MEDAREX INC
Form 10-Q
May 10, 2004

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, 2004

OR

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

For the transition period from _____ to _____.

Commission File No. 0-19312

MEDAREX, INC.

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

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

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

Indicate by check x whether registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check x whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes x No ¨

The number of shares of common stock, $.01 par value, outstanding as of April 30, 2004 was 79,103,639 shares.

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31, 2003	March 31, 2004
		(Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 72,998	$ 55,231
Marketable securities	285,460	274,808
Segregated cash	5,617	6,245
Prepaid expenses and other current assets	6,244	5,465
Total current assets	370,319	341,749
Property, buildings and equipment:		
Land	6,624	6,624
Buildings and leasehold improvements	74,764	75,066
Machinery and equipment	37,006	38,195
Furniture and fixtures	4,081	4,085
Construction in progress	4,384	3,780
	126,859	127,750
Less accumulated depreciation and amortization	(31,494)	(34,814)
	95,365	92,936
Investments in Genmab	10,976	6,768
Investments in IDM	48,199	48,199
Investments in, and advances to, other partners	11,182	11,082
Segregated cash	11,579	10,354
Other assets	10,106	8,994
Total assets	$ 557,726	$ 520,082
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Trade accounts payable	$ 2,197	$ 2,028
Accrued liabilities	13,878	9,154
Deferred contract revenue current	3,807	3,501
Total current liabilities	19,882	14,683
Deferred contract revenue long-term	661	607
Other long-term liabilities	3,172	3,184
Convertible senior notes	125,000	146,986
Convertible subordinated notes	175,000	142,000
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; 79,501,080 shares issued and 79,007,564 outstanding at	795	795

December 31, 2003 and 79,512,124 shares issued and 79,094,077 shares outstanding at March 31, 2004		
Capital in excess of par value	639,784	650,080
Treasury stock, at cost 493,516 shares in 2003 and 418,047 shares in 2004	(1,242)	(1,051)
Deferred compensation	994	855
Accumulated other comprehensive income	6,560	5,783
Accumulated deficit	(412,880)	(443,840)
Total shareholders' equity	234,011	212,622
Total liabilities and shareholders equity	$ 557,726	$ 520,082

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,	
	2003	**2004**
Sales	$ 25	$
Contract and license revenues	2,174	1,106
Sales, contract and license revenues from Genmab	1,765	823
Total revenues	3,964	1,929
Costs and expenses:		
Cost of sales	3	
Research and development	23,526	22,988
General and administrative	5,684	5,808
Total costs and expenses	29,213	28,796
Operating loss	(25,249)	(26,867)
Equity in net loss of affiliate	(3,754)	(4,766)
Interest and other income	2,632	3,988
Additional payments related to asset acquisitions	(86)	
Interest expense	(2,308)	(3,635)
Gain on extinguishment of debt		326
Pre tax loss	(28,765)	(30,954)
Provision for income taxes	28	6
Loss before cumulative effect of change in accounting principle	(28,793)	(30,960)
Cumulative effect of change in accounting principle	(830)	
Net loss	$ (29,623)	$ (30,960)
Basic and diluted net loss per share:		
Loss before cumulative effect of change in accounting principle	$ (0.37)	$ (0.39)
Cumulative effect of change in accounting principle	(0.01)	
Net loss	$ (0.38)	$ (0.39)
Weighted average number of common shares outstanding basic and diluted	77,953	79,505

See notes to these unaudited consolidated financial statements.

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MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	For the Three Months Ended March 31,	
	2003	**2004**
Operating activities:		
Net income (loss)	$ (29,623)	$ (30,960)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Cumulative effect of change in accounting principle	830	
Depreciation	2,588	2,883
Amortization	812	1,155
Stock options and awards	139	126
Non-cash revenue Genmab		(500)
Equity in net loss of Genmab	3,754	4,766
Impairment loss on investments in partners		316
Gain on exchange of convertible debt		(326)
Gain on sale of equity securities		(1,664)
Changes in operating assets and liabilities		
Other current assets	1,959	791
Trade accounts payable	283	(169)
Accrued liabilities	(5,802)	(4,021)
Deferred contract revenue	502	140
Net cash used in operating activities	(24,558)	(27,463)
Investing activities:		
Purchase of property and equipment	(1,947)	(1,545)
Increase in investments and advances to affiliates and partners	(1,000)	
Decrease (increase) in segregated cash		597
Sales of marketable securities	40,044	10,765
Net cash provided by investing activities	37,097	9,817
Financing activities:		
Cash received from sales of securities, net		67
Capitalized debt exchange costs		(149)
Principal payments under debt obligations	(113)	(39)
Net cash used in financing activities	(113)	(121)
Net increase (decrease) in cash and cash equivalents	12,426	(17,767)
Cash and cash equivalents at beginning of period	61,812	72,998

Cash and cash equivalents at end of period	$ 74,238	$ 55,231
Supplemental disclosures of cash flow information		
Cash paid during period for:		
Income taxes	$	$
Interest	$ 3,944	$ 3,107

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, 2003 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, 2003.

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, 2003 and 2004, all potentially dilutive securities have been excluded from the computation of diluted net loss per share, as their effect is antidilutive.

Marketable Securities and Long-Term Non-Marketable Investments

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

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 other external sources. Based on the information acquired through these sources, the Company records an impairment charge when it believes an investment has experienced a decline in value that is considered to be other than temporary.

