MEDAREX INC
Form 10-Q
May 09, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2003

OR

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

For the transition period from _____ to _____.

Commission File No. 0-19312

MEDAREX, INC.

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

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

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

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

Yes	No
x	o

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

Yes	No
x	o

The number of shares of common stock, $.01 par value, outstanding as of May 1, 2003 was 77,247,478 shares.

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

	December 31, 2002	March 31, 2003
		(Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,812	$ 74,238
Marketable securities	288,234	247,173
Prepaid expenses and other current assets	10,143	8,391
Total current assets	360,189	329,802
Property, buildings and equipment:		
Land	6,624	6,624
Buildings and leasehold improvements	71,277	73,601
Machinery and equipment	31,821	33,407
Furniture and fixtures	3,963	4,021
Construction in progress	2,148	2,362
	115,833	120,015
Less accumulated depreciation and amortization	(18,522)	(22,098)
	97,311	97,917
Investments in Genmab	21,206	19,600
Investments in IDM	48,199	48,199
Investments in, and advances to, other affiliates and partners	11,982	13,082
Segregated cash	1,300	1,300
Other assets	8,864	8,280
Total assets	$ 549,051	$ 518,180
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Trade accounts payable	$ 2,686	$ 2,969
Accrued liabilities	15,377	8,567
Deferred contract revenue - current	2,646	3,447
Total current liabilities	20,709	14,983
Deferred contract revenue - long-term	1,152	853
Other long-term obligations	47	2,553
Convertible subordinated notes	175,000	175,000
Commitments and contingencies		
Shareholders' equity:		

Preferred stock, $1.00 par value, 2,000,000 shares authorized; none issued and outstanding		
Common stock, $.01 par value; 200,000,000 shares authorized; 77,725,376 shares issued and 76,929,984 outstanding at December 31, 2002 and 77,967,401 shares issued and 77,247,478 shares outstanding at March 31, 2003	777	780
Capital in excess of par value	630,279	631,121
Treasury stock, at cost 795,392 shares in 2002 and 719,923 shares in 2003	(2,001)	(1,811)
Deferred compensation	1,311	1,415
Accumulated other comprehensive income	5,380	6,512
Accumulated deficit	(283,603)	(313,226)
Total shareholders' equity	352,143	324,791
Total liabilities and shareholders' equity	$ 549,051	$ 518,180

See notes to these unaudited consolidated financial statements.

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2002	**2003**
Sales	$ 100	$ 25
Contract and license revenues	7,613	2,174
Sales, contract and license revenues from Genmab (includes sales of $2,308 to Genmab in 2002)	3,058	1,765
Total revenues	10,771	3,964
Costs and expenses:		
Cost of sales ($1,438 from sales to Genmab in 2002)	1,477	3
Research and development	17,254	23,526
General and administrative	5,418	5,684
Total costs and expenses	24,149	29,213
Operating loss	(13,378)	(25,249)
Equity in net loss of affiliate	(3,589)	(3,754)
Interest and dividend income	4,946	2,632
Impairment loss on investments in partners	(1,600)	
Additional payments related to asset acquisition		(86)
Interest expense	(2,218)	(2,308)
Pre tax loss	(15,839)	(28,765)
Provision for income taxes		28

Loss before cumulative effect of change in accounting principle	(15,839)	(28,793)
Cumulative effect of change in accounting principle		(830)
Net loss	$ (15,839)	$ (29,623)
Basic and diluted net loss per share:		
Loss before cumulative effect of change in accounting principle	$ (0.21)	$ (0.37)
Cumulative effect of change in accounting principle	$	$ (0.01)
Net loss	$ (0.21)	$ (0.38)
Weighted average number of common shares outstanding - basic and diluted	74,011	77,953

See notes to these unaudited consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2002	**2003**
Operating activities:		
Net loss	$ (15,839)	$ (29,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Cumulative effect of change in accounting principle		830
Depreciation	1,586	2,588
Amortization	478	812
Stock options and awards to employees	61	139
Stock options and warrants to non-employees	(8)	
Non cash revenue - IDM	(5,058)	
Equity in net loss of Genmab	3,589	3,754
Impairment loss on investments	1,600	
Changes in operating assets and liabilities		
Other current assets	(566)	1,959
Trade accounts payable	(1,303)	283
Accrued liabilities	(4,551)	(5,802)
Deferred contract revenue	(2,389)	502
Net cash used in operating activities	(22,400)	(24,558)
Investing activities:		
Purchase of property and equipment	(12,431)	(1,947)
Increase in investments and advances to affiliates and partners		(1,000)
Purchase of marketable securities	(2,500)	
Sales of marketable securities	56,044	40,044
Net cash provided by investing activities	41,113	37,097
Financing activities:		
Cash received from sales of securities, net	28	
Principal payments under debt obligations		(113)

Net cash provided by (used in) financing activities	28	(113)
Net increase in cash and cash equivalents	18,741	12,426
Cash and cash equivalents at beginning of period	31,269	61,812
Cash and cash equivalents at end of period	$ 50,010	$ 74,238
Supplemental disclosures of cash flow information		
Cash paid during period for:		
Interest	$ 4,047	$ 3,944

See notes to these unaudited consolidated financial statements.

