

MEDAREX INC  
Form 10-Q  
November 13, 2002

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**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 10-Q**

(Mark one)

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2002

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  
(State or Other Jurisdiction of Incorporation or  
Organization)

22-2822175  
(I.R.S. Employer Identification No.)

707 State Road, Princeton, New Jersey  
(Address or Principal Executive Offices)

08540  
(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 o

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

Yes x No o

The number of shares of common stock, \$.01 par value, outstanding as of November 1, 2002 was 76,381,480 shares.

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MEDAREX, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
(In thousands, except share data)

	December 31, 2001	September 30, 2002
		(Unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 31,269	\$ 69,077
Marketable securities	435,683	300,601
Prepaid expenses and other current assets	24,860	21,400
	<u>491,812</u>	<u>391,078</u>
Property, buildings and equipment:		
Land	6,788	6,788
Buildings and leasehold improvements	56,080	66,951
Machinery and equipment	16,188	26,747
Furniture and fixtures	2,819	3,615
Construction in progress	7,767	1,921
	<u>89,642</u>	<u>106,022</u>
Less accumulated depreciation and amortization	(9,782)	(15,833)
	<u>79,860</u>	<u>90,189</u>
Investments in Genmab	65,501	29,994
Investments in IDM	48,199	48,199
Investments in, and advances to, other affiliates and partners	14,384	14,384
Segregated cash	1,300	1,900
Other assets	19,371	9,447
	<u>720,427</u>	<u>585,191</u>
<b>Total assets</b>	<b>\$ 720,427</b>	<b>\$ 585,191</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Trade accounts payable	\$ 3,139	\$ 3,247
Accrued liabilities	21,485	15,511
Deferred contract revenue - current	19,862	3,438
	<u>44,486</u>	<u>22,196</u>
<b>Total current liabilities</b>	<b>44,486</b>	<b>22,196</b>
Deferred contract revenue - long-term	1,597	1,316
Deferred income taxes and other long-term obligations	16,782	
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; 74,005,466 shares issued and 72,876,240 outstanding at December 31, 2001 and 76,220,501 shares issued and 75,349,640 shares outstanding at September 30, 2002	740	762
Capital in excess of par value	608,685	625,271
Treasury stock, at cost 1,129,226 shares in 2001 and 870,861 shares in 2002	(2,840)	(2,190)
Deferred compensation	2,188	1,326
Accumulated other comprehensive income (loss)	(149)	5,497
Accumulated deficit	(126,062)	(243,987)
	<u>(126,062)</u>	<u>(243,987)</u>

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Total shareholders' equity	482,562	386,679
Total liabilities and shareholders' equity	\$ 720,427	\$ 585,191

See notes to these unaudited consolidated financial statements.

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2001	2002	2001	2002
Sales	\$ 879	\$ 176	\$ 623	\$
Contract and license revenues	24,797	22,020	9,170	7,640
Sales, contract and license revenues from Genmab (includes sales of \$9,363 and \$6,555 to Genmab in 2002)	2,913	11,288	1,663	6,989
<b>Total revenues</b>	<b>28,589</b>	<b>33,484</b>	<b>11,456</b>	<b>14,629</b>
Costs and expenses:				
Cost of sales (\$5,678 and \$3,923 from sales to Genmab in 2002)	495	5,729	361	3,923
Research and development	23,714	56,517	11,158	20,902
General and administrative	11,801	17,022	4,690	5,826
Write-off of facility costs		11,294		28
Acquisition of in-process technology		16,312		
<b>Total costs and expenses</b>	<b>36,010</b>	<b>106,874</b>	<b>16,209</b>	<b>30,679</b>
<b>Operating loss</b>	<b>(7,421)</b>	<b>(73,390)</b>	<b>(4,753)</b>	<b>(16,050)</b>
Equity in net loss of affiliate	(3,714)	(11,318)	(1,955)	(4,053)
Interest and dividend income	18,885	14,290	6,423	4,593
Impairment loss on investment in Genmab		(30,971)		(30,971)
Impairment loss on investments in other corporate partners		(7,971)		(3,880)
Additional payments related to asset acquisition		(1,700)		(1,419)
Interest expense	(2,376)	(6,790)	(2,249)	(2,263)
<b>Income (loss) before provision for income taxes</b>	<b>5,374</b>	<b>(117,850)</b>	<b>(2,534)</b>	<b>(54,043)</b>
Provision for income taxes	450	75	150	75
<b>Net income (loss)</b>	<b>\$ 4,924</b>	<b>\$ (117,925)</b>	<b>\$ (2,684)</b>	<b>\$ (54,118)</b>
<b>Basic net income (loss) per share</b>	<b>\$ 0.07</b>	<b>\$ (1.58)</b>	<b>\$ (0.04)</b>	<b>\$ (0.72)</b>
<b>Diluted net income (loss) per share</b>	<b>\$ 0.07</b>	<b>\$ (1.58)</b>	<b>\$ (0.04)</b>	<b>\$ (0.72)</b>
Weighted average number of common shares outstanding				
- basic	73,915	74,612	73,947	75,491
- diluted	75,425	74,612	73,947	75,491

See notes to these unaudited consolidated financial statements.

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MEDAREX, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)  
(In thousands)

	For the Nine Months Ended September 30,	
	2001	2002
Operating activities:		
Net income (loss)	\$ 4,924	\$ (117,925)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	2,470	5,299
Amortization	1,113	2,062
Stock options and awards to employees	205	456
Stock options and warrants to non-employees	15	(8)
Non cash revenue - IDM	(15,175)	(14,332)
Non cash revenue - Genmab	(1,333)	
Write-off of facility costs		11,294
Write-off of in-process technology		14,157
Equity in net loss of Genmab	3,714	11,318
Impairment loss on investment in Genmab		30,971
Impairment loss on investments		7,971
Changes in operating assets and liabilities		
Other current assets	1,303	386
Trade accounts payable	672	108
Accrued liabilities	3,482	(5,376)
Deferred contract revenue	(1,571)	(2,373)
Net cash used in operating activities	(181)	(55,992)
Investing activities:		
Purchase of property and equipment	(48,552)	(32,412)
Proceeds from sale of equipment		640
Decrease in other assets		1
Increase in investments and advances to affiliates and partners	(10,750)	
Decrease (increase) in segregated cash	20,768	(600)
Purchase of marketable securities	(169,500)	(2,500)
Sales of marketable securities	50,069	128,473
Net cash provided by (used in) investing activities	(157,965)	93,602
Financing activities:		
Cash received from sales of securities, net	394	198
Proceeds from sale of convertible subordinated notes, net	169,105	
Principal payments under debt obligations	(19)	
Net cash provided by financing activities	169,480	198
Net increase in cash and cash equivalents	11,334	37,808
Cash and cash equivalents at beginning of period	78,397	31,269
Cash and cash equivalents at end of period	\$ 89,731	\$ 69,077
Non-cash investing and financing activities:		
Issuance of common stock for intangible assets	\$	\$ 5,094

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Supplemental disclosures of cash flow information

Cash paid during period for:

Interest

\$ 1 \$ 7,985

See notes to these unaudited consolidated financial statements.

**MEDAREX, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

(Dollars in thousands, except per share data)

**1. Organization and 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, 2001 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, 2001.

Certain prior period balances have been reclassified to conform with the current period presentation.