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company recorded impairment charges of $0 and $0.2 million related to investments in partners whose securities are publicly traded for the three month periods ended March 31, 2003 and 2004, respectively. In addition, the Company recorded impairment charges of $0 and $0.1 million in partners whose securities are privately held for the three month periods ended March 31, 2003 and 2004, respectively. Such impairment charges are included with Interest and other income in the Company s statement of operations for the three month period ended March 31, 2004.

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	
	2003	**2004**
Net loss, as reported	$ (29,623)	$ (30,960)
Add: Non-cash employee compensation	139	51
Deduct: Total stock-based employee compensation expense determined under fair value method	(2,482)	(3,185)
Pro forma net loss	$ (31,966)	$ (34,094)
Loss per share:		
Basic and diluted, as reported	$ (0.38)	$ (0.39)
Basic and diluted, pro forma	$ (0.41)	$ (0.43)

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

	2003	2004
Expected stock price volatility	76.7%	64.0%
Risk-free interest rate	3.5%	2.75%
Expected life of options	5 years	5 years
Expected dividend yield	0%	0%

Recently Issued Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities,* an interpretation of ARB 51. The primary objectives of this interpretation are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights (variable interest entities) and how to determine when and which business enterprise (the primary beneficiary) should consolidate the variable interest entity. This new model for consolidation applies to an entity in which either (i) the equity investors (if any) do not have a controlling financial interest; or (ii) the equity investment at risk is insufficient to finance that entity s activities without receiving additional subordinated

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

financial support from other parties. In addition, FIN 46 requires that the primary beneficiary, as well as all other enterprises with a significant variable interest in a variable interest entity, make additional disclosures. Certain disclosure requirements of FIN 46 were effective for financial statements issued after January 31, 2003.

In December 2003, the FASB issued FIN No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46-R) to address certain FIN 46 implementation issues. The effective dates and impact of FIN 46 and FIN 46-R are as follows:

(i) *Special purpose entities (SPEs) created prior to February 1, 2003.* The adoption of the provisions applicable to SPEs created prior to February 1, 2003 had no impact on our financial statements.

(ii) *Non-SPEs created prior to February 1, 2003.* The adoption of the provisions applicable to Non-SPEs created prior to February 1, 2003 had no impact on our financial statements.

(iii) *All entities, regardless of whether a SPE, that were created subsequent to January 31, 2003.* The provisions of FIN 46 were applicable for variable interests in entities obtained after January 31, 2003. The adoption of the provisions applicable to SPEs and all other variable interests obtained after January 31, 2003 had no impact on our financial statements.

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 31.3% interest in Genmab as of December 31, 2002.

In July 2003, the Company received 246,914 shares of Genmab stock valued at $2.0 million representing payment for the fourth of five annual payments under an August 2000 binding memorandum of understanding between the Company and Genmab. The Company s ownership percentage in Genmab was approximately 31.8% as of March 31, 2004.

During the three month periods ended March 31, 2003 and 2004, the value of the Company s investment in Genmab was adjusted to reflect the Company s share of Genmab s net loss ($3.8 million) and ($4.8 million), respectively, and unrealized gains of $2.1 million and $0.6 million, respectively, related to foreign exchange translation. Such foreign exchange translation adjustments are included within accumulated other comprehensive income in the Company s consolidated balance sheets.

Summary financial information for Genmab is as follows:

	As of and for the Three Months Ended March 31	
	2003	2004
Current assets	$ 186,942	$ 166,097
Non current assets	23,350	16,524
Current liabilities	17,565	12,959
Non current liabilities	3,350	2,536
Revenue		
Gross profit		
Net loss	(12,001)	(15,002)

MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Debt Exchange and Cancellation

In January 2004, the Company and certain holders of its 4.50% Convertible Subordinated Notes due 2006 (the 4.50% Notes) completed an exchange and cancellation of $33.0 million principal amount of the 4.50% Notes, for the issuance of $21.986 million in aggregate principal of a new series of the Company s 4.25% Convertible Senior Notes due August 15, 2010, in a limited number of transactions. As a result of this exchange and cancellation, the Company s total convertible debt was reduced by $11.014 million. In addition, the Company recorded a gain on the early extinguishment of debt of approximately $0.3 million for the three month period ended March 31, 2004 in connection with the exchange and cancellation.

4. Contingencies

The Company has a contingent commitment to pay $1.0 million to Essex Chemical Corporation (Essex) without interest in installments equal to 20% of net after tax earnings of the Company in future years. The Company s contingent commitment, as amended, to pay up to $1.0 million out of future earnings may be satisfied, at the Company s option, through the payment of cash or shares of the Company s common stock having a fair market value equal to the amount owed, provided that such shares are registered with the Securities and Exchange Commission. The Company accrued $0.7 million related to this liability during 2000, and such amount remains accrued at March 31, 2004.

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

5. Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net 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	
	2003	2004
Net loss	$ (29,623)	$ (30,960)
Unrealized loss on securities	(2,519)	(1,335)
Unrealized gain on foreign exchange	2,148	558
Total comprehensive loss	$ (29,994)	$ (31,737)

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MEDAREX, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Segment Information

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

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

	Three Months Ended March 31	
Customer	**2003**	**2004**
Genmab A/S	45%	43%
Novartis Pharma AG	15%	25%
Amgen, Inc.	13%	%

No other single customer accounted for more than 10% of the Company s total revenues for the three months ended March 31, 2003 and 2004, respectively.

