disease, MDX-018 (Phase I/II), is being jointly developed with our partner, Genmab A/S, and three are being developed by Genmab: HuMaxCD4 (Phase II) for psoriasis and lymphoma, HuMax-IL15 (Phase II) for rheumatoid arthritis and HuMax EGFr (Phase I/II) for head and neck cancer. Additionally, our licensing partners Novartis Pharma AG and Centocor, Inc. (a subsidiary of Johnson & Johnson) are developing a total of four antibodies, for anti-inflammatory and autoimmune diseases, that are currently in early clinical trials. We and our partners also have a number of product candidates in preclinical development. The preceding information regarding the clinical status of our partners products is based on our partners public disclosure.

Through our 1997 acquisition of GenPharm International, Inc. and our collaboration with Kirin Brewery Co. Ltd., we expanded our business to include both our HuMAb-Mouse® and Kirin s TC Mouse technologies. In December 2000 we unveiled the KM-Mouse®, a unique crossbred mouse developed in partnership with Kirin, as the newest addition to our UltiMAb Human Antibody Development System. With the UltiMAb platform, we believe we have assembled a unique family of human antibody technologies for creating the entire spectrum of high-affinity, fully human antibodies. We intend to leverage our product development capabilities with those of our partners, while also gaining access to novel therapeutic targets and complementary development, sales and marketing infrastructures. As of November 1, 2003, we have over 45 partnerships with pharmaceutical and biotechnology companies, including industry leaders such as Amgen, Inc., Centocor, Inc. (a subsidiary of Johnson & Johnson), Eli Lilly & Company, Human Genome Sciences, Inc., Abbott Laboratories,

Novartis Pharma AG, Novo Nordisk A/S, Schering AG and Pfizer, Inc., to jointly develop and commercialize products or to enable other companies to use our proprietary technology in their development and commercialization of new therapeutic products. Some of our partnerships are licensing partnerships, with the potential to pay us licensing fees, milestone payments and royalty payments; others are collaborative partnerships and provide for the sharing of product development costs, as well as any revenues, expenses and profits associated with products arising under the collaboration.

Our licensing partners typically obtain licenses to one or more of our antibody generating technologies which we expect will allow these partners to develop and commercialize antibody-based products using our technology. We could receive license fees, milestones and royalties in connection with each of these products. Under these licenses, there is usually an initial period during which our partners may elect to enter into a research license for antibodies to a particular designated target. Subsequently, our partners may elect to obtain a commercial license for monoclonal antibodies to a particular target.

We are also pursuing an Applied Genomics strategy in order to gain access to new target antigens as they are identified, while also sharing the risks and rewards of the related antibody development and commercialization. To this end, we have established a number of collaborative partnerships with companies in the fields of genomics and proteomics to jointly develop and commercialize human antibody products. Typically, our partner will provide a target antigen, and we will generate antibodies against that antigen using our UltiMAb Human Antibody Development System. We and our partners typically agree to share equally costs of clinical development and manufacturing as well as revenues, expenses and profits associated with the products arising under the collaboration.

Revenue Our revenue is principally derived through licensing our human antibody technology to pharmaceutical and biotechnology companies. The terms of these agreements typically include potential license fees and a series of milestone payments commencing upon initiation of clinical trials and continuing through commercialization. These payments may total $7.0 million to $10.0 million per product if the antibody receives approval from the FDA and equivalent foreign agencies. In the event a product is commercialized, we are also entitled to royalties on product sales. Additional revenue is earned from antibodies manufactured for and then sold to corporate partners and from government grants.

Research and Development Expenses Research and development expenses consist primarily of compensation expense, facilities, preclinical and clinical trials and supply expense relating to antibody product development and to the breeding, caring for and continued development of each of the HuMAb-Mouse and KM-Mouse, as well as to the performance of contract services for our collaborative partners.

General and Administrative Expenses General and administrative expenses consist primarily of compensation, facility, travel, legal fees and other expenses relating to our general management, financial, administrative and business development activities.

Critical Accounting Policies

The methods, estimates and judgments we use in applying our most critical accounting policies have a significant impact on the results we report in our consolidated financial statements. We evaluate our estimates and judgments on an on-going basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We believe the following accounting policies are the most critical to us, in that they are important to the portrayal of our financial statements and they require our most difficult, subjective or complex judgments in the preparation of our consolidated financial statements:

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Revenue Recognition

Historically, a significant portion of our revenue has been recognized pursuant to collaboration and license agreements with our partners. Revenue related to collaborative research with our partners is recognized and earned based upon the performance requirements of each agreement. Deferred revenue may result when we do not expend the required level of effort during a specific period in comparison to funds received during that period under the respective agreements or when funds received are refundable under certain circumstances. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements and when collectibility of such milestone payment is assured. Non-refundable upfront payments received in connection with our collaborative partnerships are deferred and recognized as revenue on a straight-line basis over the period we are obligated to perform services related to each of the respective agreements.

Investments

All marketable securities are classified as available-for-sale securities and are carried at fair value. Marketable securities include those securities of debt and publicly traded equity securities accounted for under the cost method. These securities trade on listed exchanges; therefore, fair value is readily available. These securities are also subject to an impairment charge when we believe an investment has experienced a decline in value that is other than temporary. Under our accounting policy, a decline in the value of our investments is deemed to be other than temporary and such investments are generally considered to be impaired if their value is less than our cost basis for more than six (6) months, or some other period in light of the facts and circumstances surrounding the investments.

In addition, in connection with our collaborative partnering business, we make strategic investments in the equity of companies that are privately held. These securities are carried at original investment cost. Because these securities are not listed on a financial exchange, we value these investments by using information acquired from industry trends, the management of these companies, financial statements, and other external sources. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is other than temporary.

Future adverse changes in market conditions or adverse changes in operating results of underlying investments that may not be reflected in an investment s current carrying value, may also require an impairment charge in the future.

Valuation of Long-Lived and Intangible Assets

We assess the impairment of identifiable intangible assets and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important that could trigger an impairment review include the following:

a significant underperformance relative to expected historical or projected future operating results;

a significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or

a significant negative industry or economic trend.

When we determine that the carrying value of intangible assets or long-lived assets are not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets that have not been previously recorded.

Results of Operations

Three months ended September 30, 2002 and 2003

Total revenue decreased by $12.4 million or 85%, from $14.6 million to $2.3 million, during the three-month period ended September 30, 2003, as compared to the three-month period ended September 30, 2002. The decrease relates principally to a decrease of sales revenues of $6.6 million from Genmab related to MDX-CD4 and a decrease in contract and license revenues of $4.2 million from Immuno-Designed Molecues S.A., or IDM. As a result of Genmab s announced decision to wind down its anti-CD4 program for rheumatoid arthritis, we anticipate that sales of MDX-CD4 (and corresponding cost of sales) will be significantly lower in the future. In addition, we expect contract and license revenues to be lower in the foreseeable future as a result of the completion in September 2002 of the revenue recognition associated with the transfer of technology to IDM in July 2000.

Cost of sales decreased by $3.9 million or 100%, during the three-month period ended September 30, 2003, as compared to the three-month period ended September 30, 2002. The decrease reflects the production cost of MDX-CD4 that was sold to Genmab in the third quarter of 2002. There was no corresponding production cost in the third quarter of 2003.

Research and development expenses are largely comprised of (i) personnel costs, (ii) those expenses related to facilities for our clinical research, development and clinical trial manufacturing efforts, (iii) third party research costs, (iv) supply costs, and (v) license and technology access fees. Research and development expenses for our products in development increased by $3.8 million or 18%, from $20.9 million to $24.7 million, during the three-month period ended September 30, 2003, as compared to the three-month period ended September 30, 2002. This increase relates primarily to costs associated with the following:

Personnel costs for the three-month period ended September 30, 2003 were $8.6 million, an increase of $0.6 million or 7%, as compared to the three-month period ended September 30, 2002. The increase in staff is required to support higher levels of product development and clinical trial manufacturing activities, increased clinical activities, the continued development of our UltiMAb system, and the performance of contract services for our collaborative partners. Included in this increase are salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to increase, but at a slower rate, as we continue to increase our product development activities and progress our products in clinical trials.

Clinical trial costs for the three-month period ended September 30, 2003 were $1.8 million, an increase of $1.4 million or 284%, as compared to the three-month period ended September 30, 2002. These costs represent clinical investigator site fees, monitoring costs and data management costs. We expect clinical trial costs to increase in the future as we continue to develop our therapeutic product pipeline.

Third party research costs for the three-month period ended September 30, 2003 were $1.9 million, an increase of $0.9 million or 81%, as compared to the three-month period ended September 30, 2002. Outside funding of research expenses include funds paid to certain partners for research services. We expect these types of expenses to increase in the future.

We also expect other expenses related to clinical trials to increase in the future as we continue to develop our therapeutic products and add new products to our pipeline. As part of our partnering strategy, a significant portion of the research and development expenses incurred in connection with products using our

technology is expected to be borne by our partners. We believe this allows us to participate in the research and development of substantially more potential product candidates than we could develop on our own if we bore the entire cost of development. Products using our technology are currently in various stages of preclinical and clinical development by us and our partners. The successful development of these product candidates is dependent on many factors, including among other things, the efforts of our partners, unforeseen delays in, or expenditures relating to, preclinical development, clinical testing, manufacturing or regulatory approval, failure to receive market acceptance, the emergence of competitive products and the inability to produce or market our products due to third-party proprietary rights.