**2. Net Income (Loss) per Share**

Basic and diluted earnings per share are calculated in accordance with the Financial Accounting Standards Board (FASB) SFAS No. 128, Earnings per Share. Basic earnings per share is based upon the number of weighted average shares of common stock outstanding. Diluted earnings 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 nine months ended September 30, 2001, the effect of the conversion of the subordinated notes has been excluded from the computation of diluted income per share, as its effect is antidilutive. For the nine months and three months ended September 30, 2002 and the three months ended September 30, 2001, all potentially dilutive securities have been excluded from the computation, as their effect is antidilutive.

The computation of basic and diluted earnings per share is as follows:

	Nine Months Ended September 30		Three Months Ended September 30	
	2001	2002	2001	2002
Basic:				
Net income (loss)	\$ 4,924	\$ (117,925)	\$ (2,684)	\$ (54,118)
Weighted average shares outstanding	73,915,000	74,612,000	73,947,000	75,491,000
Basic net income (loss) per share	\$ 0.07	\$ (1.58)	\$ (0.04)	\$ (0.72)

## MEDAREX, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(Dollars in thousands, except per share data)

## 2. Net Income (Loss) per Share (cont d)

	Nine Months Ended September 30		Three Months Ended September 30	
	2001	2002	2001	2002
Diluted:				
Net income (loss)	\$ 4,924	\$ (117,925)	\$ (2,684)	\$ (54,118)
Weighted average shares outstanding	73,915,000	74,612,000	73,947,000	75,491,000
Net effect of dilutive securities:				
Stock options	1,510,000			
Total adjusted weighted-average shares	75,425,000	74,612,000	75,947,000	75,491,000
Diluted net income (loss) per share	\$ 0.07	\$ (1.58)	\$ (0.04)	\$ (0.72)

## 3. 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 as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. At June, 2002, the Company's investments in the equity securities of Tularik, Inc., Oxford GlycoSciences Plc, and Seattle Genetics, Inc. had traded below the Company's original cost basis for more than six months, at which time the Company deemed that an impairment of these investments had occurred. At September 30, 2002, the Company's investment in Northwest Biotherapeutics, Inc. common stock had traded below the Company's original cost basis for more than six months, at which time the Company determined that an impairment of this investment had occurred. Accordingly, the Company recorded impairment charges of \$7,971 and \$3,880, for the nine and three month periods ended September 30, 2002, respectively, which are recorded in the Company's results of operations. If the Company deems these investments further impaired at the end of any future period, the Company may incur an additional impairment charge on these investments.

## 4. Contingencies

The Company has a contingent commitment to pay up to \$1,000 to Essex Chemical Corporation (Essex) without interest in installments equal to 20% of the Company's net after tax earnings on an annual basis in future years. The Company's contingent commitment, as amended, to pay up to \$1,000 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 an aggregate fair market value equal to the amount owed, provided that



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**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

(Dollars in thousands, except per share data)

such shares are registered with the Securities and Exchange Commission. The Company accrued \$667 related to this liability during 2000 which remains accrued at September 30, 2002.

In the ordinary course of our 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. Asset Acquisition**

On May 23, 2002, the Company and its newly created subsidiary Medarex Belgium, S.A. 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 wholly-owned 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. In addition, the Company agreed to retain approximately 30 Corixa employees related to such product candidates and programs and agreed to sublease approximately 30,000 square feet of laboratory and office space at Corixa's South San Francisco, California facility.

Under the terms of the Asset Purchase Agreement, the Company acquired the assets for \$21,000 (excluding transaction cost of \$405) payable in six equal monthly installments of \$3,500 either in cash, or at the Company's election, in shares of its common stock. As of September 30, 2002, a total of 2,054,235 shares of common stock with a fair value of \$15,750 were issued to Corixa along with cash of \$1,750 as payment for the first five monthly installments. The remaining \$3,500, representing the last monthly installment, is included as a current liability in the Company's September 30, 2002 consolidated balance sheet. In the event that, during any month during the six-month period following the closing of the transaction, Corixa sells all of the shares of the common stock delivered as payment for the preceding monthly installment and the proceeds of such sale are less than \$3,500, the Company must pay the difference to Corixa in cash. If such sale proceeds are greater than \$3,500 Corixa must pay the Company an amount equal to 50% of any such excess in cash. In the event that, during any month during the six-month period, Corixa does not sell all of the shares of common stock delivered as payment of the preceding monthly installment, then there will be no such adjustments. As of September 30, 2002, the Company paid \$854 and accrued approximately \$846, which was paid in October 2002, representing the difference between the proceeds received by Corixa from the sale of the Company's common stock and the total amount due under the first four monthly installments. The total difference of approximately \$1,700 relating to the first four monthly installments is included as a charge to earnings in the Company's consolidated statement of operations for the nine months ended September 30, 2002.

The Company also purchased from Corixa certain equipment and laboratory supplies for \$2,500, of which approximately \$2,100 has been capitalized with the remaining \$400 charged to expense.

As part of this transaction, Corixa may receive up to an additional \$6,000 in future consideration in cash or, at the Company's election, in shares of common stock, based upon certain contingencies.

**MEDAREX, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

(Dollars in thousands, except per share data)

The total cost of the asset acquisition was \$21,405, of which \$405 represented transaction costs. This amount has been allocated as follows based upon an independent third party valuation:

In-process technology	\$ 16,312
Patents	4,388
Acquired workforce	705
	<u>          </u>
	<u>\$ 21,405</u>

**6. Licensing, Research and Development Agreements**

As contemplated by a December 1999 binding letter of intent, effective September 4, 2002, the Company entered into a Collaboration and License Agreement with Kirin Brewery Co., Ltd., which provides for the exchange by Kirin and the Company of certain cross-licenses for each other's technology for the development and commercialization of human antibody products. The License Agreement supercedes the binding letter of intent. Pursuant to the letter of intent, the Company and Kirin developed the KM-Mouse, a unique crossbred mouse which combines the traits of the Company's HuMAb-Mouse<sup>®</sup> with Kirin's TC Mouse. Under the License Agreement, the Company and Kirin are exchanging cross-licenses with respect to the KM-Mouse and other antibody-generating mice. In addition, each of the cross-licenses granted under the License Agreement are subject to certain license, milestone and royalty payments by each party to the other.

**7. 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 a 33% interest in Genmab as of December 31, 2000. In December 2001, 88,600 shares of Genmab stock owned by the Company were awarded as a bonus to the President and Chief Executive Officer of the Company, reducing the Company's ownership percentage in Genmab to approximately 32.6%. In June 2002, the Company's ownership percentage was further reduced to approximately 31.2% as a result of the issuance by Genmab of new shares to a corporate partner. Due to the size of the Company's equity interest in Genmab, the Company currently accounts for its interest in Genmab under the equity method of accounting, which provides that the Company must include a portion of Genmab's income and losses equal to the Company's percentage equity interest in Genmab in the Company's financial statements. During the nine and three-month periods ended September 30, 2001, the value of the Company's investment in Genmab was adjusted to reflect the Company's share of Genmab's loss (\$3,714) and (\$1,955), respectively, and an unrealized gain (loss) of (\$1,139) and \$5,560, respectively, related to foreign exchange translation. During the nine and three-month periods ended September 30, 2002, the value of the Company's investment in Genmab was further adjusted to reflect the Company's share of Genmab's net loss (\$11,318) and (\$4,053), respectively, and an unrealized gain (loss) of \$6,782 and (\$697), respectively, related to foreign exchange translations. Such foreign exchange translation adjustments are included within accumulated other comprehensive income in the Company's consolidated balance sheet.