7. Subsequent Events

On April 9, 2004, the Company filed a registration statement with the Securities and Exchange Commission related to a proposed public offering of a portion of the common stock of its wholly-owned subsidiary, Celldex Therapeutics, Inc. (Celldex). As part of this transaction, the Company assigned and licensed to Celldex certain intellectual property related to its vaccine technology, including the rights to MDX-1307, one of the Company s product candidates for the treatment of cancer, as well as the Investigational New Drug Application associated with this product which became effective in February 2004. If the offering proceeds, the Company anticipates that it will continue to hold approximately 75% of the outstanding shares of common stock of Celldex.

On May 3, 2004, the Company completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended, of $150.0 million of 2.25% Convertible Senior Notes due May 15, 2011 (the 2.25% Notes) to qualified institutional investors. The 2.25% Notes are initially convertible into shares of Medarex common stock at the rate of 72.9129 per each $1,000 principal amount of the 2.25% Notes, which is equivalent to an initial conversion price of approximately $13.72 per share, subject to anti-dilution adjustments.

The Company will pay interest on the 2.25% Notes on May 15 and November 15 of each year beginning on November 15, 2004. The Company expects to receive net proceeds from the private placement of approximately $145.2 million (after deducting the initial purchasers discounts and

estimated offering expenses).

Concurrent with this private placement, the Company repurchased $65.6 million in aggregate principal amount of its 4.50% notes for cancellation.

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

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

Overview

We are a biopharmaceutical company focused on the discovery and development of fully human antibody-based therapeutic products. We believe that our UltiMAb Human Antibody Development System® enables us to rapidly create and develop fully human antibodies for a wide range of diseases, including cancer, inflammation, autoimmune disease and other life-threatening and debilitating diseases.

We believe that antibodies are proven candidates for therapeutic products. To date, the United States Food and Drug Administration, or FDA, has approved 17 antibody-based therapeutic products for sale in the United States. In 2003, 15 of these products generated aggregate worldwide sales in excess of $5.0 billion. We intend to participate in this market and, to this end, are developing an expanding pipeline of therapeutic antibody products generated through the use of our proprietary UltiMAb human antibody development technology.

Currently, 17 antibody products derived from our UltiMAb human antibody development technology are in human clinical trials, or have had regulatory applications submitted for such trials. These antibodies are designed to treat a wide range of diseases, such as cancer (including various lymphomas), rheumatoid arthritis and other inflammatory and autoimmune diseases. Five of these antibody products are fully owned by Medarex or its affiliates: MDX-010 (Phase II clinical trials), MDX-060 (Phase II clinical trials), MDX-070 (Phase I/II clinical trials), MDX-214 (Phase I/II clinical trials) and MDX-1307 (Phase I clinical trials). These fully-owned antibody products are being developed for the treatment of various diseases, including cancer, lymphoma and/or HIV. In the second quarter of 2004, we submitted a Special Protocol Assessment to the FDA for a pivotal program for MDX-010 in combination with the gp100 vaccine and expect to file the manufacturing data necessary to initiate this pivotal program in June 2004. Subject to final discussions with the FDA, we expect to begin enrolling patients in this pivotal program during the third quarter of 2004. In addition, one antibody product for autoimmune disease, MDX-018 (Phase I/II clinical trials), is being jointly developed with our licensing partner, Genmab A/S, and four are being developed separately by Genmab: HuMax-CD4 (Phase II clinical trials) for cutaneous T-cell lymphoma, HuMax-IL15 (Phase II clinical trials) for rheumatoid arthritis, HuMax-EGFr (Phase I/II clinical trials) for head and neck cancer and HuMax-CD20 (Phase I/II clinical trials) for non-Hodgkin s lymphoma. Additionally, our licensing partners, including Novartis Pharma AG and Centocor, Inc. (a subsidiary of Johnson & Johnson), among others, are developing a total of seven antibody products for inflammatory and/or autoimmune diseases and cancer that are currently in early clinical trials. We and our partners also have a number of product candidates in preclinical development. The preceding information regarding the clinical status of antibody products is based on our and our partners public disclosures and other publicly available information.

Our revenue is principally derived through the licensing of our fully human antibody technology to pharmaceutical and biotechnology companies. The terms of these license agreements typically include potential license fees and a series of potential milestone payments commencing upon the initiation of clinical trials and continuing through commercialization. These payments may total $7 million to $10 million per product if the antibody receives approval from the FDA and equivalent foreign agencies. We are also entitled to receive royalties on product sales. Additional revenue may be earned from the sales to, and in some cases, the manufacturing of antibodies for our partners, as well as from government grants.

Our most significant costs on an annual basis are research and development expenses and general and administrative expenses. Research and development expenses represent those costs which support the advancement of our product pipeline and primarily consist of personnel costs, facilities (including depreciation), research and laboratory supplies, funding of outside research, license and technology access fees, expenses related to antibody manufacturing and clinical trial expenses. We believe that continued investment in research and development is critical to attaining our strategic objectives. General and administrative expenses consist primarily of personnel expenses for executive, finance, legal and administrative personnel, professional fees and other general corporate expenses. We may be required to add personnel in the future and incur additional costs as we expand our business activities.