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(Dollars in thousands, unless otherwise indicated, except per share data)

1. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

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

Net Loss per Share

Basic and diluted net loss per share are calculated in accordance with the Financial Accounting Standards Board (FASB) SFAS No. 128, *Earnings per Share*. Basic net loss per share is based upon the number of weighted average shares of common stock outstanding. Diluted net loss per share is based upon the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding. Potential shares of common stock result from the assumed exercise of outstanding stock options, which are included under the treasury stock method. For the three month periods ended March 31, 2002 and 2003, all potentially dilutive securities have been excluded from the computation of diluted net loss per share, as their effect is antidilutive.

Marketable Securities

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

MEDAREX, INC. AND SUBSIDIARIES

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(Unaudited)
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In addition, the Company has investments in several of its partners whose securities are not publicly traded. Because these securities are not publicly traded, the Company values these investments by using information acquired from industry trends, the management of these companies, financial statements, and several other external sources. Based on the information acquired through these sources, the Company records an investment impairment charge when it believes an investment has experienced a decline in value that is considered to be other than temporary.

Stock Based Compensation

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

	Three Months Ended March 31	
	2002	**2003**
Net loss, as reported	$ (15,839)	$ (29,623)
Deduct: Total stock-based employee compensation expense determined under fair value method	(703)	(989)
Pro forma net loss	$ (16,542)	$ (30,612)
Loss per share:		
Basic and diluted, as reported	$ (0.21)	$ (0.38)
Basic and diluted, pro forma	$ (0.22)	$ (0.39)

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

	Three Months Ended March 31	
	2002	**2003**
Expected stock price volatility	120.1%	76.7%
Risk-free interest rate	4.0%	3.5%
Expected life of options	5 years	5 years
Expected dividend yield	0%	0%

2. Investments in Genmab

As a result of a series of transactions, including an initial public offering by Genmab A/S, a Danish biotechnology company (Genmab), of its ordinary shares in October 2000, the Company owned approximately 32.6% interest in Genmab as of December 31, 2001. In June 2002, the Company s

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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ownership percentage was reduced to approximately 31.2% as a result of the issuance by Genmab of new shares to a corporate partner in connection with an antibody collaboration.

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

During the three month periods ended March 31, 2002 and 2003 the value of the Company s investment in Genmab was adjusted to reflect the Company s share of Genmab s loss ($3.6 million) and ($3.8 million), respectively, and an unrealized gain (loss) of $(0.6 million) and $2.1 million, respectively, related to foreign exchange translation. Such foreign exchange translation adjustments are included within accumulated other comprehensive income in the Company s March 31, 2003 consolidated balance sheet.

Summary financial information for Genmab is as follows:

	As of and for the Three Months Ended March 31	
	2002	2003
Current assets	$ 181,311	$ 186,942
Non current assets	21,454	23,350
Current liabilities	8,308	17,565
Non current liabilities	3,553	3,350
Net sales		
Gross profit		
Net loss	(11,019)	(12,001)

3. Contingencies

The Company has a contingent commitment to pay $1.0 million to Essex Chemical Corporation (Essex) without interest in installments equal to 20% of net after tax earnings of the Company in future years. The Company s contingent commitment, as amended, to pay up to $1.0 million out of future earnings may be satisfied, at the Company s option, through the payment of cash or shares of the Company s common stock having a fair market value equal to the amount owed, provided that such shares are registered with the Securities and Exchange Commission. The Company accrued $0.7 million related to this liability during 2000, which remains accrued at March 31, 2003.

In May 2002, the Company entered into an Asset Purchase Agreement with Corixa Corporation, Coulter Pharmaceutical, Inc., a wholly owned subsidiary of Corixa Corporation, and Corixa Belgium S.A., a subsidiary of Corixa Corporation (collectively referred to as Corixa). Under the terms of the Asset Purchase

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Agreement, the Company acquired certain selected assets and business operations of Corixa, including certain preclinical product candidates and programs related to the research and development of therapeutic products for the treatment of autoimmune diseases, cancer and infectious diseases for $21.0 million (excluding transaction costs of $0.4 million). As part of this transaction, Corixa may receive up to an additional $6.0 million in future consideration in cash or, at the Company s election, in shares of common stock, based upon certain contingencies.

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

4. Comprehensive Income (Loss)

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

	Three Months Ended March 31	
	2002	2003
Net loss	$ (15,839)	$ (29,623)
Unrealized loss on securities	(2,519)	(1,016)
Unrealized gain (loss) on foreign exchange	(587)	2,148
Total comprehensive loss	$ (18,945)	$ (28,491)

5. Segment Information

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

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

	Three Months Ended March 31,	
Customer	2002	2003
IDM S.A.	47%	1%
Genmab A/S	28%	45%
Novartis Pharma AG	2%	15%
Amgen, Inc.	%	13%

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No other single customer accounted for more than 10% of the Company s total revenues for the three months ended March 31, 2002 and 2003, respectively.