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

(Dollars in thousands, except per share data)

On September 24, 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 24, 2002 press release, the market value of Genmab's stock decreased by approximately 60%, and accordingly, the Company recorded an impairment charge of approximately \$30,971 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.

Summary financial information for Genmab is as follows:

	As of and for the Nine months Ended September 30	
	2001	2002
Current Assets	\$ 229,744	\$ 199,320
Non Current Assets	18,823	26,788
Current Liabilities	7,094	11,969
Non Current Liabilities	3,571	1,802
Net Sales		
Gross Profit		
Net Loss	(11,262)	(35,400)

**8. Comprehensive Income (Loss)**

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

	Nine months Ended September 30		Three months Ended September 30	
	2001	2002	2001	2002
Net income (loss)	\$ 4,924	\$ (117,925)	\$ (2,684)	\$ (54,118)
Unrealized gain (loss) on securities	4,161	(1,138)	4,624	590
Unrealized foreign exchange gain (loss)	(1,139)	6,783	5,560	(697)
Total comprehensive income (loss)	\$ 7,946	\$ (112,280)	\$ 7,500	\$ (54,225)

**9. 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.

**MEDAREX, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

(Dollars in thousands, except per share data)

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

Customer	Nine months Ended September 30		Three months Ended September 30	
	2001	2002	2001	2002
IDM S.A.	53%	43%	45%	29%
Genmab A/S	13%	34%	13%	48%
Kirin Brewery Co., Ltd.	16%	0%	20%	0%

No other single customer accounted for more than 10% of the Company's total revenues for the nine and three months ended September 30, 2001 and 2002, respectively.

**10. Write-off of Facility Costs**

During the second quarter of 2002, the Company made a determination to delay indefinitely the planned construction of a large-scale manufacturing facility at its Bloomsbury, New Jersey location and, instead, to pursue late-stage clinical and commercial supply agreements with third party manufacturers with available capacity to meet the Company's current internal production timetables. As of September 30, 2002, the Company had not yet entered into any such supply agreements. As a result of this decision, the Company recorded a charge of \$11,294, representing the write-off of design, engineering and other pre-construction costs. Furthermore, the Company has expanded its existing clinical manufacturing capacity in its Annandale, New Jersey facility, which it expects will meet all near-term production demands. During the second quarter of 2002, the Company also completed the renovation of its Bloomsbury development facility, which currently accommodates approximately 150 employees for antibody research, development and manufacturing.

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**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 but are not 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**

Dollars reported in thousands, except per share data.

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<sup>SM</sup>. We believe this unique combination of human antibody technologies enables us to rapidly create and develop high affinity, fully human antibodies to a wide range of potential disease targets for therapeutic antibody products, including products for the treatment and/or diagnosis of cancer, inflammation, auto-immune and other life-threatening and debilitating diseases.

With our UltiMab platform, which includes our HuMab-Mouse®, Kirin Brewery Co., Ltd.'s TC Mouse and the KM-Mouse, a unique cross-bred mouse we developed in partnership with Kirin, we believe that 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 infrastructure. As of September 30, 2002, we have 42 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to otherwise acquire the rights to use our proprietary technology in their development of new products, including industry leaders such as Amgen, Inc., Centocor, Inc. (a subsidiary of Johnson & Johnson), Eli Lilly & Company, Human Genome Sciences, Inc., Immunex Corporation, Novartis Pharma AG, Novo Nordisk A/S, and Schering AG. Some of these are licensing partnerships, with the potential to provide us with 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 that might be sold commercially.

Our licensing partners typically obtain licenses to one or more of our antibody generating technologies which allow these partners to develop and commercialize antibody-based products. 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 corporate partner may elect to enter into a research license for antibodies to a particular designated target. Subsequently, our licensing partner may elect to obtain a commercial license for monoclonal antibodies to a particular target. As of September 30, 2002, 21 of our total partnerships were licensing partnerships, and we expect to continue adding additional licensing partnerships in the future.

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 leading companies in the fields of genomics and proteomics to jointly develop and commercialize human antibody products. Typically, our collaborators will provide target antigens, and we will generate antibodies against those antigens using our UltiMab Human Antibody Development System. We and our collaborators typically agree to share equally the costs of clinical development and manufacturing as well as our revenues, expenses and profits associated with the products. As of September 30, 2002, 21 of our total partnerships were collaborative partnerships, and we expect to continue adding additional collaborations in the future.

**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 \$7,000 to \$10,000 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 and then sold to corporate partners as well as 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 our 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 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 accounting policies that require our most difficult, subjective or complex judgments in the preparation of our consolidated financial statements to be as follows:

**Revenue Recognition.** Historically, a significant portion of our revenue has been recognized pursuant to collaboration and license agreements with our partners. Revenue is recognized as research services are performed over the related funding periods for each agreement. Deferred revenue may result when the level of effort we are required to expend during a specific period is less in comparison than the

funds we received under the respective agreements or when funds received are refundable under certain circumstances. Milestone payments are recognized as revenue upon achievement of specific milestones. Non-refundable upfront payments received in connection with our licensing partnerships are deferred and recognized as revenue on a straight-line basis over the relevant periods of the respective agreements.

**Investments.** All marketable securities are classified as available-for-sale securities and are carried at fair value. Marketable securities include publicly traded debt and equity securities accounted for under the cost method. These securities trade on listed exchanges; therefore, fair value is readily available. Under our accounting policy, a decline in the fair value of a marketable security is deemed to be other than temporary and such marketable security is generally considered to be impaired if its fair value is less than our cost basis of 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 in the fair value of a marketable security below our cost basis is determined to be other than temporary, such marketable security is written down to the estimated fair value as a new cost basis and the amount of the write down is included in earnings as an impairment charge.

In addition, in connection with our collaborative partnering business, we make strategic investments in the securities 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.

**Acquired In-Process Technology.** In-Process Technology expense is determined based on an analysis using risk-adjusted cash flows expected to be generated by products that may result from in-process technologies which have been acquired. This analysis includes forecasting future cash flows that are expected to result from the progress made on each in-process project prior to the acquisition date. Cash flows are estimated by first forecasting, on a product-by-product basis, net revenues expected from the sales of the first generation of each in-process project and risk adjusting these revenues to reflect the probability

of advancing to the next stage of the FDA approval process. The forecast data in the analysis is based on internal product level forecast information maintained by us in the ordinary course of business. The inputs used in analyzing In-Process Technology is based on assumptions, which we believe to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Appropriate operating expenses are deducted from forecasted net revenues on a product-by-product basis to establish a forecast of net returns on the completed portion of the in-process technology. Finally, net returns are discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and our company as well as product specific risks associated with the acquired in-process research and development products. The product specific risk factors include the product's phase of development, type of antibody under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, a discount rate is used for the valuation, which represents a considerable risk premium to our weighted average cost of capital. The valuations used to estimate In-Process Technology require us to use significant estimates and assumptions that if changed, may result in a different valuation for In-Process Technology. A valuation for our acquisition of assets from Corixa Corporation was completed by an independent third-party in accordance with SEC guidelines.