We have a history of operating losses and may not achieve profitability. As of March 31, 2004, we had an accumulated deficit of approximately $443.8 million. Over the next several years, we expect to incur substantial expenses as we continue to identify, develop and manufacture our potential products, invest in research and move forward with our product development. Our commitment of resources to research and the continued development of our product candidates will require substantial additional funds. Our operating expenses may also increase as we invest in research or acquire additional technologies, as additional potential products are selected as clinical candidates for further development and as some of our earlier stage product candidates move into later stage clinical development. In addition, we may incur significant milestone payment obligations as our products progress towards commercialization. In the absence of substantial revenues from new corporate collaborations or other sources, we will incur substantial operating losses and may be required to delay, reduce or eliminate certain of our research and development programs.

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 materially 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

We receive payments from our customers and partners for the sale of antibodies, for licenses to our proprietary technology, for product development services and from the achievement of product development milestones. These payments are generally non-refundable and are reported as deferred revenue until they are recognizable as revenue. We follow the following principles in recognizing revenue:

We sell antibodies primarily to partners in the United States and overseas. Revenue from these sales is recognized when the antibodies are shipped.

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We receive research fees from the licensing of our proprietary technologies for research and development performed by our customers and partners. Revenue from these research fees is recognized generally over the term of the respective license beginning only after both the license period has begun and the technology has been delivered.

We receive fees for product development services (including manufacturing) we perform for our customers and partners. These fees are recognized ratably over the entire period during which the services are performed.

Revenue from milestone payments is recognized when each milestone is achieved and when collectibility of such milestone payment is assured. Milestone payments are triggered either by the results of our research efforts or by the efforts of our partners and include such events as submission of an IND, commencement of Phase I, II or III clinical trials, submission of a BLA and approval of a product. Milestone payments are substantially at risk at the inception of an agreement. Upon achievement of a milestone event, we have no future performance obligations relating to that event.

Investments

Our investment policy calls for investments in fixed income high grade securities such as U.S. corporate debt securities, U.S. treasury obligations and money market funds for which we believe there is not a significant risk of loss. Our primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return consistent with these two objectives. However, in the course of our business, we have made and may continue to make investments in companies (both public and private) as part of our strategic collaborations. Investments in companies whose securities are publicly traded (other than Genmab) are classified as marketable securities on our consolidated balance sheets. The fair market value of investments in our partners whose securities are publicly traded was approximately 1.5% and 0.9% of total marketable securities as of December 31, 2003 and March 31, 2004, respectively.

Under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* our marketable securities are classified as available-for-sale securities and are carried at fair value. Marketable securities will 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 applicable period in light of the facts and circumstances surrounding the investments.

In addition, in connection with our collaborative partnering business, we sometimes make strategic investments in the securities of companies that are privately held. Investments in our partners whose equity is not publicly traded are classified in separate line items in our consolidated balance sheet entitled Investments in IDM and Investments in, and advances to, other partners and were approximately $59.3 million as of March 31, 2004. These securities are carried at original investment cost. Because these securities are not listed on a financial exchange, the value of these investments is inherently more difficult to estimate than investments in public companies. 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 financial condition and/or operating results of the companies in which we invest that may not be reflected in an investment s current carrying value may also require an impairment charge in the future.

Valuation of Long-Lived and Intangible Assets

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

- a significant underperformance relative to expected historical or projected future operating results;
- a significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or
- a significant negative industry or economic trend.

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

Acquired In-Process Technology

Acquired In-Process Technology expense is determined based on an analysis using risk-adjusted cash flows expected to be generated by products that may result from in-process technologies which have been acquired. This analysis includes forecasting future cash flows that are expected to result from the progress made on each in-process project prior to the acquisition date. Cash flows are estimated by first forecasting, on a product-by-product basis, net revenues expected from the sales of the first generation of each in-process project and risk adjusting these revenues to reflect the probability of advancing to the next stage of the FDA approval process. The forecast data in the analysis is based on internal product forecast information maintained by us in the ordinary course of business. The inputs used in analyzing Acquired In-Process Technology is based on assumptions, which we believe to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Appropriate operating expenses are deducted from forecasted net revenues on a product-by-product basis to establish a forecast of net returns on the completed portion of the in-process technology. Finally, net returns are discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and our company as well as product specific risks associated with the acquired in-process research and development products. The product specific risk factors include the product s phase of development, type of antibody under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, a discount rate is used for the valuation, which represents a considerable risk premium to our weighted average cost of capital. The valuations used to estimate Acquired In-Process Technology require us to use significant estimates and assumptions that if changed, may result in a different valuation for Acquired In-Process Technology.

Results of Operations

Three months ended March 31, 2003 and 2004

Contract and License Revenues

Contract and license revenues totaled $2.2 million and $1.1 million for the three month periods ended March 31, 2003 and 2004, respectively. Contract and license revenues for the three month period ended March 31, 2004 decreased by $1.1 million or 49% as compared to the three month period ended March 31, 2003. This decrease relates primarily to decreased revenue of $0.5 million from Amgen, $0.3 million from Eli Lilly and $0.3 million from Kirin. Because contract and license revenues depend to a large extent on the product development efforts of our partners and licensees, our year-to-year contract and license revenues can fluctuate significantly and are inherently difficult to predict.

Sales, Contract and License Revenues from Genmab

Sales, contract and license revenues from Genmab were $1.8 million and $0.8 million for the three month periods ended March 31, 2003 and 2004, respectively. Sales, contract and license revenues from Genmab for the three month period ended March 31, 2004 decreased by $1.0 million or 53% as compared to the three month period ended March 31, 2003. This decrease is primarily the result of a decrease in antibody exclusive licenses granted to Genmab in the first quarter of 2004 as compared to the first quarter of 2003.