6. Asset Retirement Obligations

Effective January 1, 2003, the Company changed its method of accounting for asset retirement obligations in accordance with SFAS No. 143, *Accounting for Asset Retirement Obligations*. Previously, the Company was not required to recognize amounts related to asset retirement

obligations. Under SFAS No. 143, the Company now recognizes asset retirement obligations in the period in which they are incurred if a reasonable estimate of a fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset.

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

7. Stock Option Exchange Program

In January 2003, the Company s Board of Directors approved a stock option exchange program. Under this program, eligible employees and eligible officers were given the opportunity to cancel one or more stock options previously granted to them in exchange for new stock options to be granted at least six months and one day from the date the old options are cancelled (the grant date), provided that the individual is still employed by the Company on such date. Eligible employees refers to current Company employees who are not executive officers and who hold options to purchase the Company s stock with an exercise price of $10 or more. Eligible officers refers to executive officers (excluding the President and Chief Executive Officer and the Executive Vice President) who hold options to purchase the Company s stock with an exercise price of $25 or more. Members of the Company s Board of Director s were not eligible to participate in the program. The participation deadline for the program was March 7, 2003. Eligible Employees and Eligible Officers elected to exchange a total of 2,309,401 shares of common stock underlying eligible options. The number of shares subject to the new options was determined based on the old options exercise price. Specifically, if the exercise price of the old options was between $10.00 and $24.99 per share, then the exchange ratio was equal to 0.67 of a share. If the exercise price of the old options was $25.00 per share or higher, then the exchange ratio was equal to 0.50 of a share. Based on the foregoing, eligible option holders will receive replacement options to purchase a total of 1,319,269 shares of common stock. Replacement options will not be granted until, at the earliest, September 8, 2003. The exercise price of the new options will be equal to the average of the high and low sales prices on the grant date.

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 uncertainti 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

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

Through our 1997 acquisition of GenPharm International, Inc. and our collaboration with Kirin Brewery Co. Ltd., we expanded our business to include both our HuMAb-Mouse® and Kirin s TC Mouse technologies. In December 2000 we unveiled the KM-Mouse, a unique crossbred mouse developed in partnership with Kirin, as the newest addition to our UltiMAb Human Antibody Development System. With the UltiMAb[SM] platform, we have assembled a unique family of human antibody technologies for creating the entire spectrum of high-affinity, fully human antibodies. We intend to leverage our product development capabilities with those of our partners, while also gaining access to novel therapeutic targets and complementary development, sales and marketing infrastructures. As of May 1, 2003, we have over 40 partnerships with pharmaceutical and biotechnology companies, including industry leaders such as Amgen, Inc., Centocor, Inc. (a subsidiary of Johnson & Johnson), Eli Lilly & Company, Human Genome Sciences, Inc., Abbott Laboratories, Novartis Pharma AG, Novo Nordisk A/S, Schering AG

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

Our licensing partners typically obtain licenses to one or more of our antibody generating technologies which we expect will allow these partners to develop and commercialize antibody-based products using our technology. We could receive license fees, milestones and royalties in connection with each of these products. Under these licenses, there is usually an initial period during which our partners may

elect to enter into a research license for antibodies to a particular designated target. Subsequently, our partners may elect to obtain a commercial license for monoclonal antibodies to a particular target.

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

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

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

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

Critical Accounting Policies

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

Revenue Recognition

Historically, a significant portion of our revenue has been recognized pursuant to collaboration and license agreements with our partners. Revenue related to collaborative research with our partners is recognized and earned based upon the performance requirements of each agreement. Deferred revenue may result when we do not expend the required level of effort during a specific period in comparison to funds received under the respective agreements or when funds received are refundable under certain circumstances. Revenue associated with performance milestones is recognized based upon the achievement

of the milestones, as defined in the respective agreements and when collectibility of such milestone payment is assured. Non-refundable upfront payments received in connection with our collaborative partnerships are deferred and recognized as revenue on a straight-line basis over the period we are obligated to perform services related to each of the respective agreements.

Investments

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

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

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

Valuation of Long-Lived and Intangible Assets

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

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

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

a significant negative industry or economic trend.

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

Results of Operations

Three months ended March 31, 2002 and 2003

Total revenue decreased by $6.8 million or 63%, from $10.8 million to $4.0 million, during the three-month period ended March 31, 2003, as compared to the three-month period ended March 31, 2002. The decrease relates principally to a decrease of contract and license revenues of $5.1 million from IDM and a decrease of sales revenues of $2.3 million from Genmab A/S related to MDX-CD4, partially offset by an increase of $1.0 million of contract and license revenues from Genmab. As a result of Genmab s announced decision to wind down its anti-CD4 program for rheumatoid arthritis, we anticipate that sales of MDX-CD4 (and corresponding cost of sales) will be significantly lower in the future. In addition, we expect contract and license revenues to be lower in the future as a result of the completion in September 2002 of the revenue recognition associated with the transfer of technology to IDM in July 2000.