General and administrative expenses for the three-month period ended September 30, 2003 were $5.3 million, a decrease of $0.5 million, or 9%, as compared to the three-month period ended September 30, 2002. The decrease is primarily attributable to lower legal and consulting fees. General and administrative expenses are expected to increase in the future as our products are developed and we expand our business activities.

Equity in net loss of affiliate for the three-month period ended September 30, 2003 was $4.7 million, a decrease of $30.4 million, or 87%, as compared to the three-month period ended September 30, 2002. Included in equity in net loss of affiliate for the three-month period ended September 30, 2002 is in an impairment loss on our investment in Genmab of $31.0 million resulting from an approximate 60% decrease in the market value of Genmab stock following Genmab s September 24, 2002 press release in which it announced that its HuMax-CD4 product, a fully human antibody that targets CD4 receptor on cells known as T-cells was found not to be effective in combination with methotrexate in a Phase II study of 155 patients with active rheumatoid arthritis. We recorded the impairment charge in the third quarter of 2002 as a result of the decrease in the market price of the Genmab stock. If we deem this investment to be further impaired at the end of any future period, we may incur an additional impairment charge on this investment. Excluding this impairment charge, equity in net loss of affiliate in three-month period ended September 30, 2002 was $4.1 million as compared to $4.7 million for the three-month period ending September 30, 2003 as noted above. This increase is primarily the result of Genmab s increased research and development expenses as they expand their business. Genmab is an affiliated company and is accounted for using the equity method of accounting. The recognition of our equity in Genmab s net losses reduces the carrying value (basis) of our investment in Genmab.

Interest and dividend income for the three-month period ended September 30, 2003 was $2.6 million, a decrease of $2.0 million, or 44%, as compared to the three-month period ended September 30, 2002. The decrease reflects lower interest income due to lower average cash balances as we funded our operations and capital expenditures from our cash reserves as well as lower interest rates.

During the third quarter of 2003, no impairment charges were recorded on our investments in partners. An impairment loss on investments in partners of $3.9 million was recorded during the three-month period ended September 30, 2002, representing a write-down of the value of our investment in one of our corporate partners. During the third quarter of 2002, the decline in the value of this investment was determined to be other than temporary. If we deem our investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

Additional payments related to asset acquisition of $1.4 million during the three-month period ended September 30, 2002 represents additional payments to Corixa in connection with the second, third and fourth monthly installments required under the Corixa Asset Purchase Agreement. Such payments were pursuant to the terms of that agreement, which provided that, under certain circumstances we were required to pay to Corixa an amount equal to the difference between the proceeds received by Corixa for the sale of any shares of our common stock delivered as payment of any installment of the purchase price of the assets and the total amount of the purchase price installment due under the agreement.

Interest expense for the three-month period ended September 30, 2003 was $3.4 million, an increase of $1.1 million, or 50%, as compared to the three-month period ended September 30, 2002. The increase reflects interest on our $125 million of 4.25% Convertible Senior Notes due August 15, 2010 issued on July 23, 2003.

Nine months ended September 30, 2002 and 2003

Total revenue decreased by $25.0 million or 75%, from $33.5 million to $8.5 million, during the nine-month period ended September 30, 2003, as compared to the nine-month period ended September 30, 2002. The decrease relates principally to a decrease of contract and license revenues of $14.3 million from IDM and a decrease of sales revenues of $9.4 million from Genmab related to MDX-CD4, partially offset by $1.9 million in higher contract and license revenues from Genmab. As a result of Genmab s announced decision to wind down its anti-CD4 program for rheumatoid arthritis, we anticipate that sales of MDX-CD4 (and corresponding cost of sales) will be significantly lower in the future. In addition, we expect contract and license revenues to be lower in the future as a result of the completion in September 2002 of the revenue recognition associated with the transfer of technology to IDM in July 2000.

Cost of sales decreased by $5.7 million or 100%, from $5.7 million to $3 thousand, during the nine-month period ended September 30, 2003, as compared to the nine-month period ended September 30, 2002. The decrease reflects the production cost of MDX-CD4 that was sold to Genmab during the first nine months of 2002. There was no corresponding production cost in the first nine months of 2003.

Research and development expenses are largely comprised of (i) personnel costs, (ii) those expenses related to facilities for our clinical research, development and clinical trial manufacturing efforts, (iii) third party research costs, (iv) supply costs, and (v) license and technology access fees. Research and development expenses for our products in development increased by $15.5 million or 27%, from $56.5 million to $72.0 million, during the nine-month period ended September 30, 2003, as compared to the nine-month period ended September 30, 2002. This increase relates primarily to costs associated with the following:

Personnel costs for the nine-month period ended September 30, 2003 were $25.6 million, an increase of $5.5 million or 27%, as compared to the nine-month period ended September 30, 2002. The increase is primarily the result of a full nine-months of salary and benefits for employees hired between January 1, 2002 and September 30, 2002. The increase in staff is required to support higher levels of product development and clinical trial manufacturing activities, increased clinical activities, the continued development of our UltiMAb system, and the performance of contract services for our partners. Included in the increase are salaries, benefits, payroll taxes and recruiting costs. We expect personnel costs to increase, but at a slower rate, as we continue to increase our product development activities and progress our products in clinical trials.

Facility costs for the nine-month period ended September 30, 2003 were $14.7 million, an increase of $3.5 million or 32% over the nine-month period ended September 30, 2002. The increase in 2003 primarily relates to the substantial investments made in our three research and development facilities during 2001 and the first half of 2002. Such investments included: building and land improvements and the purchase of machinery and lab equipment and furniture and fixtures. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for the nine-month period ended September 30, 2003, as compared to the nine-month period ended September 30, 2002. In addition, the 2003 facility costs also include rent and related costs for our Sunnyvale, California facility which opened during the fourth quarter of 2002. We expect facility costs to increase in the future as a result of continued capital expansion, renovations and replacements, but at a slower rate.

Clinical trial costs for the nine-month period ended September 30, 2003 were $3.6 million, and increase of $2.5 million or 242% over the nine-month period ended September 30, 2002. Included in these costs are clinical investigator site fees, monitoring costs and data management costs. We also expect expenses related to clinical trials to increase in the future as we continue to develop our therapeutic product pipeline.

General and administrative expenses for the nine-month period ended September 30, 2003 were $16.2 million, a decrease of $0.8 million or 5%, as compared to the nine-month period ended September 30, 2002. The decrease is primarily attributable to a reduction in legal fees of $1.3 million and a reduction in consulting fees of $0.8 million, partially offset by higher personnel costs of $0.8 million. General and administrative expenses are expected to increase in the future as our products are developed and we expand our business activities.

Write-off of facility costs relates to a determination we made during the second quarter of 2002 to delay indefinitely the planned construction of a manufacturing facility at our Bloomsbury, New Jersey location and to pursue late-stage clinical and commercial supply agreements with third party manufacturers with available capacity meeting our current internal production timetables. As a result of this determination, we recorded a charge of $11.3 million in the second quarter of 2002, representing the write-off of design, engineering and other pre-construction costs. We have expanded our existing clinical manufacturing capacity in our Annandale, New Jersey facility, which we expect will meet all near-term production demands. Further, we are in negotiation with third party manufacturers for clinical and commercial supply agreements. As of October 31, 2003 we had not entered into any such supply agreements.

Acquisition of in-process technology relates to our acquisition of certain assets of Corixa in May 2002. The total cost of the acquisition (including transaction costs), discussed more fully under the section herein entitled Liquidity and Capital Resources, was $21.4 million. Based upon an independent third party valuation, $16.3 million of this amount was charged to operations as acquisition of in-process technology in the second quarter of 2002.

Equity in net loss of affiliate for the nine-month period ended September 30, 2003, was $11.6 million, a decrease of $30.7 million, or 73% as compared to nine-month period ended September 30, 2002. Included in equity in net loss of affiliate for the nine-month period ended September 30, 2002 is in an impairment loss on our investment in Genmab of $31.0 million resulting from an approximate 60% decrease in the market value of Genmab stock following Genmab s September 24, 2002 press release in which it announced that its HuMax-CD4 product, a fully human antibody that targets CD4 receptor on cells known as T-cells was found not to be effective in combination with methotrexate in a Phase II study of 155 patients with active rheumatoid arthritis. We recorded the impairment charge in the third quarter of 2002 as a result of the decrease in the market price of the Genmab stock. If we deem this investment to be further impaired at the end of any future period, we may incur an additional impairment charge on this investment. Excluding this impairment charge, equity in net loss of affiliate in nine-month period ended September 30, 2002 was $11.3 million as compared to $11.6 million for the nine-month period ended September 30, 2003 as noted above. This increase is primarily the result of Genmab s increased research and development expenses as they expand their business. Genmab is an affiliated company and is accounted for using the equity method of accounting. The recognition of our equity in Genmab s net losses reduces the carrying value (basis) of our investment in Genmab.

Interest and dividend income for the nine-month period ended September 30, 2003 was $8.3 million, a decrease of $6.0 million or 42%, as compared to the nine-month period ended September 30, 2002. The decrease reflects lower interest income primarily due to lower average cash balances as we funded our operations and capital expenditures from our cash reserves as well as lower interest rates. We anticipate lower interest and dividend income in the future as the result of lower interest rates partially offset by interest earned on the proceeds received from the July 23, 2003 private placement of $125 million of 4.25% Convertible Senior Notes due August 15, 2010.