Research and Development Expenses

Research and development expenses for our products in development were $23.5 million and $23.0 million for the three month periods ended March 31, 2003 and March 31, 2004, respectively. Research and development expenses for the three month period ended March 31, 2004 decreased by $0.5 million, or 2% as compared to the three month period ended March 31, 2003. Historically, due to the relatively small number of our products in clinical trials, we have not accounted for our research and development expenses on a project-by-project basis and, therefore, we do not provide a breakdown of such historical information in that format. We have, historically, tracked our costs in the categories discussed below: research and product development and by the types of costs as outlined below. We separate research and development expenditures on the basis of amounts associated with research and amounts associated with product development. Our research costs consist of costs associated with the breeding, care and continued development of our HuMAb-Mouse and KM-Mouse, as well as costs associated with research and testing of our product candidates prior to reaching the preclinical stage. Such research costs primarily include personnel costs, facilities (including depreciation), research supplies, funding of outside research and license and technology access fees. Our product development costs consist of costs of preclinical development (including manufacturing) and conducting and administering clinical trials. Such product development costs also include personnel costs, facilities (including depreciation), supply expense related to antibody manufacturing and clinical trial expenses.

The following table sets forth a breakdown of our research and development expenses by those associated with research and those associated with product development for the periods indicated.

	Three Months Ended March 31,	
	2003	**2004**
Research	$ 9,136	$ 9,163
Product Development	14,390	13,825
Total	$ 23,526	$ 22,988

Research Costs

Research costs for the three month period ended March 31, 2004 increased by $27 thousand, or 0.3% as compared to the three month period ended March 31, 2003. The increase in research costs primarily relates to the following:

Facility costs for the three month period ended March 31, 2004 were $2.0 million, an increase of $0.4 million or 23% as compared to the three month period ended March 31, 2003. The increase in facility costs primarily relates to the substantial investments made in our research facilities in recent years. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for the three month period ended March 31, 2004, as compared to the three month period ended March 31, 2003. We expect to incur increased facility costs as a result of continued capital expansion, renovations and replacements but at a slower rate.

License and technology access fees for the three month period ended March 31, 2004 were $0.4 million, a decrease of $0.4 million or 52% as compared to the three month period ended March 31, 2003. These

costs represent fees paid to certain partners and research organizations in connection with certain of our collaboration and license agreements. Included in the 2003 cost are payments to certain entities for licenses to certain technologies for which no comparable payments were made in 2004. We expect license fees, including funds paid to certain partners, to increase in the future.

Product Development Costs

Product development costs for the three month period ended March 31, 2004 decreased by $0.6 million, or 4% as compared to the three month period ended March 31, 2003. The decrease in product development costs primarily relates to the following:

Personnel costs for the three month period ended March 31, 2004 were $5.5 million, an increase of $0.3 million or 6% as compared to the three month period ended March 31, 2003. The increased personnel costs are a result of the increased staff needed to support higher levels of clinical trial manufacturing activities and more extensive clinical trial activities. Personnel costs primarily include salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase, but at a slower rate, as we continue to increase our product development activities and progress our products through clinical trials.

Supply costs for the three month period ended March 31, 2004 were $1.1 million, a decrease of $0.8 million or 42% as compared to the three month period ended March 31, 2003. In 2003 we began manufacturing material in anticipation of a pivotal trial for MDX-010, which resulted in increased supply costs. Included in these costs are material and small equipment associated with the manufacture of material for clinical trials. We expect these costs to increase as we continue to expand our product development efforts and increase our clinical trial activities. Such costs in the future may also include payments to third party commercial manufacturers to support the advancement of our clinical pipeline.

We expect product development costs to increase in the future as more of our products enter clinical trials. In addition, we may be obligated to make milestone payments on certain of our products as they progress through the clinical trial process.

Completion of clinical trials may take several years or more. The length of time varies according to the type, complexity and intended use of the product candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following periods:

Clinical Phase	Estimated Completion Period
Phase I	1-2 Years
Phase II	1-2 Years
Phase III	2-4 Years

The duration and cost of clinical trials may vary significantly over the life of a particular project as a result of, among other things, the following factors:

the length of time required to recruit qualified patients for clinical trials;

the duration of patient dosing and follow-up in light of trial results;

the number of clinical sites required for trials; and

the number of patients that ultimately participate.

We continue to explore new collaborative arrangements that may affect future spending for research and development. 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 II. 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

General and administrative expenses include compensation, professional services, consulting, travel and facilities (including depreciation) and other expenses related to legal, business development, finance, information systems and investor relations. General and administrative expenses totaled $5.7 million and $5.8 million for the three month periods ended March 31, 2003 and 2004, respectively. General and administrative expenses increased by $0.1 million for the three month period ended March 31, 2004, or 2% as compared to the three month period ended March 31, 2003. This increase is primarily attributable to higher insurance costs of $0.2 million and increased facility costs of $0.1 million, partially offset by a reduction in legal fees of $0.2 million. 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

Equity in net loss of affiliate represents our share of Genmab s net loss for the three month periods ended March 31, 2003 and 2004. Genmab is an affiliated company and is accounted for using the equity method of accounting. The recognition of our share of Genmab s net losses reduces the carrying value, or basis, of our investment in Genmab. We expect that during the second half of 2004 the remaining basis of our investment in Genmab will be reduced to zero and, accordingly, recognition of our share of Genmab s net losses will be suspended.