Cost of sales decreased by $1.5 million or 100%, from $1.5 million to $3 thousand, during the three-month period ended March 31, 2003, as compared to the three-month period ended March 31, 2002. The decrease reflects the production cost of MDX-CD4 that was sold to Genmab in the first quarter of 2002.

Research and development expenses are largely comprised of (i) personnel costs, (ii) those expenses related to facilities for our clinical research, development and clinical trial manufacturing efforts, (iii) third party research costs, (iv) supply costs, and (v) license and technology access fees. Research and development expenses for our products in development increased by $6.3 million or 36%, from $17.3 million to $23.5 million, during the three-month period ended March 31, 2003 as compared to the three-month period ended March 31, 2002. The increases relate primarily to costs associated with the following:

Personnel costs for the three-month period ended March 31, 2003 were $8.6 million, an increase of $3.0 million or 55% as compared to the three-month period ended March 31, 2002. The increase in staff is 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 collaborative partners and clinical activities. Included in the increase are salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to increase, but at a slower rate, as we continue to increase our product

development activities and progress our products in clinical trials.

Facility costs for the three-month period ended March 31, 2003 were $4.8 million, an increase of $2.1 million or 80% as compared to the three-month period ended March 31, 2002. The increase in 2003 primarily relates to the substantial investments made in our three research and development facilities during 2001 and 2002. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for the three-month period ended March 31, 2003, as compared to the three-month period ended March 31, 2002. We expect facility costs to increase as a result of our continued capital expansion, renovation and replacements but at a reduced rate.

License and technology access fees for the three-month period ended March 31, 2003 were $0.8 million, a decrease of $2.0 million or 71% as compared to the three-month period ended March 31, 2002. These costs represent fees paid to partner and research organizations in connection with our collaboration and license

agreements. In the first quarter of 2002 we paid $2.5 million for technology access rights as part of our collaboration and license agreement with Tularik, Inc. 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 of these product candidates is dependent on many factors, including among other things, the efforts of our partners, unforeseen delays in, or expenditures relating to, preclinical development, clinical testing, manufacturing or regulatory approval, failure to receive market acceptance, the emergence of competitive products and the inability to produce or market our products due to third-party proprietary rights.

General and administrative expenses for the three-month period ended March 31, 2003 were $5.7 million, an increase of $0.3 million, or 5% as compared to the three-month period ended March 31, 2002. The increase is primarily attributable to higher personnel costs as well as increased depreciation expense. 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 March 31, 2003 was $3.8 million, an increase of $0.2 million, or 5% as compared to the three-month period ended March 31, 2002. The increase is the result of Genmab s increased activity in research and 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 future as a result of Genmab s publicly stated intention to make additional investments in research and development to develop its own product pipeline. The recognition of our equity in Genmab s net losses reduces the carrying value (basis) of our investment in Genmab.

Interest and dividend income for the three-month period ended March 31, 2003 was $2.6 million, a decrease of $2.3 million, or 47% as compared to the three-month period ended March 31, 2002. The decrease reflects lower interest income due to lower average cash balances as we funded our operations and capital expenditures from our cash reserves. We anticipate lower investment income in the future as we continue to liquidate our investments to fund our operations and capital expenditures.

During the first quarter of 2003, no impairment charges were recorded on our investments in partners. An impairment loss on investments in partners of $1.6 million was recorded during the three-month period ended March 31, 2002, representing a write-down of the value of our investment in one of our partners. During the first quarter of 2002, the decline in the value of the investment was determined to be other than temporary. If we deem our investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

Additional payments related to asset acquisition of $0.1 million during the three month period ended March 31, 2003 represents additional payments to Northwest Biotherapeutics, Inc. Pursuant to the terms of the agreement, under certain circumstances we were required to pay an amount equal to the difference between the proceeds received by Northwest Biotherapeutics 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.

Interest expense during the three-month period ended March 31, 2003 was $2.3 million, an increase of $0.1 million, or a 4% increase as compared to the three-month period ended March 31, 2002.

Cumulative effect of change in accounting principle during the three-month period ended March 31, 2003 was $0.8 million. Effective January 1, 2003, we changed our method of accounting for asset retirement obligations in accordance with SFAS No. 143, *Accounting for Asset Retirement Obligations*. Previously, we were not required to recognize amounts related to asset retirement obligations. Under SFAS No. 143, we now recognize asset retirement obligations in the period in which they are incurred if a reasonable estimate of a fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately $1.4 million, recognition of an asset retirement obligation liability of approximately $2.2 million and a cumulative effect of a change in accounting principle of approximately $0.8 million. Adoption of SFAS No. 143 had no material impact on net loss before the cumulative effect of adoption in the first quarter of 2003, nor do we expect it to have a material impact on our financial position or results of operations in the future.