## Results of Operations

### *Nine months ended September 30, 2001 and 2002*

Revenue increased by \$4,895, from \$28,589 to \$33,484, during the nine-month period ended September 30, 2002, a 17% increase as compared to the nine-month period ended September 30, 2001. The increase relates principally to \$8,550 of sales of MDX-CD4 to Genmab A/S, partially offset by \$4,500 in lower contract and license revenues from Kirin. As a result of Genmab's recently 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 increased by \$5,234, from \$495 to \$5,729, during the nine-month period ended September 30, 2002, a 1,057% increase as compared to the nine-month period ended September 30, 2001. The increase primarily reflects the production cost of MDX-CD4 that was sold to Genmab in 2002.

Research and development expenses are largely comprised of personnel costs, those expenses related to facilities for our clinical research, development and clinical trial manufacturing efforts, third party research costs, research supply costs and license and technology access fees. Research and development expenses for our products in development increased by \$32,803, from \$23,714 to \$56,517, during the nine-month period ended September 30, 2002, a 138% increase as compared to the nine-month period ended September 30, 2001. The increases relate primarily to costs associated with the following:

Personnel costs for the nine-month period ended September 30, 2002 increased by \$10,528, from \$9,159 to \$19,687, a 115% increase as compared to the nine-month period ended September 30, 2001, primarily as the result of the hiring of an additional 182 employees since September 30, 2001. The increase in staff was required to support higher levels of product development and clinical trial manufacturing activities, the continued development of our UltiMab system, and the performance of contract services for our partners and clinical activities. Included in the increase are salaries, benefits, payroll taxes and recruiting costs. We expect personnel costs to increase further, but at a slower rate, as we continue



to increase our product development activities and progress our products in clinical trials.

Research supply costs for the nine-month period ended September 30, 2002 increased by \$6,429, from \$4,571 to \$11,000, a 141% increase as compared to the nine-month period ended September 30, 2001. Included in these costs are materials and small equipment associated with the development of our products. We expect these costs to increase as we continue to expand our research and product development activities.

Third party research costs for the nine-month period ended September 30, 2002 increased by \$5,767, from \$(2,490) to \$3,277, as compared to the nine-month period ended September 30, 2001. In 2000 we paid a \$5,000 upfront fee to Eos Biotechnology, Inc. under our binding letter of intent. In April 2001, Eos refunded the \$5,000 fee as part of a restructuring of the collaboration. This refund was recorded as a reduction of research and development expenses during 2001. Excluding the refund, the periods were comparable. 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.

Facility costs for the nine-month period ended September 30, 2002 increased by \$5,206, from \$5,951 to \$11,157, an 87% increase as compared to the nine-month period ended September 30, 2001. The increase in facility costs primarily relates to the substantial investments made in our three research and development facilities during 2001 and the first nine months of 2002. Such expenditures included: building and land improvements, machinery and lab equipment, furniture and fixtures and other related costs. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for the nine-month period ended September 30, 2002, as compared to the same period in 2001. We expect to incur future facility costs as a result of continued capital expansion, renovations and replacements but at a reduced rate.

License and technology access fees for the nine-month period ended September 30, 2002 increased by \$2,060, from \$1,115 to \$3,175, a 185% increase as compared to the nine-month period ended September 30, 2001. In connection with our collaboration and license agreement with Tularik, Inc. during the first quarter of 2002 we paid a premium of \$2,500 for the purchase of Tularik common stock, representing technology access rights. This premium was charged to expense. We expect license fees, including funds paid to certain partners, to increase in the future.

We also expect expenses related to clinical trials to increase in the future as we continue to develop our therapeutic product 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 development from preclinical to Phase III. The successful development and commercialization 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

regulatory approval or 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 include compensation and other expenses related to finance and administrative personnel, legal services and business development. General and administrative expenses for the nine-month period ended September 30, 2002, increased by \$5,221, from \$11,801 to \$17,022, a 44% increase as compared to the nine-month period ended September 30, 2001. The increase is primarily attributable to higher personnel costs of \$2,460, consulting expenses of \$1,000 and depreciation expense of \$481. 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 large scale 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 to meet our current internal production timetables. As of September 30, 2002, we had not yet entered into any such supply agreements. As a result of this decision, we recorded a charge of \$11,294 during the nine-month period ended September 30, 2002, representing the write-off of design, engineering and other pre-construction costs. Furthermore, we have expanded our existing clinical manufacturing capacity in our Annandale, New Jersey facility, which we expect will meet all near-term production demands. We now expect our capital expenditures to be approximately \$36,000 in 2002 rather than \$60,000, as originally contemplated in the first quarter of 2002, but this is subject to change.

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 \$21,405. Based upon an independent third party valuation, \$16,312 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, 2002, increased by \$7,604, from \$3,714 to \$11,318, a 205% increase as compared to nine-month period ended September 30, 2001. This increase was primarily the result of Genmab's increased activity in the research, development and expansion of its business. Due to the size of our equity investment in Genmab (approximately 31.2%), Genmab is an affiliated company and is accounted for using 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 financial statements. We expect equity in net loss of Genmab to increase in the near future due to Genmab's publicly stated intention to make additional investments in research and development to develop its own product pipeline.

Interest and dividend income for the nine-month period ended September 30, 2002, decreased by \$4,595, from \$18,885 to \$14,290 a 24% decrease as compared to the nine-month period ended September 30, 2001. The decrease reflects lower interest income due to decreasing interest rates received on our investments partially offset by our higher average cash balances as the result of proceeds received from the June 26, 2001 public offering of our 4.50% convertible subordinated notes due in 2006.

Impairment loss on investment in Genmab of \$30,971 resulted 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 an impairment charge in the third quarter of 2002 as a result

of the decrease in the market 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.

Impairment loss on investments in other corporate partners of \$7,971 during the nine-month period ended September 30, 2002 represents a write-down of the value of our investments in Oxford GlycoSciences Plc, Northwest Biotherapeutics, Inc., Seattle Genetics, Inc. and Tularik, Inc. as part of our collaborations with these 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 these investments to be further impaired at the end of any future period, we may incur an additional impairment charges on these investments.

Additional payments related to asset acquisition of \$1,700 represents additional payments to Corixa in connection with the first four monthly installments required under the Corixa Asset Purchase Agreement. Under the terms of this agreement, under certain circumstances, we are required to pay to Corixa an amount equal to the difference between the proceeds received by Corixa 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 agreement. We anticipate additional charges in the fourth quarter of 2002 related to payment of the final two installments of the purchase price.

Interest expense during the nine-month period ended September 30, 2002 increased by \$4,414 from \$2,376 to \$6,790, a 186% increase, as compared to the nine-month period ended September 30, 2001. This increase reflects interest expense incurred on our 4.50% convertible subordinated notes issued on June 26, 2001 and due in 2006. Interest on the notes is due on January 1 and July 1 of each year.

#### ***Three months ended September 30, 2001 and 2002***

Revenue increased by \$3,173 during the three-month period ended September 30, 2002, from \$11,456 to \$14,629, a 28% increase as compared to the three-month period ended September 30, 2001. The increase relates principally to higher sales revenues of MDX-CD4 to Genmab of \$5,972 partially offset by lower contract and license revenues from Kirin of \$1,500 and Genmab of \$1,229. As a result of Genmab's recently announced decision to wind down its anti-CD4 program for rheumatoid arthritis, we anticipate that sales of MDX-CD4 (and corresponding cost of sales) to Genmab 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 increased by \$3,562 during the three-month period ended September 30, 2002, from \$361 to \$3,923, a 987% increase as compared to the three-month period ended September 30, 2001. The increase primarily reflects the production cost of MDX-CD4 that was sold to Genmab in the third quarter of 2002.