Equity in net loss of affiliate was $3.8 million and $4.8 million for the three month periods ended March 31, 2003 and 2004, respectively. Equity in net loss of affiliate for the three month period ended March 31, 2004 increased by $1.0 million or 27% as compared to the three month period ended March 31, 2003. This increase reflects an increase in Genmab s net loss as a result of its expanded research and development efforts.

Interest and Other Income

Interest and other income consists primarily of interest earned from our cash, cash equivalents and marketable securities. Interest and other income was $2.6 million and $4.0 million for the three month periods ended March 31, 2003 and 2004, respectively. Interest and other income for the three month period ended March 31, 2004 increased by $1.4 million, or 52% as compared to the three month period ended March 31, 2003. Included in interest and other income for the three month period ended March 31, 2004 is a gain on the sale of common stock of Protein Design Labs, Inc. of approximately $1.7 million offset by an impairment loss on investments in certain of our partners of $0.3 million. Excluding the impact of this gain and impairment loss, interest and other income would have been comparable to the three month period ended March 31, 2003.

Additional Payments Related to Asset Acquisitions

Additional payments related to asset acquisitions of $0.1 million for the three month period ended March 31, 2003 represents additional purchase 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. No similar payments were made in the three-month period ended March 31, 2004.

Interest Expense

Interest expense was primarily related to interest and amortization of issuance costs on our 4.25% Convertible Senior Notes issued in July 2003, or the 4.25% Notes and our 4.50% Convertible Subordinated Notes issued in June 2001, or the 4.50% Notes. Interest expense was $2.3 million and $3.6 million for the three month periods ended March 31, 2003 and 2004, respectively. Interest expense for the three month period ended March 31, 2004 increased by $1.3 million, or 58% as compared to the three month period ended March 31, 2003 reflecting the addition of interest expense on our 4.25% Notes which were issued in July 2003. The 4.25% Notes are due in August 2010 and interest is payable semi-annually on February 15 and August 15 of each year.

Gain on Extinguishment of Debt

In January 2004, we and certain holders of our 4.50% Notes completed in a limited number of transactions, an exchange and cancellation of $33.0 million in aggregate principal amount of the 4.50% Notes, for the issuance of $21.986 million in aggregate principal of a new series of 4.25% Convertible Senior Notes due August 15, 2010. As a result of this exchange and cancellation, our total convertible debt was reduced by $11.014 million and we recorded a gain of approximately $0.3 million for the three month period ended March 31, 2004.

Cumulative Effect of a Change in Accounting Principle

Cumulative effect of a change in accounting principle for 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.

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 notes. 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, 2004, we had $330.0 million in cash, cash equivalents and marketable securities. We primarily 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

Cash used in operating activities was $24.6 million and $27.5 million for the three month periods ended March 31, 2003 and 2004, respectively. This reflects an increase of $2.9 million for the three month period ended March 31, 2004 as compared to the three month period ended March 31, 2003. The increase is primarily the result of a decrease in cash received from our partners. This decrease in cash received from our partners is a direct result of decreased contract and license revenues and decreased sales, contract and license revenues from Genmab. As previously indicated, revenues can fluctuate significantly since they depend in large part, on the product development efforts of our partners and licensees.

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical and clinical trials, as our products are developed. We plan to spend significant amounts to

progress our current products through the clinical trial and commercialization process as well as to develop additional product candidates on our own or with our partners. As our products progress through the clinical trial process, we may be obligated to make significant milestone payments on certain of our products. We also expect to incur future facility costs as a result of our continued capital expansion, renovations and replacements, but at a reduced rate. To a lesser extent, we expect our general and administrative costs to increase as we expand our administrative and business development activities. Furthermore, we expect our investment income to decrease as we fund our future operations and capital expenditures from our cash reserves. We anticipate that our operating expenditures may be partially offset by revenues from partners for license fees, milestone payments, and development and manufacturing services.

Cash Provided by Investing Activities

Cash provided by investing activities was $37.1 million and $9.8 million for the three month periods ended March 31, 2003 and 2004, respectively. The decrease in cash provided by investing activities of $27.3 million for the three month period ended March 31, 2004 as compared to the three month period ended March 31, 2003 was primarily the result of a decrease in the sales of marketable securities of approximately $29.3 million offset, in part, by decreased capital expenditures for the three month period ended March 31, 2004. Operations and capital expenditures for the three month period ended March 31, 2003 were primarily funded through the sales of marketable securities while operations and capital expenditures for the three month period ended March 31, 2004 were funded through a combination of cash on hand and, to a lesser extent, the sales of marketable securities.

We expect 2004 capital expenditures to be approximately $12.0 million representing the purchase of machinery and scientific equipment, additional investment in lab automation, and the planned expansion of our Bloomsbury facility to accommodate the relocation of our clinical staff from our Clinton, New Jersey, facility whose lease expires in late 2004.

Cash Used by Financing Activities

Cash used by financing activities was $0.1 million and $0.1 million for the three month periods ended March 31, 2003 and 2004, respectively. Cash used by financing activities for the three month period ended March 31, 2003 was the result of principal payments made under existing capital lease obligations. Cash used by financing activities for the three month period ended March 31, 2004 was the result of costs associated with our debt exchange and cancellation (discussed below) of $0.1 million, offset, in part, by cash received from the exercise of stock options of $67 thousand.