Liquidity and Capital Resources

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

At March 31, 2003, we had approximately $321.4 million in cash, cash equivalents and marketable securities. We invest our cash equivalents and marketable securities in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

Cash Used in Operating Activities. Operating activities consumed $22.4 million and $24.6 million of cash for the three-month periods ended March 31, 2002 and 2003, respectively. The increase in cash used in operating activities in 2003 relates in part to the increase in research and development expense. Total research and development expense increased by $6.3 million, from $17.3 million for the three-month period ended March 31, 2002 to $23.5 million for the three-month period ended March 31, 2003. The increase in research and development expense resulted from higher personnel costs, those expenses related to facilities for our clinical research, development and manufacturing efforts, and clinical trial costs (offset by lower license and technology access fees). To a lesser extent, the increase in cash used in operations also resulted from higher general and administrative costs, attributable mainly to higher personnel costs. Partially offsetting the use of cash for these operating expenses were depreciation and amortization, non-cash compensation, and cash received from corporate partners. Lastly, the increase in cash used in operations also resulted from reduced investment income as a result of both lower interest rates and lower average cash balances.

Cash Provided by Investing Activities. Net cash provided by investing activities was $41.1 million for the three-month period ended March 31, 2002 as compared to $37.1 million for the three-month period ended March 31, 2003. The decrease in cash provided by investing activities was primarily the result of the following factors:

Capital expenditures of $12.4 million and $1.9 million for the three-month periods ended March 31, 2002 and 2003, respectively. The decrease in capital spending was primarily related to the

completion in 2002 of the renovation of our Bloomsbury, New Jersey facility, which was opened in May 2001;

Net sales of marketable securities of $53.5 million and $40.0 million for the three-month periods ended March 31, 2002 and 2003, respectively. As the amounts of cash used to fund operations were comparable, the decrease in securities sold was due to less cash required to fund capital expenditures.

Cash Used in Financing Activities. Financing activities for the three-month period ended March 31, 2003 used $0.1 million of cash compared to cash provided of $28 thousand for the three-month period ended March 31, 2002. Cash used in financing activities for the three-month period ended March 31, 2003 was primarily the result of principal payments on equipment leases.

Other Liquidity Matters. In connection with our merger with Essex Medical Products, or Essex, in 1987, we are committed to pay to Essex 20% of our net after-tax income until a total of $1.0 million has been paid, contingent upon the occurrence of certain events. As the result of our net income in 2000 we accrued $0.7 million payable to Essex, which remains accrued at March 31, 2003. At our option, this obligation may be satisfied by the payment of shares of our common stock having a fair market value equal to the amount owed, provided such shares are registered for sale with the SEC.

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

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

As part of this transaction, Corixa may receive up to an additional $6.0 million in future consideration in cash or, at our election, in shares of common stock, based upon certain contingencies.

Future Liquidity Resources. Our current sources of liquidity are cash, cash equivalents and marketable securities, interest and dividends earned on such cash, cash equivalents and marketable securities, contract and licensing revenue and sales of our products for research. We believe that such sources of liquidity will be sufficient to meet our operating, debt service, and capital requirements for at least the next 24 months; however, this 24-month period assumes the use of a portion of the $175.0 million required to meet our repayment obligations with respect to our convertible notes due on July 1, 2006. The notes are convertible into shares of our common stock at a ratio of 34.6789 shares per each $1,000 principal amount of the notes ($28.84 per share), subject to adjustment. To the extent our convertible notes are converted into shares of our common stock on or before July 1, 2006, we will have use of that portion of the $175.0 million of notes so converted to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other

financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We can not assure you that we will be able to raise such additional funds.

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

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

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

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures: Our principal executive and financial officers reviewed and evaluated our disclosure and procedures (as defined in Securities Exchange Act Rule 13a-14 and 15d-4) as of a date within 90 days before the filing date of this Form 10-Q. Based on that evaluation, our principal executive and financial officers concluded that our disclosure controls and procedures are effective in timely providing them with material information relating to us, as required to be disclosed in the reports we file under the Exchange Act.

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

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

Part II Other Information

Item 1. Legal Proceedings

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

Item 5. Other Information

Additional factors that might affect future results.

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 the early stages of development. Only a limited number of fully human antibody product candidates employing our human antibody technology have been generated by us or pursuant to our partnerships. 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. In addition, we are not aware of any commercialized fully human monoclonal antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond the early stages of product development or demonstrate clinical safety and effectiveness.

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

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

We have entered into 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 product candidates is dependent upon the efforts of our partners in developing these product candidates in the future. Neither we nor our partners know if any of these product candidates will be effective. To date, no products employing our human antibody technology have been approved for sale by the FDA.

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;

inability to manufacture on our own, or through others, product candidates on a commercial scale;

inability to market products due to third-party proprietary rights;

election by our partners not to pursue product development;

failure by our partners to develop products successfully; and

failure to achieve market acceptance.