During the nine-month period ended September 30, 2003, no impairment charges were recorded on our investments in partners. An impairment loss on investments in partners of $8.0 million was recorded during the nine-month period ended September 30, 2002 representing a write-down of the value of our investments in four of our partners. During the first nine months of 2002, the decline in the value of these investments was determined to be other than temporary. If we deem our investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

Additional payments related to asset acquisition of $1.7 million and $0.1 million during the nine-month periods ended September 30, 2002 and 2003, respectively, represents additional payments to Corixa and Northwest Biotherapeutics, respectively. Pursuant to the terms of these agreements, under certain circumstances, we were required to pay an amount equal to the difference between the proceeds received by these companies from the sale of any shares of our common stock delivered as payment of any installment of the purchase price of the assets and the total amount of the purchase price installment due under the agreements.

Interest expense during the nine-month period ended September 30, 2003 was $8.0 million, an increase of $1.2 million, or 18% as compared to the nine-month period ended September 30, 2002. The increase reflects interest on our $125 million of 4.25% Convertible Senior Notes due August 15, 2010 issued on July 23, 2003.

Cumulative effect of a change in accounting principle during the nine-month period ended September 30, 2003 was $0.8 million. Effective January 1, 2003, we changed our method of accounting for asset retirement obligations in accordance with SFAS No. 143, *Accounting for Asset Retirement Obligations.* Previously, we were not required to recognize amounts related to asset retirement obligations. Under SFAS No. 143, we now recognize asset retirement obligations in the period in which they are incurred if a reasonable estimate of a fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately $1.4 million, recognition of an asset retirement obligation liability of approximately $2.2 million and a cumulative effect of a change in accounting principle of approximately $0.8 million.

Liquidity and Capital Resources

We require cash to fund our operations, to make capital expenditures and strategic investments, and to pay debt service on our convertible note issues. Since inception, we have financed our operations through the sale of our securities in public and private placements, sales of our products for research purposes, development and manufacturing services, technology transfer and license fees and milestone payments. We expect to continue to fund our cash requirements from these funding sources in the future.

At September 30, 2003, we had approximately $381.8 million in cash, cash equivalents and marketable securities. We invest our cash equivalents and marketable securities in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

Cash Used in Operating Activities. Operating activities consumed $56.0 million and $68.5 million of cash for the nine month periods ended September 30, 2002 and 2003, respectively. The increase in cash used in operating activities in 2003 relates mainly to the increase in research and development expense. Total research and development expense increased by $15.5 million, from $56.5 million for the nine-month period ended September 30, 2002 to $72.0 million for the nine-month period ended September 30, 2003. The increase in research and development expense resulted from higher personnel costs, those expenses related to facilities for our clinical research, development and manufacturing efforts, and clinical trial costs. Partially offsetting the use of cash for these operating expenses were depreciation and amortization, non-cash compensation, and cash received from corporate partners. Lastly, the increase in cash used in operations also resulted from reduced investment income as a result of both lower interest rates and lower average cash balances.

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Cash Provided by Investing Activities. Net cash provided by investing activities was $93.6 million for the nine month period ended September 30, 2002 as compared to $7.0 million for the nine-month period ended September 30, 2003. The decrease in cash provided by investing activities was due mainly to the purchase of marketable securities with the net proceeds received from our July 23, 2003 issuance of 4.25% $125 million convertible notes (described below).

Cash Provided by Financing Activities. Financing activities for the nine-month period ended September 30, 2002 provided $198 thousand of cash compared to cash provided of $122.4 million for the nine-month period ended September 30, 2003. The increase in cash provided by financing activities was due primarily to the proceeds received from our July 23, 2003 private placement of $125 million of 4.25% Senior Convertible Notes due August 15, 2010.

Other Liquidity Matters. In connection with our merger with Essex Medical Products in 1987, we are committed to pay to Essex Chemical Corporation, or Essex, 20% of our net after-tax income until a total of $1.0 million has been paid, contingent upon the occurrence of certain events. As the result of our net income in 2000 we accrued $0.7 million payable to Essex, which remains accrued at September 30, 2003. At our option, this obligation may be satisfied by the payment of shares of our common stock having a fair market value equal to the amount owed, provided such shares are registered for sale with the Securities and Exchange Commission.

On May 23, 2002, we entered into an Asset Purchase Agreement with Corixa Corporation, Coulter Pharmaceutical, Inc., a wholly owned subsidiary of Corixa Corporation and Corixa Belgium S.A., a subsidiary of Corixa Corporation (collectively referred to as Corixa). Under the terms of the Asset Purchase Agreement, we acquired certain selected assets and business operations of Corixa, including certain preclinical product candidates and programs related to the research and development of therapeutic products for the treatment of autoimmune diseases, cancer and infectious diseases for $21.0 million (excluding transaction costs of $0.4 million). In addition, we retained approximately 30 Corixa employees related to such product candidates and programs.

A total of 3,086,075 shares of common stock with a fair value of $19.25 million were issued to Corixa along with a cash payment of $1.75 million as payment of the $21.0 million purchase price. In addition, pursuant to the terms of the Asset Purchase Agreement, we paid an additional $2.3 million representing the net cash shortfall experienced by Corixa from the sale of the 3,086,075 shares of our common stock.

On October 17, 2003, we entered into an Amended and Restated License Agreement with Kyowa Hakko Kogyo Co., Ltd., or Kyowa, referred to herein as the Kyowa License. Under the terms of the Kyowa License, we received certain intellectual property rights relating to the development and commercialization of the Ultra-Potent Toxin technology. As partial consideration for these rights, we agreed to pay Kyowa a total of $4.0 million, $3.6 million of which was paid through the issuance of 552,020 shares of our common stock to Kyowa on October 28, 2003 with the balance of $0.4 million paid in cash, representing applicable withholding taxes. The number of shares of our common stock was determined by dividing $3.6 million by the average of the closing sales prices of our common stock for each of the trading days during the twenty-trading-day period ending two trading days immediately prior to October 17, 2003 (the effective date of the Kyowa License) as publicly reported by NASDAQ. In the event that, during the 60-day period following October 28, 2003, Kyowa sells all of the shares of our common stock delivered as payment under the Kyowa License, and the proceeds of such sale are less than $3.6 million, we must pay the difference to Kyowa in cash. If such sale proceeds exceed $3.6 million, Kyowa must pay us 50% of any such excess in cash. In the event that, during such 60-day period, Kyowa does not sell all of the shares of our common stock, there will be no such adjustment. Kyowa has agreed not to sell more than 20% of shares issued to them in any five-trading-day period.

Under the terms of the Corixa Asset Purchase Agreement, upon the execution of the Kyowa License, we were required to make a final payment to Corixa in the amount of $2.5 million. Such amount was payable, at our option, either in cash or in shares of our common stock. We made such payment through the issuance of 353,807 shares of our common stock on October 29, 2003 in satisfaction of this obligation. The number of shares of our common stock was determined by dividing $2.5 million by the average of the closing sales prices of our common stock for each of the trading days during the five-trading-day period ending two trading days immediately prior to October 17, 2003 (the effective date of the Kyowa License) as publicly reported by NASDAQ. We have no further obligation to pay additional consideration to Corixa in connection with the Corixa Asset Purchase Agreement.

On July 23, 2003, we completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended, of $125 million of 4.25% convertible senior notes due August 15, 2010 to qualified institutional investors. The notes are initially convertible into shares of our common stock at the rate of 148.8261 per each $1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately $6.72 per share, subject to anti-dilution adjustments.

We will pay interest on these notes on February 15 and August 15 of each year beginning on February 15, 2004. We received net proceeds from the private placement of approximately $121.3 million (after deducting the initial purchasers discounts and offering expenses). Approximately $15.8 million of the net proceeds have been used to purchase U.S. Treasury security strips to collateralize the notes in an amount sufficient to pay the initial six interest payments on the notes.

Prior to August 15, 2006, we may redeem some or all of the notes at any time at a redemption price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest to the redemption date and the make-whole payment described below, if the closing price of our common stock has exceeded 150% of the conversion price then in effect for at least 20trading days within a period of 30 consecutive trading days ending on the trading day before the date of mailing of the provisional redemption notice. Upon any such provisional redemption, we will make an additional make-whole payment equal to $130.10 per $1,000 principal amount of notes redeemed, less the amount of any interest actually paid and any interest accrued and unpaid on these notes before the provisional redemption date. We may make such additional payment at our option in cash or shares or a combination thereof. Payments made in shares of our common stock will be valued at 95% of the average of the closing sale prices of our common stock for the five consecutive trading days ending on the third trading day immediately prior to the provisional redemption date. Noteholders have the option, subject to certain conditions, to require us to repurchase the notes in the event of a change in control at a price equal to 100% of the principal amount of the notes plus accrued and unpaid interest to the date of repurchase.

Pursuant to a May, 2003 research and development collaboration, the Company and Cell Genesys, Inc. expect to initiate a Phase I clinical study during the next year to evaluate combination therapy with Cell Genesys GVAX® prostate cancer vaccine and our anti-CTLA-4 antibody. We expect that the cost of this clinical trial will be shared equally by both companies.