In January 2004, we and certain holders of our 4.50% Notes completed in a limited number of transactions, an exchange and cancellation of $33.0 million in aggregate principal amount of the 4.50% Notes, for the issuance of $21.986 million in aggregate principal of a new series of 4.25% Notes. As a result of this exchange and cancellation, our total convertible debt was reduced by $11.014 million.

Other Liquidity Matters

In connection with our merger with Essex Medical Products in 1987, we are committed to pay to Essex Chemical Corporation, or Essex, 20% of our net after-tax income until a total of $1.0 million has been paid, contingent upon the occurrence of certain events. As the result of our net income in 2000 we accrued $0.7 million payable to Essex, which remains accrued at March 31, 2004. At our option, this obligation may be satisfied by the payment of shares of our common stock having a fair market value equal to the amount owed, provided such shares are registered for sale with the Securities and Exchange Commission.

We have filed a registration statement with the Securities and Exchange Commission related to a proposed public offering of a portion of the common stock of our wholly-owned subsidiary Celldex Therapeutics, Inc. As part of this transaction, we have assigned or licensed to Celldex certain intellectual property related to our

vaccine technology, including the rights to MDX-1307, one of our product candidates for the treatment of cancer, as well as the IND associated with this product which became effective in February 2004. If the offering proceeds, we anticipate that we will continue to hold approximately 75% of the outstanding shares of common stock of Celldex. We cannot assure you that this transaction will be consummated.

On May 3, 2004, we completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended, of $150.0 million of 2.25% Convertible Senior Notes due May 15, 2011 (the 2.25% Notes) to qualified institutional investors. The 2.25% Notes are initially convertible into shares of our common stock at the rate of 72.9129 per each $1,000 principal amount of the 2.25% Notes, which is equivalent to an initial conversion price of approximately $13.72 per share, subject to anti-dilution adjustments.

We will pay interest on the 2.25% Notes on May 15 and November 15 of each year beginning on November 15, 2004. We expect to receive net proceeds from the private placement of approximately $145.2 million (after deducting the initial purchasers discounts and estimated offering expenses).

Concurrent with this private placement, we repurchased $65.6 million in aggregate principal amount of our 4.50% Notes for cancellation. We intend to continue to purchase or redeem all or a portion of the 4.50% Notes with the proceeds from the private placement.

Financial Uncertainties Related to Potential Future Milestone Payments

Effective September 4, 2002, we entered into a Collaboration and License Agreement with Kirin Brewery Co., Ltd., which provides for us to exchange with Kirin certain cross-licenses for each other s technology for the development and commercialization of human antibody products. Pursuant to a letter of intent that was superceded by the Collaboration and License Agreement, we and Kirin developed the KM-Mouse®, a unique crossbred mouse which combines the traits of our HuMAb-Mouse® with Kirin s TC Mouse. Under the Collaboration and License Agreement, we are exchanging cross-licenses with Kirin with respect to the KM-Mouse and other antibody-generating mice. In addition, certain of the cross-licenses granted under the Collaboration and License Agreement are subject to license, milestone and royalty payments by one party to the other.

Through March 31, 2004, we have not made any milestone payments to Kirin. Based on a total of three products we are developing which use or, we believe may use, Kirin technology that (i) are currently in clinical trials, or (ii) we anticipate may enter clinical trials through the end of 2005, we may be required to make milestone payments to Kirin aggregating up to approximately $12.75 million with respect to such products, or a maximum of approximately $4.25 million per product. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

- whether or not a decision is made to request a license from Kirin;
- the type of license requested (research or commercial);
- the success and timing of development efforts and clinical trials of product candidates covered by any such licenses;
- the type of product developed, (payment obligations differ depending on whether a product is an *ex vivo* therapeutic, *in vivo* therapeutic, research reagent or diagnostic); and

other financial provisions of the Kirin agreement that provide for variations in fee levels and netting of certain payments over specified periods of time that may impact the total amount potentially payable to Kirin for any particular license fee or milestone payment.

We have also entered into a number of other agreements that contain licenses of third-party technology which may be used together with our own platform technologies for the generation, development and/or

manufacture of our antibody products. In addition, we have entered into other third-party agreements that contain licenses associated with antibody products that target specific antigens. Many of these agreements contain milestone payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of our products currently under development trigger such milestone payments. Through March 31, 2004, we have made no milestone payments under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of five products we are developing for which milestones are potentially due and that (i) are now in clinical trials, or (ii) which we anticipate may enter clinical trials before the end of 2005, we may be obligated to make future milestone payments aggregating up to approximately $30.625 million with respect to such products. In general, potential milestone payments for our antibody products may or may not be triggered under these licenses, and may vary in size, depending on a number of variables, almost all of which are currently uncertain. Typically, the events that trigger these payments per product include:

submission of IND(s) or foreign equivalents;

commencement of Phase I, Phase II and/or Phase III clinical trials or foreign equivalents;

submission of BLA(s) or foreign equivalents; and

receipt of marketing approval(s) to sell products in a particular country or region.

In addition, the licenses above may trigger royalty payments in connection with the commercialization of certain of our products. To date, we have not made any royalty payments on sales of our products and believe we are at least a few years away from selling any products that would require us to make any such royalty payments. Whether we will be obligated to make milestone or royalty payments in the future is subject to the success of our product development efforts and, accordingly, is inherently uncertain.