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

Because we and our partners have not begun commercial sales of our products, our revenue and profit potential are unproven and our limited operating history makes it difficult for an investor to evaluate our business and prospects. Our technology may not result in any meaningful benefits to our current or potential partners. Further, due to our limited operating history, we have difficulty accurately forecasting our revenue. Our business and prospects should be considered in light of the heightened risks and unexpected expenses and problems we may face as a company in an early stage of development in a new and rapidly evolving industry.

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

We have incurred large operating losses and these losses may continue. In particular, as of March 31, 2003, we had an accumulated deficit of approximately $313.2 million. Our losses have resulted principally from:

research and development costs relating to the development of our technology and antibody product candidates;

costs associated with the establishment of our new laboratory and manufacturing facilities and manufacturing of products; and

general and administrative costs relating to our operations.

We intend to continue to make significant investments in:

research and development;

preclinical testing and clinical trials;

establishing new collaborations; and

new technologies.

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

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

Our operating results may vary significantly from period-to-period.

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

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

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

delays in preclinical testing and clinical trials;

changes in regulatory requirements for clinical trials;

costs and expenses associated with preclinical testing and clinical trials;

the timing of regulatory approvals, if any;

sales and marketing expenses; and

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

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

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

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

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

the size and complexity of research and development programs;

the scope and results of preclinical testing and clinical trials;

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

continued scientific progress in our research and development programs;

the time and expense involved in seeking regulatory approvals;

competing technological and market developments;

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

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

We believe our current sources of liquidity will be sufficient to meet our near term operating, debt service and capital requirements. However, we may require additional financing within this time frame, and we cannot make assurances that we will be able to raise such additional funds. We may be unable to raise sufficient funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

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.

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 partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our partners will have to conduct extensive preclinical testing and adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. Moreover, we will continue to be affected by delays associated with the preclinical testing and clinical trials of certain product

candidates conducted by our partners over which we have no control. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices, or cGMPs, for use in clinical trials;
- slower than expected rates of patient recruitment;
- the inability to adequately observe patients after treatment;
- changes in regulatory requirements for clinical trials;
- the lack of effectiveness during the clinical trials;
- unforeseen safety issues;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or clinical holds requiring suspension or termination of the trials.

Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our human antibody technology. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of that product candidate as well as other product candidates, and our business, financial condition and results of operations may be materially harmed.

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

- establishment and demonstration of clinical efficacy, potency and safety, especially as compared to conventional treatments;
- cost-effectiveness;

alternative treatment methods;

reimbursement policies of government and third-party payors; and

marketing and distribution support for our product candidates.

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

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

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

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

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

We have limited manufacturing capabilities.

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

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

We may also encounter problems with the following:

production yields;

quality control and assurance;

shortages of qualified personnel;

compliance with FDA regulations, including the demonstration of purity and potency;

changes in FDA requirements;

production costs; and/or

development of advanced manufacturing techniques and process controls.

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. 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, financial condition and results of operations may be materially harmed.

We are, in part, dependent on our partners to support our business and to develop products generated using our human antibody technology.

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

access proprietary antigens for the development of product candidates;

access skills and information that we do not possess;

fund our research and development activities;

manufacture products;

fund and conduct preclinical testing and clinical trials;

seek and obtain regulatory approvals for product candidates; and/or

commercialize and market future products.

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

our partners have significant discretion whether to pursue planned activities;

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

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

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

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

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

We have entered into binding letters of intent or memoranda of understanding with Genmab, Athersys, Inc., and Regeneron Pharmaceuticals, Inc. These binding letters of intent or memoranda of understanding include the principal terms of these transactions, which will be incorporated into definitive agreements. By their terms, these letters of intent and memoranda of understanding will remain in full force

and effect and the parties will operate in accordance with their terms until such time as definitive agreements are executed. If we are unable to agree on the terms of a definitive agreement with respect to one or more of these partners, our business may be harmed.

Our licensing partners generally have the right to terminate our partnerships at any time. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays or termination in the research, development or commercialization of product candidates. If we are not able to establish additional partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely:

limit the number of product candidates that we will be able to develop and commercialize;

significantly increase our need for capital; and/or

place additional strain on management s time.

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

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

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

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 generated through the use of our human antibody technology. In addition, we have an equity position in IDM of approximately 9%, which intends to develop and commercialize antibodies generated through the use of our technology. 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 26%, 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.

Due to the size of our interest in Genmab, we are currently required to account for our equity interest in Genmab under the equity method of accounting, which provides that we must include a portion of Genmab s income and losses equal to our percentage equity interest in Genmab in our consolidated financial statements. For the years ended December 31, 2000, 2001 and 2002, our share of Genmab s losses were approximately $0.4 million, $7.3 million and $19.6 million, respectively. For the three-month period ended March 31, 2003, our share of Genmab s net loss was $3.8 million. Genmab has publicly stated that it anticipates that it will incur substantial losses as it expands its research and product development efforts. As Genmab s losses continue to increase, the aggregate amount of such losses we must include in our consolidated financial statements will also increase.