Research and development expenses are largely comprised of personnel costs, those expenses related to facilities for our clinical research, development and clinical trial manufacturing efforts, third party research costs and supply costs. Research and development expenses for our products in development increased by \$9,744 during the three-month period ended September 30, 2002, from \$11,158 to \$20,902, an 87% increase as compared to the three-month period ended September 30, 2001. The increases relate primarily to costs associated with the following:

Personnel costs for the three-month period ended September 30, 2002 increased by \$4,162, from \$3,741 to \$7,903, a 111% increase as compared to the three-month period ended September 30, 2001 primarily as the result of the hiring of an additional 182 employees since September 30, 2001. The increase in staff was

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required in order to support higher levels of product development and clinical trial manufacturing activities, the continued development of our UltiMab system, and the performance of contract services for our partners and clinical activities. Included in the increase are salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to increase further, 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 three-month period ended September 30, 2002 increased by \$2,478, from \$2,311 to \$4,789, a 107% increase as compared to the three-month period ended September 30, 2001. The increase in 2002 primarily relates to the substantial investments made in our three research and development facilities during 2001 and the first nine months of 2002. Such expenditures included: building and land improvements, machinery and lab equipment, furniture and fixtures and other related costs. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for the three-month period ended September 30, 2002, as compared to the same period in 2001. We expect facility costs to increase in future periods as a result of our continued capital expansion plans but at a reduced rate.

Research supply costs for the three-month period ended September 30, 2002 increased by \$1,637, from \$2,240 to \$3,877, a 73% increase as compared to the three-month period ended September 30, 2001. Included in these costs are materials and equipment associated with the development of our products. We expect these costs to increase as we continue to expand our research and product development activities.

As stated earlier herein, we expect expenses related to clinical trials to increase in the future as we continue to develop our therapeutic product pipeline.

General and administrative expenses include compensation and other expenses related to finance and administrative personnel, legal services and business development. General and administrative expenses for the three-month period ended September 30, 2002, increased by \$1,136, from \$4,690 to \$5,826, a 24% increase as compared to the three-month period ended September 30, 2001. The increase is primarily attributable to higher personnel costs (\$806), consulting expenses (\$215), legal fees (\$155) and insurance costs (\$155). 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, 2002, increased by \$2,098, from \$1,955 to \$4,053, a 107% increase as compared to the three-month period ended September 30, 2001. This increase was primarily the result of Genmab's increased activity in research, development and expansion of its business. Genmab is an affiliated company and is accounted for using the equity method. We expect equity in net loss of Genmab to increase in the near future due to the Genmab's publicly stated intention to make additional investments in research and development to develop its own product pipeline.

Interest and dividend income for the three-month period ended September 30, 2002, decreased by \$1,830, from \$6,423 to \$4,593, a 28% decrease as compared to the three-month period ended September 30, 2001. The decrease reflects lower interest rates received on our investments, partially offset by our higher

average cash balances as the result of proceeds received from the June 26, 2001 public offering of our 4.50% convertible subordinated notes due in 2006.

Impairment loss on investment in Genmab of \$30,971 resulted 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. The Company recorded an impairment charge in the third quarter of 2002 as a result of the decrease in the market value 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.

Impairment loss on investments in other corporate partners of \$3,880 during the three-month period ended September 30, 2002 represents a write-down of the value of the common stock of Northwest Biotherapeutics, Inc. as part of our collaboration. During the third quarter of 2002, the decline in the value of this investment was determined to be other than temporary.

Additional payments related to asset acquisition of \$1,419 represents additional payments to Corixa in connection with the second, third and fourth monthly installments required under the Corixa Asset Purchase Agreement. Under the terms of this agreement, under certain circumstances, we are required to pay to Corixa an amount equal to the difference between the proceeds received by Corixa 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 agreement. We anticipate additional charges in the fourth quarter of 2002 related to payment of the final two installments of the purchase price.

Interest expense during the three-month period ended September 30, 2002 increased by \$14 from \$2,249 to \$2,263 as compared to the three-month period ended September 30, 2001. This increase reflects interest expense on our 4.50% convertible subordinated notes issued on June 26, 2001 and due in 2006. Interest on the notes is due on January 1 and July 1 of each year.

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

As of September 30, 2002, we had cash, cash equivalents and marketable securities of \$369,678. We invest our cash equivalents and marketable securities primarily in highly liquid, interest bearing, investment grade and government securities in order to preserve capital.

We require cash to fund our operations, make capital expenditures and strategic investments, and to pay debt service on our convertible note issue. 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 and technology transfer and license fees. We expect to continue to fund our cash requirements from these sources in the future.

**Cash Used in Operations.** Net cash used in operating activities for the nine months ended September 30, 2002 was \$55,992 compared with net cash used in operating activities of \$181 for the nine months ended September 30, 2001. The increase in cash used in operating activities compared to the same period in 2001 relates primarily to the following significant increases:

an increase of \$29,881 (adjusted for non cash expense of \$2,922) of research and development expenditures related to the development of new products;

an increase of \$5,234 in the cost of sales including the particular cost of MDX-CD4 that was sold to Genmab;

an increase of \$4,647 (adjusted for non cash expense of \$574) in general and administrative expenses primarily related to an increase in higher personal costs and consulting expenses.

As indicated in the section herein entitled *Results of Operations*, the increase in research and development expenditures results from higher personnel costs, those expenses related to facilities for our clinical research, development and manufacturing efforts, third party research costs, research supply costs and license and technology access fees. The increase in cash used in operations also resulted from reduced investment income and interest paid to our convertible noteholders.

***Cash Provided by Investing Activities.*** Investing activities for the nine months ended September 30, 2002 provided \$93,602 of cash as compared to a use of \$157,965 of cash for the corresponding period in 2001. The decrease in cash provided by investing activities was primarily the result of the following factors:

Investments of \$32,412 and \$48,552 in capital expenditures for the nine months ended September 30, 2002 and 2001, respectively. The decrease in capital spending was primarily related to the completion of the renovation of our existing Bloomsbury, New Jersey facility, which was opened in May 2001;

Net purchases of securities for the nine months ended September 30, 2001 of \$119,431 was primarily a result of the proceeds received from our convertible note offering in June 2001;

Net sales of securities for the nine months ended September 30, 2002 of \$125,973 was primarily to fund 2002 operations and capital expenditures.

***Cash Provided by Financing Activities.*** Net cash provided by financing activities for the nine months ended September 30, 2002 was \$198 as compared to \$169,480 for the nine months ended September 30, 2001. This decrease in cash provided by financing activities is due to the \$175,000 4.50% convertible subordinated notes due 2006 which were issued during the second quarter of 2001.

***Other Liquidity Matters.*** In November 2000, we purchased our Milpitas, California facility for approximately \$14,600. We previously leased this facility. This property contains approximately 57,000 square feet of laboratory and office space and, as of September 30, 2002, we had cumulatively expended approximately \$25,000 on renovating and expanding this facility.