We are in the process of exploring various financing options with respect to our vaccine technology program, including, among other things, a possible spin-off or a sale to a third party. To date, no arrangements or agreements have been entered into regarding these financing options.

Future Liquidity Resources. Our current sources of liquidity are cash, cash equivalents and marketable securities, interest and dividends earned on such cash, cash equivalents and marketable securities, contract and licensing revenue and sales of our products for research. We believe that such sources of liquidity

will be sufficient to meet our operating, debt service, and capital requirements for at least the next 24 months. However, this 24-month period assumes the use of a portion of the $175.0 million and/or $125.0 million required to meet our repayment obligations with respect to our convertible notes due on July 1, 2006 and August 15, 2010, respectively. The $175.0 million notes are convertible into shares of our common stock at a ratio of 34.6789 shares per each $1,000 principal amount of the notes ($28.84 per share), subject to adjustment. The $125.0 million notes are convertible into shares of our common stock at a ratio of 148.8261 shares per each $1,000 principal amount of the notes ($6.72 per share), subject to adjustment. To the extent our convertible notes are converted into shares of our common stock on or before their maturity dates, we will have use of that portion of the notes so converted to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We cannot assure you that we will be able to raise such additional funds. We may be unable to raise sufficient funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

We do not use derivative financial instruments in our operations or investment portfolio. We regularly invest excess operating cash in deposits with major financial institutions, money market funds, notes issued by the U.S. Government, as well as fixed income investments and U.S. bond funds both of which can be readily purchased or sold using established markets. We believe that the market risk arising from our holdings of these financial instruments is minimal. We do not believe we have material exposure to market risks associated with changes in interest rates, as we have no variable interest rate debt outstanding. While we do not believe we have any material exposure to market risks associated with interest rates, we may experience reinvestment risk as fixed income securities mature and are reinvested in securities bearing lower interest rates.

We may be exposed to exchange conversion differences in translating the foreign results of our investment in Genmab to U.S. dollars. Depending upon the relative strengthening or weakening of the U.S. dollar, the conversion difference could be significant.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures: The Company maintains disclosure controls and procedures , as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in the Company s Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to the Company s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, the Company s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance the Company s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has carried out an evaluation under the supervision and with the participation of the Company s management, including the Company s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief

Financial Officer concluded that the Company s disclosure controls and procedures were effective in ensuring that material information relating to the Company is made known to the Chief Executive Officer and Chief Financial Officer by others within the Company during the period in which this report was being prepared.

Changes in internal controls: There were no significant changes in our internal controls or other factors that could significantly affect those controls subsequent to the date of our management s evaluation.

Limitations on the Effectiveness of Controls: Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls 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; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Part II Other Information

Item 1. Legal Proceedings

In the ordinary course of our business, we are at times subject to various legal proceedings. We do not believe that any of our current legal proceedings, individually or in the aggregate, will have a material adverse effect on our operations or financial condition.

Item 5. Other Information

Additional factors that might affect future results include the following:

Our product candidates are in early stages of development, and they have not been and may not ever be approved for sale and/or commercialized.

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Product candidates employing our human antibody technology are in the early stages of development. Only a limited number of product candidates employing our human antibody technology have been generated by us or our partners. Based on public disclosures, regulatory applications, including Investigational New Drug Applications, or INDs, have been submitted to the United States Food and Drug Administration, or FDA, or comparable foreign authorities, for eleven of these candidates. To date, neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA and/or commercialized. In addition, we are not aware of any commercialized fully human monoclonal

antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond the early stages of product development or demonstrate clinical safety and effectiveness.

Our human antibody technology may not generate antibodies against all the antigens to which it is exposed in an efficient and timely manner, if at all. If our human antibody technology fails to generate antibody product candidates, or if we or our partners do not succeed in the development of products employing our antibody technology, those product candidates may not be approved or commercialized and our business, financial condition and results of operations may be materially harmed.

Successful development of our products is uncertain. To date, no revenues have been generated from the commercial sale of our products and our products may not generate revenues in the future.

Our development of current and future product candidates is subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

- delays in product development, clinical testing or manufacturing;
- unplanned expenditures in product development, clinical testing or manufacturing;
- failure in clinical trials or failure to receive regulatory approvals;
- emergence of superior or equivalent products;
- inability to manufacture on our own, or through others, product candidates on a commercial scale;
- inability to market products due to third-party proprietary rights;
- election by our partners not to pursue product development;
- failure by our partners to develop products successfully; and
- failure to achieve market acceptance.

In certain instances, we have experienced delays in our product development and clinical testing as a result of slower than anticipated patient recruitment. In a small number of instances, we have terminated the development of certain products in the early stages of clinical testing due to a lack of effectiveness. In addition, we determined not to continue the development of one late-stage product candidate due to both a lack of effectiveness and unforeseen safety issues that arose in clinical testing. None of these products employed our core fully human antibody technology.

Because of these risks, our research and development efforts or those of our partners may not result in any commercially viable products. If a significant portion of these development efforts is not successfully completed, required regulatory approvals are not obtained or any approved products are not commercially successful, our business, financial condition and results of operations may be materially harmed.

Because we and our partners have not begun commercial sales of our products, our revenue and profit potential are unproven and our limited operating history makes it difficult for an investor to evaluate our business and prospects. Our technology may not result in any meaningful benefits to our current or potential partners. No revenues have been generated from the commercial sale of our products, and our products may not generate revenues in the future. Further, due to our limited operating history, we have difficulty accurately forecasting our revenue. Our business and prospects should be considered in light of the heightened risks and unexpected expenses and problems we may face as a company in an early stage of development in a new and rapidly evolving industry.

We have incurred large operating losses and we anticipate that these losses will continue.

We have incurred large operating losses and we anticipate that these losses will continue for the foreseeable future. In particular, as of September 30, 2003, we had an accumulated deficit of approximately $375.6 million. Our net losses were $157.5 million and $92.0 million for the year ended December 31, 2002 and the nine month period ended September 30, 2003, respectively. Our losses have resulted principally from:

- research and development costs relating to the development of our technology and antibody product candidates;
- costs associated with the establishment of our new laboratory and manufacturing facilities and manufacturing of products; and
- general and administrative costs relating to our operations.

We intend to continue to make significant investments in:

- research and development;
- preclinical testing and clinical trials;
- establishing new collaborations; and
- new technologies.

We do not know when or if we or our partners will complete any pending or future product development efforts, receive regulatory approval or successfully commercialize any approved products.

We may continue to incur substantial operating losses even if our revenues increase. As a result, we cannot predict the extent of future losses or the time required for us to achieve profitability, if at all.

Our operating results may vary significantly from period-to-period, which may result in a decrease in the price of our securities.

Our future revenues and operating results are expected to vary significantly from period-to-period due to a number of factors. Many of these factors are outside of our control. These factors include:

- the timing of the commencement, completion or termination of partnership agreements;

the introduction of new products and services by us, our partners or our competitors;

delays in preclinical testing and clinical trials;

changes in regulatory requirements for clinical trials;

costs and expenses associated with preclinical testing and clinical trials;

the timing of regulatory approvals, if any;

sales and marketing expenses; and

the amount and timing of operating costs and capital expenditures relating to the expansion of our business operations and facilities.

Period-to-period comparisons of our results of operations may not be relied upon as an indication of future performance.

It is possible that in some future periods, our operating results may be below expectations of analysts and investors. If this happens, the price of our securities may decrease.

We may need substantial additional funding. We may not be able to obtain sufficient funds to grow our business or continue our operations.

We will continue to expend substantial resources for research and development, including costs associated with developing our antibody technology and conducting preclinical testing and clinical trials. Our future capital requirements will depend on a number of factors, including, by way of example:

the size and complexity of research and development programs;

the scope and results of preclinical testing and clinical trials;

the retention of existing and establishment of further partnerships, if any;

continued scientific progress in our research and development programs;

the time and expense involved in seeking regulatory approvals;

competing technological and market developments;

the time and expense of filing and prosecuting patent applications and enforcing patent claims; and

the cost of establishing manufacturing capabilities, conducting commercialization activities and arrangements and in-licensing products.

We believe our current sources of liquidity will be sufficient to meet our near term operating, debt service and capital requirements for at least the next 24 months. However, this 24-month period assumes the use of a portion of the proceeds from our convertible notes. To the extent our convertible notes are converted into shares of our common stock on or before their maturity dates, we will have use of that portion of the principal amount of the notes so converted to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We may be unable to raise sufficient

funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of debt and debt service obligations, which, unless converted to shares of our common stock or redeemed, will mature in 2006 ($175 million) and 2010 ($125 million), respectively. Our ability to make payments on our debt, including the notes offered by this prospectus, will depend on our future operating performance and ability to generate cash and may also depend on our ability to obtain additional debt or equity financing. Generally, during the last five years and the nine months ended September 30, 2003, our operating cash flows were negative and insufficient to cover our fixed charges. Our ability to generate sufficient operating cash flow to service our indebtedness, including the notes, and fund our operating requirements will depend on our ability, alone or with others, to successfully develop, manufacture, and obtain required regulatory approvals and market our product candidates, as well as other factors, including general economic, financial, competitive, legislative and regulatory conditions, some of which are beyond our control. If we are unable to generate sufficient operating cash flow to service our indebtedness and fund our operating requirements, we may need to obtain additional debt or equity financing to do so, which may not be available to us on satisfactory terms or at all. In addition, if new indebtedness is incurred, the risks relating to our ability to service our indebtedness that we face could intensify.