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

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

We are exposed to equity price risk on our strategic investments in our publicly-traded partners, including Genmab, Northwest Biotherapeutics, Inc., Oxford GlycoSciences Plc, Seattle Genetics, Inc., Protein Design Labs, Inc. and Tularik, Inc., and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. As these investments are the result of strategic alliances with our collaborative partners, we typically do not attempt to reduce or eliminate our market exposure of these types of strategic investments. Under SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, these investments are designated as available-for-sale and are reported at fair value on our consolidated balance sheet. Unrealized holding gains and losses on available-for-sale securities are generally excluded from earnings and reported within other comprehensive income which is a separate component of shareholders equity. Under our accounting policy, marketable equity securities are generally considered to be impaired if their fair value is less than our cost

basis in such securities for more than six months, or some other period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of available-for-sale securities is considered to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. For the year ended December 31, 2002, we recorded impairment charges of approximately $40.5 million (of which approximately $31.0 million related to Genmab) on our strategic investments in publicly traded companies. During the first quarter of 2003, no impairment charges were recorded related to the value of our investments. If we deem these investments to be further impaired at the end of any future reporting period, we may incur additional impairment charges on these investments.

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

We are dependent on our key personnel.

We are highly dependent on the members of our scientific and management staff. If we are not able to retain any of these persons, our business may suffer. In particular, we depend on the services of Donald L. Drakeman, Ph.D., our President and Chief Executive Officer, and Nils Lonberg, Ph.D., our Senior Vice President and Scientific Director. For us to pursue product development, marketing and commercialization plans, we will need to hire additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. We may not be able to attract and retain personnel on acceptable terms, given

the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. If we are not able to attract and retain qualified personnel, our business, financial condition and results of operations may be materially harmed.

We depend on patents and proprietary rights.

Our success depends in part on our ability to:

protect trade secrets;

operate without infringing upon the proprietary rights of others;

in-license certain technologies; and

apply for, obtain, protect and enforce patents.

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

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

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

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 outcomes are uncertain.

If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expense and the efforts of our technical and

management personnel will be diverted. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Therefore, we and our partners may be restricted or prevented from manufacturing and selling products employing our human antibody technology, which would harm our business.

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

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

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

Moreover, other parties could have blocking patent rights to products made using HuMAb-Mouse technology, such as antibodies, and their production and uses, either because of a proprietary position covering the antibody or the antibody s target. For example, we are aware of certain United States and European patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets and bispecific products, and the manufacture and use of such products. In particular, we are aware of certain United States and foreign patents owned by third parties that pertain to monoclonal antibodies against CTLA-4 and their uses. We are also aware of certain United States and foreign patents held by third parties relating to 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 restricted in our ability to make 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, including CHO cells, which may be relevant to our current or future manufacturing techniques.

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

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

We are not the exclusive owner of the technology underlying 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 $38.6 million during 1997 and 1998. This payment was in exchange for a non-exclusive license to certain patents, patent applications, third-party licenses and inventions pertaining to the development and use of certain transgenic rodents, including mice, that produce fully human antibodies that are integral to our products and business. These patents, licenses and inventions form the basis of our HuMAb-Mouse technology. Our business may suffer from the competition of these entities or if any of these entities breach the cross-license and settlement agreement.

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

We 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. It is unlikely that we will resume clinical trials with respect to this product. As a result of these or other SAEs, we have received a small number of claims, of which five resulted in lawsuits being filed. All of these lawsuits have been settled for insubstantial amounts. We cannot make assurances that additional claims will not be filed against us relating to these SAEs or arising out of any other clinical trial we have conducted or will conduct in the future. Any such claims against us, regardless of their merit, could result in significant awards against us which could materially harm our business, financial condition and results of operations.

We face intense competition and rapid technological change.

The development of biotechnology and pharmaceutical products is a highly competitive business subject to significant and rapid technological change. We face competition in several different forms. First, our human antibody generation activities currently face competition from several competitors with similar

technology to ours as well as distinctly different technologies. The actual products being developed by us or by our partners also face actual and potential competition. Developments by our competitors may render our human antibody technology obsolete or non-competitive.

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

Other technologies can also be applied to the treatment of the diseases that we or our partners are pursuing. For example, immunoconjugates monoclonal antibodies linked to toxins or radioactive isotypes are being developed by others. In addition, the application of

recombinant DNA technology to develop potential products consisting of proteins (such as growth factors, hormones, enzymes, receptor fragments and fusion proteins, or cytokines) that do not occur normally in the body, or occur only in small amounts, has been underway for some time. Included in this group are interleukins such as IL-2 and IL-11, interferons alpha, beta and gamma, colony stimulating factors such as G-CSF and GM-CSF, clotting factors, growth hormones, erythropoeitin, DNAse, tPA, glucocerebrosidase, PDGF, and a number of other biological response modifiers. Continuing development of new chemical entities and other drugs by large pharmaceutical companies carries with it the potential for discovery of agents for treating disease indications also targeted by drugs that we or our partners are developing.