In January 2001, we purchased a facility and adjacent land in Bloomsbury, New Jersey for approximately \$9,200. The Bloomsbury facility is situated on approximately 106 acres of land and currently contains space for approximately 165,000 square feet of laboratory and office space. We currently are using 75,000 square feet as laboratory and office space. We have completed the initial phase of the Bloomsbury facility and have cumulatively expended approximately \$55,000. We had originally intended to build a large-scale clinical and commercial manufacturing facility on this property, but during the second quarter of 2002, we made a determination to delay indefinitely planned construction at the Bloomsbury location and to pursue late-stage clinical and commercial supply agreements with third party manufacturers with available capacity to meet our current internal production timetables. For the balance of 2002, we expect to expand our research facility in Milpitas, California and continue the expansion of the existing laboratory and development capacity in Bloomsbury and Annandale, New Jersey. We currently expect the total costs for this expansion in 2002 to be up to approximately \$36,000, rather than \$60,000, as originally contemplated in the first quarter of 2002, but this is subject to change.

In July 2002, we entered into a lease for 36,676 square feet of laboratory and office space in Sunnyvale, California. We plan to spend \$4,400 on leasehold improvements for this space and expect to occupy this space during the fourth quarter of 2002. This space will replace the Corixa facility in South San Francisco that is presently occupied by 30 employees retained in connection with our acquisition of certain assets of Corixa, discussed more fully below.

In connection with our merger with Essex Medical Products in 1987, we issued promissory notes to Essex Chemical Corporation in the principal amount of \$100 and committed to pay 20% of our net after-tax income until a total of \$1,000 has been paid, contingent upon the occurrence of certain events. On June 6, 1991, we repaid the \$100 of notes, plus accrued interest to Essex. As the result of our net income in 2000 we accrued \$667 payable to Essex, which remains accrued at September 30, 2002. 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 SEC.

In July 2000, we entered into an agreement with Immuno-Designed Molecules S.A. whereby we licensed to IDM certain of our technologies in exchange for equity units in IDM. As a result of this transaction, we realized a gain from the transfer of technology of approximately \$40,500 (based upon an independent valuation). In accordance with Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, we will recognize this gain over a 24-month period as contract revenue. Accordingly, during the nine months ended September 30, 2002, we recognized the remaining amount of \$14,332 as contract revenue. As of September 30, 2002, there is no additional revenue to recognize regarding this transaction.

On May 23, 2002, we entered into an Asset Purchase Agreement with 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. In addition, we agreed to retain approximately 30 Corixa employees related to such product candidates and programs and agreed to sublease approximately 30,000 square feet of laboratory and office space at Corixa's South San Francisco facility. This sublease is for a six month period with an option to renew for an additional six months.

Under the terms of the Asset Purchase Agreement, we acquired the Corixa assets for \$21,000 (excluding transaction cost of \$405) payable in six equal monthly installments of \$3,500 either in cash, or at our election, in shares of common stock. As of September 30, 2002, a total of 2,054,235 shares of common stock with a fair value of \$15,750 were issued to Corixa along with cash of \$1,750 as payment for the first five monthly installments. The remaining \$3,500, representing the last monthly installment, is included as a current liability in our September 30, 2002 consolidated balance sheet. In the event that, during any month during the six-month period following the closing of the transaction, Corixa sells all of the shares of the common stock delivered as payment for the preceding monthly installment and the proceeds of such sale are less than \$3,500, we must pay the difference to Corixa in cash. If such sale proceeds are greater than \$3,500, Corixa must pay us an amount equal to 50% of any such excess in cash. In the event that, during any month during the six-month period, Corixa does not sell all of the shares of common stock delivered as payment of the preceding monthly installment, then there will be no such adjustments. For the three and nine-months periods ended September 30, 2002, we expensed approximately \$1,419 and \$1,700, respectively, representing the cash shortfall experienced by Corixa, of which \$846 was accrued as of September 30, 2002 and paid in October 2002. Such amounts are reflected as Additional payments related to asset acquisition

in our consolidated statement of operations for the nine and three-month periods ended September 30, 2002. We anticipate additional charges in the fourth quarter of 2002 related to payment of the final two installments of the purchase price.

We also purchased from Corixa certain equipment and laboratory supplies for \$2,500 of which approximately \$2,100 has been capitalized with the remaining \$400 charged to expense.

As part of this transaction, Corixa may receive up to an additional \$6,000 in future consideration in cash or, at our election, in shares of common stock, based upon certain contingencies.

During the third quarter of 2002, we terminated all consulting arrangements with members of our board of directors and adopted new compensation arrangements for board members. Each board member other than the Chairman will now receive an annual retainer of \$20 and 14,000 stock options. The Chairman of our board will receive an annual retainer of \$40 and 28,000 stock options. In addition, board members will receive nominal fees for participation on board committees and attendance at board meetings.

**Future Liquidity Resources.** Our current sources of liquidity are cash, cash equivalents and marketable securities, interest and dividends earned on such cash, sales of our products for research, and contract and licensing revenue. 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, we may require additional financing within this time and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods.

Our future capital requirements will depend on numerous factors, including interest income, the expansion of our research and development activities, including pre-clinical and clinical product development and clinical trials. This will include amounts spent on proprietary and co-development of product candidates.

We intend to use our available cash to finance these programs, but we may also pursue other financing alternatives to meet these requirements. The use of cash on hand or other financial alternatives will depend on several factors including the future success of our products in clinical development, the prevailing interest rate environment, and the access to capital as the condition of the financial markets changes.

#### **Recently Issued Accounting Pronouncements**

In September 2001, the Financial Accounting Standards Board, or FASB, issued Statement No. 142, *Goodwill and Other Intangible Assets*, effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill and intangible assets deemed to have infinite lives will no longer be amortized but will be subject to annual impairment tests in accordance with the Statement. Other intangible assets will continue to be amortized over their useful lives. The January 1, 2002 adoption of Statement No. 142 did not have any impact on our consolidated financial position or results of operations as we currently have no goodwill or intangible assets with indefinite useful lives.

In August 2001, the FASB issued Statement of Financial Accounting Standards, or Statement No. 143, *Accounting for Asset Retirement Obligations*, which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. Statement 143 requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of tangible long-



lived assets. Since the requirement is to recognize the obligation when incurred, approaches that have been used in the past to accrue the asset retirement obligation over the life of the asset are no longer acceptable. Statement 143 also requires the enterprise to record the contra to the initial obligation as an increase to the carrying amount of the related long-lived asset (i.e., the associated asset retirement costs) and to depreciate that cost over the life of the asset. The liability is increased at the end of each period to reflect the passage of time (i.e., accretion expense) and changes in the estimated future cash flows underlying the initial fair value measurement. Enterprises are required to adopt Statement 143 for fiscal years beginning September 15, 2002. We are currently reviewing the impact of Statement 143 and do not believe adoption of this Statement will have a material impact on our operating results or financial position.

In October 2001, the FASB issued Statement No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, effective for fiscal years beginning after December 15, 2001. Statement No. 144 supersedes Statement No. 121 and identifies the methods to be used in determining fair value. The January 1, 2002 adoption of Statement No. 144 did not have any impact on our consolidated financial position or results of operations.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risks.**

We do not currently use derivative financial instruments in our investment portfolio. However, 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 have exposure to market risks associated with changes in interest rates, as we have no variable interest rate debt outstanding. We do not believe we have any material exposure to market risks associated with interest rates.