Even if we are able to meet our debt service obligations, the amount of debt we have could adversely affect us in a number of ways, including by:

- limiting our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business;
- placing us at a competitive disadvantage relative to our competitors who have lower levels of debt;
- making us more vulnerable to a downturn in our business or the economy generally; and
- requiring us to use a substantial portion of our cash to pay principal and interest on our debt, instead of applying those funds to other purposes such as working capital and capital expenditures.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA approval to market a new drug product, we or our partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our partners will have to conduct extensive preclinical testing and adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. Moreover, we will continue to be affected by delays associated with the preclinical testing and clinical trials of certain product candidates conducted by our partners over which we have no control. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices, or cGMPs, for use in clinical trials;
- slower than expected rates of patient recruitment;

the inability to adequately observe patients after treatment;

changes in regulatory requirements for clinical trials;

the lack of effectiveness during the clinical trials;

unforeseen safety issues;

delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and

government or regulatory delays or clinical holds requiring suspension or termination of the trials.

Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our human antibody technology. In a small number of instances, we have terminated the development of certain products in the early stages of clinical testing due to a lack of effectiveness. None of these products employed our core fully human antibody technology. In addition, we have determined not to continue the development of one late-stage product candidate due to both a lack of effectiveness and unforeseen safety issues that arose in clinical testing. This product did not employ our core fully human antibody technology. Furthermore, in clinical trials of certain of our fully human antibody products, a number of patients have experienced adverse events such as fever, chills and nausea. The events were expected and were of the type normally associated with clinical trials of antibody based products. These events generally responded to standard medical therapy. In addition, in clinical trials of one of our fully human antibody products, a small number of patients experienced anticipated drug-related autoimmune adverse events, such as dermatitis and colitis, ranging from mild in most cases to severe in a very small number of instances. Almost all of these events responded to medical therapy. We cannot assure you that additional safety issues will not arise with respect to our products in the future.

To date, we have experienced slower than expected rates of patient recruitment in certain of our clinical trials. As a result, in certain instances, we have experienced delays in our product development and clinical testing. In addition, data obtained from clinical trials of our products to date have been insufficient to demonstrate safety and efficacy under applicable FDA guidelines. As a result, these data will not support an application for regulatory approval without further clinical trials. Clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for any of our product candidates. We expect to commence new clinical trials from time to time in the course of our business as our product development work continues. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of that product candidate as well as other product candidates. Any change in, or termination of, our clinical trials could materially harm our business, financial condition and results of operations.

Success in early clinical trials may not be indicative of results obtained in later trials.

Results of our early clinical trials and those of our partners using our human antibody technology are based on a limited number of patients and may, upon review, be revised or negated by authorities or by later stage clinical results. Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and effectiveness data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. For example, the FDA is in the process of moving several product categories currently regulated by the agency s Center for Biologics Evaluation and Research, or CBER, to the agency s Center for Drug Evaluation and Research, or CDER. These product categories include monoclonal antibodies as well as cytokines, growth factors, enzymes, interferons and certain proteins. The effect that this reorganization at the FDA will have on clinical trials and product approval outcomes or timing is uncertain, but could cause delays or other currently unforeseeable effects.

Product candidates employing our antibody technology may fail to gain market acceptance.

Even if clinical trials demonstrate the safety, effectiveness, potency and purity of products developed by us or our partners using our technology and all regulatory approvals have been obtained, product candidates employing our antibody technology may not gain market acceptance among physicians, patients, third-party payors and the medical community. For example, the current delivery systems for antibody-based therapeutic products are intravenous and subcutaneous injection, which are generally less well received by patients than tablet or capsule delivery. The degree of market acceptance of any product candidates employing our technology will depend on a number of factors, including, for example:

- establishment and demonstration of clinical efficacy, potency and safety, especially as compared to conventional treatments;
- cost-effectiveness;
- alternative treatment methods;
- reimbursement policies of government and third-party payors; and
- marketing and distribution support for our product candidates.

In addition, many of our activities involve genetic engineering in animals and animal testing. These types of activities have been the subject of controversy and adverse publicity. Animal rights groups and various other organizations and individuals have attempted to stop genetic engineering activities and animal testing by lobbying for legislation and regulation in these areas.

If products employing our technology do not achieve significant market acceptance, our business, financial condition and results of operations may be materially harmed.

The successful commercialization of our antibody products will depend on obtaining coverage and reimbursement for use of these products from third-party payors.

Sales of pharmaceutical products largely depend on the reimbursement of patients medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payors, the market for products employing our human antibody technology will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products. Such studies may require us to dedicate a significant amount of resources. Our project candidates may not be considered cost-effective. Third-party payors may not reimburse sales of products employing our human antibody technology, or enable us or our partners to sell them at profitable prices.

Third-party payors control health care costs by limiting both coverage and the level of reimbursement for new health care products. In the future, the United States government may institute price controls and further limits on Medicare and Medicaid spending. Internationally, medical reimbursement systems vary with differing degrees of regulation. Pricing controls and reimbursement limitations could affect the payments we receive from sales of products generated using our human antibody technology. These variations could harm our ability and the ability of our partners to sell products generated using our human antibody technology in commercially acceptable quantities at profitable prices.

Our manufacturing facilities may not continue to meet regulatory requirements and have limited capacity.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured are in compliance with current good manufacturing practices, or cGMP requirements. To be successful, our therapeutic products must be manufactured for development and, following approval, in commercial quantities, in compliance with regulatory requirements and at acceptable costs. While we believe our current facilities are adequate for the limited production of product candidates for clinical trials, our facilities are not adequate to produce sufficient quantities of any products for commercial sale.

If we are unable to establish and maintain a manufacturing facility or secure third party manufacturing capacity within our planned time and cost parameters, the development and sales of our products and our financial performance may be materially harmed.

We may also encounter problems with the following:

- production yields;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with FDA regulations, including the demonstration of purity and potency;
- changes in FDA requirements;

production costs; and/or

development of advanced manufacturing techniques and process controls.

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. We are currently pursuing late-stage clinical and commercial supply agreements with cGMP-compliant third party manufacturers with available capacity to meet our internal production timetables. As of September 30, 2003, we had not yet entered into any such agreements. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin producing antibodies under cGMP regulations. We cannot make assurances that we will be able to contract with any of these companies on acceptable terms or in a timely manner, if at all.

In addition, we and any third-party manufacturer will be required to register manufacturing facilities with the FDA and other regulatory authorities. The facilities will be subject to inspections confirming compliance with cGMP or other regulations. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

We are, in part, dependent on our partner s willingness and/or ability to devote resources to the development of product candidates or otherwise support our business as contemplated in our partnership agreements.

We depend, in part, on our partners to support our business, including the development of products generated through the use of our antibody technology. We currently, or in the future may, rely on our partners to:

- access proprietary antigens for the development of product candidates;
- access skills and information that we do not possess;
- fund our research and development activities;
- manufacture products;
- fund and conduct preclinical testing and clinical trials;
- seek and obtain regulatory approvals for product candidates; and/or
- commercialize and market future products.

Our dependence on our partners subjects us to a number of risks, including:

- our partners have significant discretion whether to pursue planned activities;
- we cannot control the quantity and nature of the resources our partners may devote to product candidates;

our partners may not develop products generated using our antibody technology as expected; and

business combinations or significant changes in a partner s business strategy may adversely affect that partner s willingness or ability to continue to pursue these product candidates.

If we do not realize the contemplated benefits from our partners, our business, financial condition and results of operations may be materially harmed.

Our existing partnerships may not be completed or may be terminated, and we may not be able to establish additional partnerships.

We have entered into binding letters of intent or memoranda of understanding with Genmab A/S, Athersys, Inc., and Regeneron Pharmaceuticals, Inc. These binding letters of intent or memoranda of understanding include the principal terms of these transactions, which will be incorporated into definitive agreements. By their terms, these letters of intent and memoranda of understanding will remain in full force and effect and the parties will operate in accordance with their terms until such time as definitive agreements are executed. If we are unable to agree on the terms of a definitive agreement with respect to one or more of these partners, our business may be harmed.

Our licensing partners generally have the right to terminate our partnerships at any time. Our ability to continue our current partnerships and to enter into additional partnerships is dependent in large part on our ability to successfully demonstrate that our HuMab-Mouse technology is an attractive method of developing fully human antibody therapeutic products. We have generated only a limited number of fully human antibody therapeutic product candidates pursuant to our collaboration agreements and eleven product candidates generated with our human antibody technology have entered clinical testing. Existing or potential partners may pursue alternative technologies, including those of our competitors, or enter into other transactions that could make a collaboration with us less attractive to them. For example, if an existing partner purchases a company that is one of our competitors, that company could be less willing to continue its collaboration with us. In addition, a company that has a strategy of purchasing companies rather than entering into partnership arrangements might have less incentive to enter into a collaboration agreement with us. Moreover, disputes may arise with respect to the ownership of rights to any technology or products developed with any current or future partner. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays or termination in the research, development or commercialization of product candidates. If we are not able to establish additional partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely:

- limit the number of product candidates that we will be able to develop and commercialize;
- significantly increase our need for capital; and/or
- place additional strain on management s time.

Any of the above may materially harm our business, financial condition and results of operations.

Our goals and/or strategy may conflict with those of our partners.