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

developing products;

undertaking preclinical testing and clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing and marketing products.

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

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

We are subject to extensive and costly government regulation.

Product candidates employing our human antibody technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, state and local governments and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of biopharmaceutical products. The FDA regulates human antibodies as biologics, subject to a Biologic License Application, or BLA, under the Public Health Services Act, as amended. If products employing our human antibody technology are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

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

adversely affect the successful commercialization of any drugs that we or our partners develop;

impose additional costs on us or our partners;

diminish any competitive advantages that we or our partners may attain; and

adversely affect our receipt of revenues or royalties.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once

obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. If we, our partners or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things:

- delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;
- warning letters;
- fines;
- import and/or export restrictions;
- product recalls or seizures;
- injunctions;
- total or partial suspension of production;
- civil penalties;
- withdrawals of previously approved marketing applications or licenses;
- recommendations by the FDA or other regulatory authorities against governmental contracts; and
- criminal prosecutions.

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

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

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

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

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

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

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

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

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

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to FDA s current good manufacturing practice requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, and

similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

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 whether or not 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, by way of example:

fluctuations in our operating results;

announcements of technological innovations or new commercial therapeutic products by us or our competitors;

published reports by securities analysts;

progress with clinical trials;

governmental regulation;

developments in patent or other proprietary rights;

developments in our relationship with collaborative partners;

public concern as to the safety and effectiveness of our products; and

general market conditions.

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 March 31, 2003, we had 7,600,543 shares of common stock reserved for issuance pursuant to options which had been granted under our stock option plans having a weighted average exercise price of $9.56 per share. We have filed registration statements on Form S-8 covering those shares. Shares issued pursuant to these plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

In addition, as of that date, there were 686,083 shares reserved for issuance pursuant to a deferred compensation plan. The shares reserved for the deferred compensation plan will be issued in various amounts over various periods of time during the next four years. We have filed a registration statement on Form S-8 covering those shares. Shares issued pursuant to this plan, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

In addition, as of March 31, 2003, we had reserved 4,376,038 shares of common stock for issuance pursuant to future grants of options under our stock option plans. We have filed registration statements on Form S-8 covering those shares. As a result of our stock option exchange program, we expect to issue options to purchase a total of 1,319,269 shares of common stock on September 8, 2003, at the earliest. As of March 31, 2003, we had reserved 353,018 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 covering those shares. Shares issued under our plans, other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirement of Rule 144.

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

As of March 31, 2003, we had 6,067,961 shares of common stock reserved for issuance pursuant to the conversion of $175.0 million aggregate principal amount of our 4.50% Convertible Subordinated Notes due 2006. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 34.6789 shares per each $1 thousand principal amount of notes ($28.84 per share), subject to adjustment.

Pursuant to our license agreement with Novartis, Novartis may purchase $2 million of our common stock at a price equal to 110% 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 (December 2004) of the agreement, Novartis may purchase $1 million of our common stock at a price equal to 110% 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 March 31, 2003, we had 77,247,478 shares of common stock outstanding, of which 1,972,523 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 $303.25 million of any of the following securities:

Debt Securities;

Preferred Stock;

Common Stock; or

Warrants to Purchase Debt Securities, Preferred Stock or Common Stock.

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 March 31, 2003, $175.0 million 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, shareholder 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 shareholder rights plan. The shareholder rights plan provides for a dividend of one preferred share purchase right on each outstanding share of our common stock. Each right entitles shareholders to buy 1/1000th of a share of our Series A junior participating preferred stock at an exercise price of $150.00. Each right will become exercisable following the tenth day after a person or group announces an acquisition of 20% or more of our common stock. We will be entitled to redeem the rights at $0.001 per right at any time on or before the close of business on the tenth day following acquisition by a person or group of 20% or more of our common stock.

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

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

a classified board of directors;

a requirement that special meetings of shareholders be called only by our board of directors, chairman of the board, chief executive officer or president;

advance notice requirements for shareholder proposals and nominations;

limitations on the ability of shareholders to amend, alter or repeal our by-laws; and

the authority of the board of directors to issue, without shareholder approval, preferred stock with such terms as the board of directors may determine.

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

(a) Reports on Form 8-K: None

(b) Exhibits:

Exhibit 99.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Signatures

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

MEDAREX, INC.

(Registrant)

Date: May 9, 2003 By: /s/ DONALD L. DRAKEMAN

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

Date: May 9, 2003 By: /s/ CHRISTIAN S. SCHADE

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

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: May 9, 2003

/s/ Donald L. Drakeman

President and Chief Executive Officer
(Principal Executive Officer)

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: May 9, 2003

/s/ CHRISTIAN S. SCHADE

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