We have been and may continue to be exposed to exchange conversion differences in translating the foreign results from operations of our investment in Genmab to U.S. dollars. Depending upon the strengthening or weakening of the U.S. dollar, the conversion difference could be significant to our recording of our investment in Genmab. Foreign exchange translation gains or losses have been and will continue to be recorded within accumulated other comprehensive income in the equity section of our balance sheet.

### **Item 4. Controls and Procedures**

Based upon an evaluation within the 90 days prior to the filing date of this report, our Chief Executive Officer and Chief Financial Officer have each concluded that our disclosure controls and procedures as defined in Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as amended, are effective, as of the evaluation date, in timely alerting them to material information relating to our Company required to be included in our reports filed or submitted under the Exchange Act. Since the date of the evaluation, there have been no significant changes in our internal controls or in other factors that could significantly affect such controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

## **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. Dollars reported in thousands, except per share data.

#### **Our product candidates are in early stages of development.**

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 early stages of development. Only a limited number of fully human antibody product candidates employing our human antibody technology have been generated pursuant to our collaborations. Investigational New Drug Applications, or INDs, have been submitted to the United States Food and Drug Administration, or FDA, for only a subset of these candidates, and clinical trials have not yet commenced for all of these candidates. Only one of these product candidates is currently in the Phase III clinical trial stage. 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 will suffer.

#### **Our products are still under development, and no revenues have been generated from their sale.**

We have entered into corporate partnerships with a number of companies and are seeking additional alliances that will support the costs of developing our portfolio of antibody-based product candidates. The success of these products is dependent upon the efforts of our corporate partners in developing these products in the future. Neither we nor our corporate partners know if any of these products will be effective.

#### **Successful development of our products is uncertain.**

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;

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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 collaborative partners not to pursue product development;

failure by our collaborative partners to develop products successfully; and

failure to achieve market acceptance.

Because of these risks, our research and development efforts or those of our licensing 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 collaborative 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 collaborative partners. 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 decided, in consultation with our partners, to discontinue our clinical development programs for MDX-33 and MDX-44, respectively. MDX-33 is a humanized antibody targeting CD64 that is designed for the treatment of idiopathic thrombocytopenia purpura, or ITP. MDX-44 is a humanized antibody targeting CD64 that has been studied in connection with atopic dermatitis.

**We have incurred large operating losses and these losses may continue.**

We have incurred large operating losses and these losses may continue. In particular, as of September 30, 2002, we had an accumulated deficit of approximately \$243,987. 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;

investing in new technologies; and

expanding of our manufacturing and production capabilities.

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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.**

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 collaborative agreements;
- the introduction of new products and services by us, our collaborative 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.

**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, the company or our licensees must demonstrate proof of safety and efficacy in humans, as well as quality manufacturing capability. For biological products, purity and potency must also be demonstrated. To meet these requirements, we or our licensees 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 subject to the preclinical testing and clinical trials of certain product candidates conducted by our licensees and collaborative partners over which we have no control. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

- 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; and

delays, suspension, or termination of the trial 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 trial.

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. The failure of clinical trials to demonstrate safety, effectiveness, potency and/or purity for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations will suffer.

**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 recently announced that it is 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 corporate 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 tablets or capsule delivery. The degree of market acceptance of any product candidates employing our technology will depend on a number of factors, including:

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 will suffer.

**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 provide 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 corporate 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 employing our human antibody technology. These variations could harm our ability and the ability of our corporate partners to sell products employing our human antibody technology in commercially acceptable quantities at profitable prices.

**We have limited manufacturing capabilities.**

Before approving a new drug or biologic product, 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 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;
- changes in FDA requirements;
- production costs; and
- 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. 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 have no sales or marketing experience.**

We currently have no sales, marketing or distribution capabilities. We may need to enter into arrangements with third parties to market and sell certain of our products. We may not be able to enter into marketing and sales arrangements with others on acceptable terms, if at all. To the extent that we enter into marketing and sales arrangements with other companies, our revenues, if any, will depend on the efforts of others. These efforts may not be successful. We may choose to market some of our products directly through a sales and marketing force. In order to do this, we will have to develop a sales and marketing staff and establish distribution capability. Developing a sales and marketing force would be expensive and time-consuming and could delay any product launch. If we choose to market any of our products directly but are unable to successfully implement a marketing and sales force, our business and operating results will be harmed.

**We are, in part, dependent on our collaborative and licensing partners to support our business and to develop products employing our human antibody technology.**

We depend on our collaborative and licensing partners to support our business and to develop products employing our antibody technology. We currently, or in the future may, rely on our collaborative and licensing 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

commercialize and market future products.

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

our collaborative and licensing partners have significant discretion whether to pursue planned activities;



we cannot control the quantity and nature of the resources our collaborative and licensing partners may devote to product candidates;

our collaborators may not develop products employing our antibody technology as expected; and

business combinations or significant changes in a collaborative and licensing 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 collaborators, our business will suffer.

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

We have entered into binding letters of intent or memoranda of understanding with Eos Biotechnology, Inc., Genmab, 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 partners generally have the right to terminate our partnerships at any time. 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 collaboration or licensing partnerships on terms that are favorable to us or if a significant number of our existing corporate 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

place additional strain on management's time.

Any of the above may harm our business.

**Our goals and/or strategy may conflict with those of our collaborative or licensing 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 collaborative or licensing 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 licensing or collaborative 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 will suffer.

**We have a significant minority interest in two entities. There may be conflicts of interest between us and these entities.**

We currently have an equity interest of approximately 31% in Genmab, which intends to develop and commercialize a portfolio of fully human antibodies derived from our human antibody technology. In addition, we have an equity position in IDM of approximately 6%. In the event that we exercise certain warrants held by us to purchase convertible or redeemable bonds of IDM and such bonds are converted or redeemed, our equity position in IDM would be approximately 29%, based on the shares currently outstanding. These warrants are exercisable between September 2002 and September 2010, and such bonds may be converted or redeemed within six months of such exercise. Each of IDM and Genmab intends to develop and commercialize a portfolio of antibody-based products.

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, 1999, 2000 and 2001, our share of Genmab's losses were \$0, \$353 and \$7,334 respectively. For the nine-month period ended September 30, 2002, our share of Genmab's net loss was \$11,318. 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 corporate partners whose securities are publicly traded expose us to equity price risk and, in addition, investments in our corporate 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 collaborative partners, including Genmab, Northwest Biotherapeutics, Inc., Oxford GlycoSciences Plc, Seattle Genetics, 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 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. Through September 30, 2002, we have recorded impairment charges of approximately \$38,942 (of which approximately \$30,971 relates to Genmab) on our strategic 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 corporate partners whose securities are not publicly traded such as IDM. Because these securities are not publicly traded, 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 considered to be other than temporary. 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, our President and Chief Executive Officer, and Nils Lonberg, Ph.D., Senior Vice President and Scientific Director. 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 will suffer.

**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; 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. 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.

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 for our human antibody technology 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 corporate partners may be prevented from pursuing product development, manufacturing or commercialization. Such a result would harm our business.

**The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property disputes are costly and time-consuming to pursue and their outcome is uncertain.**

If we become involved in any 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 collaborative 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 permitted 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 monoclonal 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 owned by a third party that pertain to monoclonal antibodies against CTLA-4 and their uses. We are also aware of certain United States and foreign patents held by third parties relating to particular anti-CD4 antibodies, anti-EGFr antibodies, anti-PSMA antibodies, and anti-heparanase antibodies.