We may have goals and/or strategies that may conflict with those of our partners that could adversely affect our business. For example, our partners may pursue alternative technologies, including those of our competitors. Disputes may arise with respect to the ownership of rights to any technology or products developed with any partner. If our partners pursue alternative technologies or fail to develop or commercialize successfully any product candidate to which they have obtained rights from us, our business, financial condition and results of operations may be materially harmed.

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Due to the size of our equity interest in Genmab, we must include a portion of its income and losses in our financial statements.

Due to the size of our interest in Genmab, we are currently required to account for our equity interest in Genmab under the equity method of accounting, which provides that we must include a portion of Genmab s income and losses equal to our percentage equity interest in Genmab in our consolidated financial statements. For the years ended December 31, 2000, 2001 and 2002, our share of Genmab s losses were approximately $0.4 million, $7.3 million and $19.6 million, respectively. For the nine-month period ended September 30, 2003, our share of Genmab s net loss was $11.6 million. Genmab has publicly stated that it anticipates that it will incur substantial losses as it expands its research and product development efforts. As Genmab s losses continue to increase, the aggregate amount of such losses we must include in our consolidated financial statements will also increase.

Our strategic investments in our partners whose securities are publicly traded expose us to equity price risk and, in addition, investments in our partners may be deemed impaired, which would affect our results of operations.

We have a number of strategic investments which expose us to equity price risk. These investments may become impaired which would adversely affect our results of operations.

We are exposed to equity price risk on our strategic investments in our publicly-traded partners, including Genmab, Northwest Biotherapeutics, Inc., Seattle Genetics, Inc., Protein Design Labs, Inc. and Tularik, Inc., and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. As these investments are the result of strategic alliances with our collaborative partners, we typically do not attempt to reduce or eliminate our market exposure of these types of strategic investments. Under SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, these investments are designated as available-for-sale and are reported at fair value on our consolidated balance sheet. Unrealized holding gains and losses on available-for-sale securities are generally excluded from earnings and reported within other comprehensive income which is a separate component of shareholders equity. Under our accounting policy, marketable equity securities are generally considered to be impaired if their fair value is less than our cost basis in such securities for more than six months, or some other period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of available-for-sale securities is considered to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. For the year ended December 31, 2002, we recorded impairment charges of approximately $40.5 million (of which approximately $31.0 million related to Genmab) on our strategic investments in publicly traded companies. During the nine months ended September 30, 2003, no impairment charges were recorded related to the value of our investments. If we deem these investments to be further impaired at the end of any future reporting period, we may incur additional impairment charges on these investments.

In addition, we have investments in several of our partners whose securities are not publicly traded such as IDM. Because these securities are not publicly traded, the value of our investments in these companies are inherently more difficult to estimate than our investments in publicly traded companies. We estimate the value of these investments by using information acquired from industry trends, the management of these companies, financial statements, and other external sources. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is considered to be other than temporary. For the year ended December 31, 2002, we recorded impairment charges of approximately $2.4 million on our investments in privately-held companies. During the nine months ended September 30, 2003, no impairment charges were recorded related to the value of our investments in

privately held companies. Future adverse changes in market conditions or adverse changes in operating results of these companies may also require an impairment charge in the future.

We are dependent on our key personnel.

We are highly dependent on the members of our scientific and management staff. If we are not able to retain any of these persons, our business may suffer. In particular, we depend on the services of Donald L. Drakeman, Ph.D., our President and Chief Executive Officer, and Nils Lonberg, Ph.D., our Senior Vice President and Scientific Director. We have entered into employment agreements with Dr. Drakeman and certain of our other executive officers, which expire at various times over the next two years. Thereafter, all of these agreements are automatically renewed for successive one (1) year terms unless we or the employee elect not to renew. We are currently in the process of establishing new employment agreements with certain of our executive officers, including Dr. Drakeman and Dr. Lonberg. However, we cannot assure you that we will be able to complete these new employment agreements.

For us to pursue product development, marketing and commercialization plans, we will need to hire additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. We may not be able to attract and retain personnel on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. If we are not able to attract and retain qualified personnel, our business, financial condition and results of operations may be materially harmed.

We depend on patents and proprietary rights.

Our success depends in part on our ability to:

- protect trade secrets;
- operate without infringing upon the proprietary rights of others;
- in-license certain technologies; and
- apply for, obtain, protect and enforce patents.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We protect our proprietary position by filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. While a number of patents have been issued in the United States and Europe relating to our human antibody technology, we may not be able to obtain patent protection in other countries. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued or enforceable. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide sufficient protection against competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

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In addition to patents, we rely on trade secrets and proprietary know-how. We seek protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide protection or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information, or breach of these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. In the event that our technologies may infringe on the patents or violate other proprietary rights of third parties, we and our partners may be prevented from pursuing product development, manufacturing or commercialization. Such a result may materially harm our business, financial condition and results of operations.

Third parties may challenge the validity of our patents and other intellectual property rights, resulting in litigation or other time-consuming and expensive proceedings which could deprive us of valuable rights.

If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expense and the efforts of our technical and management personnel will be diverted. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Therefore, we and our partners may be restricted or prevented from manufacturing and selling products employing our human antibody technology, which would harm our business.

Even though we have received patents pertaining to the HuMAb-Mouse technology, this does not mean that we and our licensees of HuMAb-Mouse technology will have exclusive rights to antibodies against all targets that are made using this technology, or that we or our licensees will have the right to make, develop, use or sell such antibodies.

Our patents covering the HuMAb-Mouse technology include patents that cover particular human antibodies. These patents do not cover all human antibodies.

Our patents may not protect against the importation of products, such as antibodies, made using HuMAb-Mouse technology.

Moreover, other parties could have blocking patent rights to products made using HuMAb-Mouse technology, such as antibodies, and their production and uses, either because of a proprietary position covering the antibody or the antibody s target. For example, we are aware of certain United States and European patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets and bi-specific products, and the manufacture and use of such products. In particular, we are aware of certain United States and foreign patents and patent applications owned by third parties that pertain to monoclonal antibodies against CTLA-4 and their uses. We are also aware of certain United States and foreign patents and patent applications held by third parties relating to anti-CD4 antibodies, anti-CD30 antibodies, anti-EGFr antibodies, anti-PSMA antibodies, and anti-heparanase antibodies as well as other antibody products under development by us.

We are also aware of a United States patent owned by Genentech, Inc., relating to the production of recombinant antibodies in host cells. We currently produce certain of our products and our partners products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in this patent, then we may need to obtain a license, should one be available. If we are unable to obtain a license on commercially reasonable terms, we may be restricted in our ability to make recombinant antibodies using Genentech s techniques. In addition to the

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Genentech patent, we are also aware of certain United States patents held by third parties relating to antibody expression in particular types of host cells, including CHO cells, which may be relevant to our current or future manufacturing techniques.

If our antibody products (or those antibody products of our partners using our human antibody technology) or their commercial use or production meet all of the requirements of any of the claims of the aforementioned patents, or patents which may issue from the aforementioned patent applications, then we or our partners may need a license to one or more of these patents. Further, we are aware of a number of other third party patent applications which, if granted, with claims as currently drafted, may cover our and our partners current or planned activities. We expect to seek to obtain licenses to such patents when, in our judgment, such licenses are needed. If any licenses are required, there can be no assurance that we will be able to obtain any such license on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from using certain of our technologies for the generation of our recombinant human antibody products. Our failure to obtain a license to any technology that we may require may materially harm our business, financial condition and results of operations. We cannot assure you that our products and/or actions in developing or selling recombinant human antibody products will not infringe such patents.

In general, our patent protection may not prevent others from developing competitive products using our technology or other technologies. Similarly, others may obtain patents that could limit our ability and the ability of our partners to use, import, manufacture, market or sell products or impair our competitive position and the competitive position of our partners.

We are not the exclusive owner of the technology underlying the HuMAb-Mouse®. In March 1997, prior to our acquisition of GenPharm International, Inc., GenPharm entered into a cross-license and settlement agreement with Abgenix, Inc., Cell Genesys, Inc., Xenotech, L.P. and Japan Tobacco, Inc., pursuant to which Abgenix and these entities paid us and GenPharm a total of approximately $38.6 million during 1997 and 1998. This payment was in exchange for a non-exclusive license to certain patents, patent applications, third-party licenses and inventions pertaining to the development and use of certain transgenic rodents, including mice, that produce fully human antibodies that are integral to our products and business. These patents, licenses and inventions form the basis of our HuMAb-Mouse technology. Our business may suffer from the competition of these entities or if any of these entities breach the cross-license and settlement agreement.

We are not the exclusive owner of the technology underlying the KM-Mouse®. Effective September 4, 2002, we entered into a collaboration and license agreement with Kirin Brewery Co., Ltd., superseding the letter of intent entered into by us with Kirin in December 1999. Under this agreement, we and Kirin have exchanged certain cross-licenses for each other s technology for the development and commercialization of human antibody products made using the HuMAb-Mouse, the Kirin mice (TC Mouse and HAC Mouse) and the KM-Mouse. Kirin has certain rights to distribute and use such mice throughout the world. Our business may suffer as a consequence of competition from Kirin or if the collaboration and license agreement were breached or terminated for any reason.

We have had and may continue to face product liability claims related to the use or misuse of products employing our antibody technology.