We are also aware of a United States patent owned by Genentech 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 impaired from making recombinant antibodies using Genentech's techniques. In addition to the 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 which may be relevant to our 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 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 have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that our products and/or actions in developing or selling its 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 licensees to use, import, manufacture, market or sell products or impair our competitive position and the competitive position of our licensees.

We are not the exclusive owner of the technology underlying our HuMAb-Mice. 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 \$38,600 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 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 license agreement were breached or terminated for any reason.

**We may 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 currently maintain liability insurance with specified coverage limits. 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. 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. As a result of these or other SAEs, we have received a small number of claims, of which

five have resulted in lawsuits being filed. Four of these lawsuits have been settled for insubstantial amounts. The remaining lawsuit is in a preliminary stage and we cannot assure you that it too will be settled or that it will be settled for an insubstantial amount. In addition, we cannot assure you that additional claims will not be filed against us relating to these SAEs. Any such claims against us, regardless of their merit, could result in significant awards against us which could 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 development activities currently face competition from several competitors and from other technologies. The actual products being developed by our collaborators or by us 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 which are actively engaged in research and development in areas related to antibody therapy. 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 corporate partners. Also, we compete with companies that offer antibody generation services to companies that have 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, which 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. 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 synthetic antibodies comprising human antibody sequence. For example, phage and yeast display technology is being used by companies, such as Abbott Laboratories, Inc., Cambridge Antibody Technology Group plc, or CAT, Dyax Corp., Genetastic, Inc. and MorphoSys AG to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, Medimmune, Inc., Immunex, IDEC Pharmaceuticals Corporation, Novartis, Genentech, Inc., Protein Design Labs, Inc. and Wyeth have generated therapeutic products derived from recombinant DNA that comprise human antibody components that are currently being marketed.

Other technologies can also be applied to the treatment of the diseases that we or our corporate 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, erythropoietin, DNase, tPA, glucocerebrosidase, PDGF, and a number of other biological response modifiers. Continuing development of conventional 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 corporate partners, have substantially greater financial resources and larger research and development staffs than we or some of our corporate 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 corporate partners do. If we or our corporate partners commence commercial product sales, we or our corporate partners will be competing against companies with greater marketing and manufacturing capabilities, areas in which we and certain of our corporate partners have limited or no experience.

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

**If our operating losses are greater than anticipated, 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:

- 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 corporate 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 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 will suffer.

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**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, and state and local governments. 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 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 U.S. 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 corporate 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 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 corporate partners develop;
- impose additional costs on us or our corporate partners;
- diminish any competitive advantages that we or our corporate 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 corporate 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 corporate partners to file INDs with the FDA and to direct the regulatory approval process for products employing our human antibody technology. Our corporate 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 corporate 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 may be 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 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 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 corporate partners and other third parties to manufacture products employing our human antibody technology. Before commercializing a new drug, manufacturers must demonstrate compliance with the applicable cGMP regulations which include 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 employing 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 FDA to modify or withdraw a product approval.

**Our operations involve hazardous materials and are subject to environmental controls and regulations.**

As a biopharmaceutical company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with 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 adversely affect our business, financial condition and results of operations.

**If our license agreements violate the competition provisions of the Treaty of Rome, then some terms of our key agreements may be unenforceable.**

Certain license agreements that we have entered into or may enter into will grant or may grant exclusive worldwide licenses of patents, patent applications and know-how, which are or may be arguably restrictive of competition under Article 81(1) of the Treaty of Rome. Article 81(1) prohibits agreements which restrict competition within the European Community and affect trade between member states. We determine on an agreement-by-agreement basis where an exemption from the application of Article 81(1) applies to the agreement and, if it does not, whether to apply to the European Commission for an individual exemption from the application of Article 81(1). If an exemption is not applicable and we do not apply for, or are unsuccessful in obtaining, an exemption from the European Commission, provisions of any license agreement which are found to be restrictive of competition under Article 81(1), including those relating to the exclusivity of rights, may be unenforceable and we could lose the benefit of the rights granted under the provisions.

**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:

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;

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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.

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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 October 31, 2002, we have 10,048,809 shares of common stock reserved for issuance pursuant to options, which have been granted under our stock option plans having a weighted average exercise price of \$13.61 per share. In addition, as of that date, there are 837,021 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 five 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.

In addition, as of October 31, 2002, we have reserved 1,916,622 shares of common stock for issuance pursuant to future grants of options under our stock option plans. We have filed or intend to file registration statements on Form S-8 covering those shares. We have reserved 500,000 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.

The exercise of all or a portion of the outstanding options and warrants 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, 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 October 31, 2002, we had 6,067,961 shares of common stock reserved for issuance pursuant to the conversion of \$175,000 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, subject to adjustment.

Pursuant to our license agreement with Novartis, Novartis may purchase \$2,000 of our common stock at a price equal to one hundred and ten percent of the average of the closing sales prices of our common stock on Nasdaq, on the twenty consecutive days prior to the fifth anniversary (December 2003) of the agreement. Additionally, on the sixth anniversary of the agreement, Novartis may purchase \$1,000 of our common stock at a price equal to one hundred and ten percent of the average of the closing sales prices of such stock on the Nasdaq on the twenty consecutive days prior to such anniversary.

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

As of October 31, 2002, we have 76,381,480 shares of common stock outstanding, of which 2,158,215 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.

In addition, we have filed a shelf registration statement on Form S-3 under the Securities Act relating to the sale of up to \$305,750 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 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 convertible debt and debt service obligations, which, unless converted to shares of our common stock, will mature in 2006. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. 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.

**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 September 30, 2002, \$175,000 aggregate principal amount of the notes was outstanding. We may pay the repurchase price in cash or, at our option, in common stock. Such repurchase right 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, stockholder rights plan and New Jersey law contain provisions that could delay or prevent an acquisition of our company.**

In May 2001, our board of directors adopted a stockholder rights plan. The stockholder rights plan provides for a dividend of one preferred share purchase right on each outstanding share of our common stock. Each right entitles stockholders to buy 1/1000<sup>th</sup> 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 stockholder 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 restated certificate of incorporation and by-laws and New Jersey law may discourage third parties from acquiring control of our company.

**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.

**Item 6. Exhibits and reports on Form 8-K**

(b) Reports on Form 8-K :

Form 8-K on September 18, 2002, relating to a cross-license agreement with Kirin Brewery Co., Ltd.

Form 8-K on September 24, 2002, relating to Genmab A/S press release dated September 24, 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.**

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**(Registrant)**

Date: November 13, 2002

By: */s/* DONALD L. DRAKEMAN

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**Donald L. Drakeman  
President and Chief  
Executive Officer  
(Principal Executive Officer)**

Date: November 13, 2002

By: */s/* CHRISTIAN S. SCHADE

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**Christian S. Schade  
Senior Vice President  
Finance & Administration,  
Chief Financial Officer  
(Principal Financial and Accounting Officer)**

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**CERTIFICATION**

I, Donald L. Drakeman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Medarex, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ DONALD L. DRAKEMAN

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**President and Chief Executive Officer  
(Principal Executive Officer)**



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**CERTIFICATION**

I, Christian S. Schade, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Medarex, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ CHRISTIAN S. SCHADE

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**Senior Vice President/Finance & Administration  
and Chief Financial Officer  
(Principal Financial and Accounting Officer)**