The administration of drugs to humans, in clinical trials or after commercialization, may expose us to product liability claims. Consumers, healthcare producers or persons selling products based on our technology may be able to bring claims against us based on the use of our products in clinical trials and the sale of products based on our technology. Product liability claims may be expensive to defend and may result in large judgments against us. We have obtained limited product liability coverage for our clinical trials, under which coverage limits are $10 million per occurrence and $10 million in the aggregate. Although we believe these coverage

limits are adequate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. We intend to increase our coverage limits as we progress into additional late-stage clinical trials and to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for products in development. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

In November 1998, we voluntarily suspended clinical trials for one of our products after some patients experienced serious adverse events, or SAEs. This product did not employ our core fully human antibody technology and we have determined not to pursue further development of this product. As a result of these SAEs, we received a small number of claims, of which five resulted in lawsuits being filed. All of these lawsuits have been settled for insubstantial amounts. We cannot make assurances that additional claims will not be filed against us relating to these SAEs or arising out of any other clinical trial we have conducted or will conduct in the future.

Generally, our trials are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and during the course of treatment, these patients could die or suffer adverse medical effects for reasons that may not be related to our products. To date, in trials of one of our products, we have experienced mortalities in a very small number of patients which we believe will not materially affect our ability to continue with trials of this product as planned. Any of these events could result in a product liability claim. Any such claims against us, regardless of their merit, could result in significant awards against us which could materially harm our business, financial condition and results of operations.

We face intense competition and rapid technological change.

The development of biotechnology and pharmaceutical products is a highly competitive business subject to significant and rapid technological change. We face competition in several different forms. First, our human antibody generation activities currently face competition from several competitors with similar technology to ours as well as distinctly different technologies. The actual products being developed by us or by our partners also face actual and potential competition. Developments by our competitors may render our human antibody technology obsolete or non-competitive.

We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapeutics. Some of these companies have commenced clinical trials of antibody products or have successfully commercialized antibody products. Many of these companies are addressing the same diseases and disease indications as we and our partners. Also, we compete with companies that offer antibody generation services to companies that have disease related target antigens. These competitors have specific expertise or technology related to antibody development. We compete directly with Abgenix, with respect to the generation of fully human antibodies from transgenic mice. In addition, we have entered into agreements with each of Kirin and Genmab, respectively, that grant these companies licenses to our proprietary technology platform, enabling them to compete with us in offering antibody generation and development services in certain markets. Xenerex Biosciences and XTL Biopharmaceutical, Ltd. have developed technology that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies in functionally modified mice. Numerous additional companies are developing therapeutic products comprising human antibody components. Furthermore, several companies are developing, or have developed, technologies that do not involve immunization of animals for creating antibodies comprising human antibody sequences. For example, phage and yeast display technology is being used by companies, such as Abbott Laboratories, Cambridge Antibody Technology Group plc, or CAT, Dyax Corp., Genetastix Corporation and MorphoSys AG to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, MedImmune, Inc., Amgen, IDEC Pharmaceuticals Corporation,

Novartis, Genentech, Inc., Protein Design Labs, Inc., Wyeth, Abbott and Corixa Corporation have generated therapeutic products that are currently on the market and that are derived from recombinant DNA that comprise human antibody components.

Other technologies can also be applied to the treatment of the diseases that we or our partners are pursuing. For example, immunoconjugates monoclonal antibodies linked to toxins or radioactive isotopes are being developed by others. In addition, the application of recombinant DNA technology to develop potential products consisting of proteins (such as growth factors, hormones, enzymes, receptor fragments and fusion proteins, or cytokines) that do not occur normally in the body, or occur only in small amounts, has been underway for some time. Included in this group are interleukins such as IL-2 and IL-11, interferons alpha, beta and gamma, colony stimulating factors such as G-CSF and GM-CSF, clotting factors, growth hormones, erythropoeitin, DNAse, tPA, glucocerebrosidase, PDGF, and a number of other biological agents. Continuing development of new chemical entities and other drugs by large pharmaceutical companies carries with it the potential for discovery of agents for treating disease indications also targeted by drugs that we or our partners are developing.

Some of our competitors have received regulatory approval or are developing or testing product candidates that compete directly with product candidates employing our antibody technology. Many of these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development staffs than we or some of our partners do. In addition, many of these competitors have significantly greater experience than we do in:

developing products;

undertaking preclinical testing and clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing and marketing products.

Accordingly, our competitors may obtain patent protection, receive FDA approval or commercialize products before we or our partners do. If we or our partners commence commercial product sales, we or our partners will be competing against companies with greater marketing and manufacturing capabilities, areas in which we and certain of our partners have limited or no experience.

We also face intense competition from other pharmaceutical and biotechnology companies to establish partnerships, as well as relationships with academic and research institutions, and to license proprietary technology. These competitors, either alone or with their partners, may succeed in developing technologies or products that are more effective than ours.

We are subject to extensive and costly government regulation.

Product candidates employing our human antibody technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, state and local governments and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of biopharmaceutical products. The FDA regulates human antibodies as biologics, subject to a Biologic License Application, or BLA, under the Public Health Services Act, as amended. If products employing our human antibody technology are marketed abroad, they will also be

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subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost of researching, developing, manufacturing, and selling our products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. We or our partners must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product s safety, efficacy, potency and purity for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals may:

- adversely affect the successful commercialization of any drugs that we or our partners develop;
- impose additional costs on us or our partners;
- diminish any competitive advantages that we or our partners may attain; and
- adversely affect our receipt of revenues or royalties.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. If we, our partners or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things:

- delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;
- warning letters;
- fines;
- import and/or export restrictions;
- product recalls or seizures;
- injunctions;

total or partial suspension of production;

civil penalties;

withdrawals of previously approved marketing applications or licenses;

recommendations by the FDA or other regulatory authorities against governmental contracts; and

criminal prosecutions.

In certain cases, we expect to rely on our partners to file investigational new drug applications, or INDs, with the FDA and to direct the regulatory approval process for products employing our human antibody technology. Our partners may not be able to conduct clinical testing or obtain necessary approvals from the FDA or other regulatory authorities for their product candidates employing our human antibody technology. If they fail to obtain required governmental approvals, our partners will be delayed or precluded from marketing these products. As a result, commercial use of products employing our technology will not occur and our business, financial condition and results of operations may be materially harmed.

We do not have, and may never obtain, the regulatory approvals we need to market our product candidates.

Following completion of clinical trials, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of a BLA or a New Drug Application, or NDA, in order to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to a BLA or NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study or reporting requirements or other restrictions on product distribution, or may deny the application. The timing of final FDA review and action varies greatly, but can take years in some cases and often involves the input of an FDA advisory committee of outside experts. Product sales in the United States may commence only when a BLA or NDA is approved.

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our products in the United States or in any foreign jurisdiction. None of our product candidates has been determined to be safe and effective, and we have not submitted an NDA or BLA to the FDA or to any foreign regulatory authorities for any of our product candidates. We have only limited experience in filing and pursuing applications necessary to obtain regulatory approval. As a result, it is possible that none of our product candidates will be approved for marketing.

Product candidates that appear promising in the early phases of development, such as in early human clinical trials, may fail to reach the market for a number of reasons, such as the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results; the product candidate was not effective in treating the specified disease or condition; the product candidate had harmful side effects on humans or presented unacceptable safety risks; the governing regulatory authorities (such as the FDA) denied approval to the product candidate altogether or denied a commercially important indicated use; the product candidate was not economical for us to manufacture; and/or the product candidate was not cost effective in light of alternative therapies. We cannot guarantee that we will ever be able to produce commercially successful products.

If we or our manufacturing partners do not obtain and maintain current Good Manufacturing Practices, we will not be able to commercialize our product candidates.

We will depend on our own manufacturing facilities and on those of our partners and other third parties to manufacture products generated through the use of our human antibody technology. Before commercializing a new drug, manufacturers must demonstrate compliance with the applicable cGMP regulations which include

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quality control and quality assurance requirements as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of our technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. We, our partners or third party contract manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements, may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and/or civil or criminal sanctions.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved BLA or NDA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the BLA or NDA. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to FDA s current good manufacturing practice requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval.

Our operations involve hazardous materials and are subject to environmental, health and safety controls and regulations.

As a biopharmaceutical company, we are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with environmental, health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials and we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources and may materially harm our business, financial condition and results of operations.

Our stock price may be volatile.

There has been significant volatility in the market prices of biotechnology companies securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- fluctuations in our operating results;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- published reports by securities analysts;
- progress with clinical trials;
- governmental regulation;
- developments in patent or other proprietary rights;
- developments in our relationship with collaborative partners;
- public concern as to the safety and effectiveness of our products; and
- general market conditions.

During the two-year period ending September 30, 2003, the trading price of our common stock ranged between $2.70 and $24.73. The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these or other factors, including the sale or attempted sale of a large amount of our common stock into the market. Broad market fluctuations may also adversely affect the market price of our common stock.

We have obligations to issue shares of our common stock in the future, which may have a dilutive effect on the shares of our common stock currently outstanding.

As of September 30, 2003, we had 8,443,542 shares of common stock reserved for issuance pursuant to options which had been granted under our stock option plans having a weighted average exercise price of $8.92 per share and we had reserved 6,614,739 shares of common stock for issuance pursuant to future grants of options under our stock option plans. We have filed registration statements on Form S-8 covering all of these shares. Shares issued pursuant to these plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

In addition, as of that date, there were 535,145 shares reserved for issuance pursuant to a deferred compensation plan. The shares reserved for the deferred compensation plan will be issued in various amounts over various periods of time during the next four years. We have filed a registration statement on Form S-8 covering those shares. Shares issued pursuant to this plan, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

As of September 30, 2003, we had reserved 272,578 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 covering those shares. Shares issued under our plans, other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

The exercise of all or a portion of the outstanding options may result in a significant increase in the number of shares of our common stock that will be subject to trading on The Nasdaq National Market, Inc. or NASDAQ, and the issuance and sale of the shares of our common stock upon the exercise thereof may have an adverse effect on the price of our common stock.

As of September 30, 2003, we had 6,067,961 shares of common stock reserved for issuance pursuant to the conversion of $175.0 million aggregate principal amount of our 4.50% Convertible Subordinated Notes due 2006. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 34.6789 shares per each $1,000 principal amount of notes ($28.84 per share), subject to adjustment. Shares issued upon conversion of these notes will be freely tradeable in the open market without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144.

As of September 30, 2003, we had 18,601,190 shares of common stock reserved for issuance pursuant to the conversion of $125.0 million aggregate principal amount of our 4.25% Convertible Senior Notes due 2010. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 148.8261 shares per each $1,000 principal amount of the notes ($6.72 per share), subject to adjustment.

Future sales of our common stock or other securities could cause the market price of our common stock to decline.

As of September 30, 2003, we had 77,897,156 shares of common stock outstanding, of which 1,966,520 are restricted securities as that term is defined in Rule 144 under the Securities Act. Under certain circumstances, these restricted securities may be sold without registration pursuant to such rule. We are unable to predict the effect that sales made under Rule 144 or pursuant to any registration may have on the market price of our common stock. The sale of a significant number of additional securities, or even the possibility thereof, may lower the market price of our common stock.

We have a filed registration statement on Form S-3 under the Securities Act relating to 3,791,346 shares of common stock that may be offered by one of our stockholders. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitations of Rule 144.

On October 17, 2003, we entered into an Amended and Restated License Agreement with Kyowa Hakko Kogyo Co., Ltd., referred to herein as the Kyowa License. Under the terms of the Kyowa License, we received certain intellectual property rights relating to the development and commercialization of our Ultra-Potent Toxin technology. As partial consideration for these rights, we agreed to pay Kyowa a total of $4.0 million, $3.6 million of which was paid through the issuance of 552,020 shares of our common stock to Kyowa on October 28, 2003 with the balance of $0.4 million paid in cash on the same date, representing applicable withholding taxes.

The Kyowa License was the result of the renegotiation of a pre-existing license agreement with respect to Ultra-Potent Toxin technology between Kyowa and Corixa Corporation which license agreement we acquired as part of our purchase of certain assets of Corixa in May 2002. Under the terms of the Corixa Asset Purchase Agreement, upon the execution of the Kyowa License, we are required to make a final payment to Corixa in the amount of $2.5 million. Such amount is payable, at our option, either in cash or in shares of our common stock. We made such payment through the issuance of 353,807 shares of our common stock in satisfaction of this obligation on October 29, 2003.

All shares of our common stock issued to Kyowa and Corixa are fully registered and freely tradeable, provided, however, that Kyowa has agreed not to sell more than 20% of the shares issued to it in any five-trading day period.

In addition, we have filed a shelf registration statement on Form S-3 under the Securities Act relating to the sale of up to $297.15 million of any of the following securities:

debt securities;

preferred stock;

common stock; or

warrants to purchase debt securities, preferred stock or common stock.

We have also filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of our $125.0 million convertible senior notes due August 15, 2010, and up to 18,601,190 shares of our common stock which may be issued upon the conversion of the notes. Upon the effectiveness of this registration statement, the notes and the shares of common stock will be freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitation of Rule 144. In connection therewith, we have agreed to use our best efforts to keep the registration statement continuously effective until the earliest of (i) the sale of all outstanding registrable securities registered under the registration statement; (ii) the expiration of the period referred to in Rule 144(k) of the Securities Act with respect to the notes held by non-affiliates of us; (iii) all the registrable securities have ceased to be outstanding (whether as a result of redemption, repurchase, cancellation, conversion or otherwise); and (iv) two years after the effective date of the registration statement.

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our debt, which may adversely affect our business and the price of our common stock.

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our outstanding 4.50% convertible subordinated notes due 2006. As of the date of this prospectus, $175.0 million aggregate principal amount of these notes was outstanding. In addition, in such event we will be required to offer to repurchase all of our outstanding 4.25% convertible senior notes due August 15, 2010. As of the date of this prospectus, $125.0 million aggregate principal amount of these notes was outstanding. In each instance, we may pay the repurchase price in cash or, at our option, in common stock. These change of control events include, without limitation, (i) the acquisition by any third party of at least 50% of our common stock; or (ii) our merger or consolidation with or into any other person, any merger or consolidation of another person into us or our sale or other disposal of all or substantially all of our assets, except in certain limited circumstances provided in the indentures relating to the notes. Such repurchase rights may be triggered at a time at which we do not have sufficient funds available to pay the repurchase price in cash or determine that payment in cash is otherwise inadvisable. In such event, the issuance of a significant number of additional shares of common stock in payment of the repurchase price may lower the market price of our common stock.

Our restated certificate of incorporation, by-laws, shareholder rights plan and New Jersey law contain provisions that could delay or prevent an acquisition of our company even if the acquisition would be beneficial to our shareholders, and as a result, our management may be come entrenched and hard to replace.

In May 2001, our board of directors adopted a shareholder rights plan. The shareholder rights plan provides for a dividend of one preferred share purchase right on each outstanding share of our common stock. Each right entitles shareholders to buy 1/1000th of a share of our Series A junior participating preferred stock at an exercise price of $150.00. Each right will become exercisable following the tenth day after a person or group announces an acquisition of 20% or more of our common stock. We will be entitled to redeem the rights at $0.001 per right at any time on or before the close of business on the tenth day following acquisition by a person or group of 20% or more of our common stock.

The shareholder rights plan and certain provisions of our restated certificate of incorporation and amended and restated by-laws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. This could limit the price that certain investors might be willing to pay in the future for our common stock.

The provisions of our restated certificate of incorporation and by-laws include:

- a classified board of directors;
- a requirement that special meetings of shareholders be called only by our board of directors, chairman of the board, chief executive officer or president;
- advance notice requirements for shareholder proposals and nominations;
- limitations on the ability of shareholders to amend, alter or repeal our by-laws; and
- the authority of the board of directors to issue, without shareholder approval, preferred stock with such terms as the board of directors may determine.

We are also afforded the protections of the New Jersey Shareholders Protection Act. This New Jersey statute contains provisions that impose restrictions on shareholder action to acquire control of our company.

The effect of the provisions of our shareholder rights plan, restated certificate of incorporation and by-laws and New Jersey law may discourage third parties from acquiring control of our company. In addition, these measures may result in the entrenchment of our management and may prevent or frustrate any attempt by shareholders to replace or remove our current management.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We intend to retain any future earnings to finance the growth and development of our business and we do not plan to pay cash dividends on our common stock in the foreseeable future.

Legislative and regulatory actions, Nasdaq rules, potential new accounting pronouncements and higher insurance costs may impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. For example, effective January 1, 2003, we changed our method of accounting for asset retirement obligations in accordance with Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations* (SFAS No. 143). Previously, we were not required to recognize amounts related to asset retirement obligations. Under SFAS No. 143, we now recognize asset retirement obligations in the period in which they are incurred if a reasonable estimate of a fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately $1.4 million, recognition of an asset retirement obligation liability of approximately $2.2 million and a cumulative effect of a change in accounting principle of approximately $0.8 million or $0.01 per share for the nine month period ended September 30, 2003.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules, are creating uncertainty with respect to, among other things, the enforcement of these new standards and the potential effect thereof for companies such as ours. Insurance costs are increasing as a result of this uncertainty and other factors. Investments required to comply with changes in SEC, Nasdaq and accounting rules may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Item 6. Exhibits and reports on Form 8-K

(a) Reports on Form 8-K:

Form 8-K on July 17, 2003 relating to our offering of $100 million of convertible senior notes due 2010.

Form 8-K on July 18, 2003 relating to the pricing of $100 million of convertible senior notes due 2010.

Form 8-K on July 22, 2003 relating to exercise by initial purchasers of an additional $25 million of convertible senior notes due 2010.

Form 8-K on July 29, 2003 relating to the completion of the sale of $125 million 4.25% convertible senior notes due 2010.

Form 8-K on August 13, 2003 relating to a press release of the Company s financial results for the quarter ended June 30, 2003.

The Company furnished, but did not file, this Current Report on Form 8-K with the SEC.

(b) Exhibits:

Exhibit 31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Exhibit 31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Exhibit 32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
Exhibit 32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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.

MEDAREX, INC.

(Registrant)

Date: November 13, 2003

By: /s/ DONALD L. DRAKEMAN

Donald L. Drakeman

President and Chief

Executive Officer

(Principal Executive Officer)

Date: November 13, 2003

By: /s/ CHRISTIAN S. SCHADE

Christian S. Schade

Senior Vice President

Finance & Administration,

Chief Financial Officer

(Principal Financial and

Accounting Officer)