Future Liquidity Resources

Our current sources of liquidity are our 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 $76.4 million and/or the $146.986 million required to meet our repayment obligations with respect to our convertible notes due on July 1, 2006, and August 15, 2010, respectively. To the extent our convertible notes are converted into shares of our common stock on or before their respective maturity dates, we will have use of that portion of the notes to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We cannot assure you that we will be able to raise such additional funds. We may be unable to raise sufficient funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

Recently Issued Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities,* an interpretation of ARB 51. The primary objectives of this interpretation are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights (variable interest entities) and how to determine when and which business enterprise (the primary beneficiary)

should consolidate the variable interest entity. This new model for consolidation applies to an entity in which either (i) the equity investors (if any) do not have a controlling financial interest; or (ii) the equity

investment at risk is insufficient to finance that entity s activities without receiving additional subordinated financial support from other parties. In addition, FIN 46 requires that the primary beneficiary, as well as all other enterprises with a significant variable interest in a variable interest entity, make additional disclosures. Certain disclosure requirements of FIN 46 were effective for financial statements issued after January 31, 2003.

In December 2003, the FASB issued FIN No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46-R) to address certain FIN 46 implementation issues. The effective dates and impact of FIN 46 and FIN 46-R are as follows:

(i) *Special purpose entities (SPEs) created prior to February 1, 2003.* The adoption of the provisions applicable to SPEs created prior to February 1, 2003 had no impact on our financial statements.

(ii) *Non-SPEs created prior to February 1, 2003.* The adoption of the provisions applicable to Non-SPEs create prior to February 1, 2003 had no impact on our financial statements.

(iii) *All entities, regardless of whether a SPE, that were created subsequent to January 31, 2003.* The provisions of FIN 46 were applicable for variable interests in entities obtained after January 31, 2003. The adoption of the provisions applicable to SPEs and all other variable interests obtained after January 31, 2003 had no impact on our financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

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

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

Item 4. Controls and Procedures

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

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

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

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

PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 5. Other Information

Additional factors that might affect future results include the following:

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

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Active product candidates employing our human antibody technology are in the early and middle stages of clinical development. Based on public disclosures, regulatory applications, including INDs, have been submitted to the FDA or comparable foreign authorities, for 17 product candidates derived from our UltiMAb platform. To date, neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA or comparable foreign authorities and/or commercialized. In addition, we are not aware of any commercialized fully human monoclonal antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond the early or middle stages of product development or demonstrate clinical safety and effectiveness.

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

business, financial condition and results of operations may be materially harmed.

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

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

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

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

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

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

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

We have incurred large operating losses and we anticipate that these losses will continue for the foreseeable future. In particular, as of March 31, 2004, we had an accumulated deficit of approximately $443.8 million. Our net losses were $129.3 million and $31.0 million for the year ended December 31, 2003 and the three month period ended March 31, 2004, respectively. Our losses have resulted principally from:

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

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

general and administrative costs relating to our operations.

We intend to continue to make significant investments in:

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

In addition, we may be obligated to make milestone payments on certain of our products as they progress through the clinical trial process.

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

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

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

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

- the timing of the commencement, completion or termination of partnership agreements;
- the introduction of new products and services by us, our partners or our competitors;
- delays in, or termination of, preclinical testing and clinical trials;
- changes in regulatory requirements for clinical trials;
- costs and expenses associated with preclinical testing and clinical trials;
- the timing of regulatory approvals, if any;

sales and marketing expenses; and

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

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

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

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

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

the size and complexity of research and development programs;

the scope and results of preclinical testing and clinical trials;

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

- continued scientific progress in our research and development programs;
- the time and expense involved in seeking regulatory approvals;
- competing technological and market developments;
- the time and expense of filing and prosecuting patent applications and enforcing patent claims; and
- the cost of establishing manufacturing capabilities, conducting commercialization activities and arrangements and in-licensing products.

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

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

We have a significant amount of existing debt and debt service obligations, which, unless converted to shares of our common stock or redeemed, will mature in 2006 (approximately $76.4 million), 2010 (approximately $147.0 million) and 2011 ($150.0 million), respectively. Our ability to make payments on our debt will depend on our future operating performance and ability to generate cash and may also depend on our ability to obtain additional debt or equity financing. Generally, during the last five years, our operating cash flows were negative and insufficient to cover our fixed charges. Our ability to generate sufficient operating cash flow to service our indebtedness, including the notes, and fund our operating requirements will depend on our ability, alone or with others, to successfully develop, manufacture, and obtain required regulatory approvals and market our product candidates, as well as other factors, including general economic, financial, competitive, legislative and regulatory conditions, some of which are beyond our control. If we are unable to generate sufficient operating cash flow to service our indebtedness and fund our operating requirements, we may need to obtain additional debt or equity financing to do so, which may not be available to us on satisfactory terms or at all. In addition, if new indebtedness is incurred, the risks relating to our ability to service our indebtedness that we face could intensify.

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

- limiting our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business;

placing us at a competitive disadvantage relative to our competitors who have lower levels of debt;

making us more vulnerable to a downturn in our business or the economy generally; and

requiring us to use a substantial portion of our cash to pay principal and interest on our debt, instead of applying those funds to other purposes such as working capital and capital expenditures.

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

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

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

Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our human antibody technology. In a number of instances, we have terminated the development of certain products in the early stages of human clinical testing due to a lack of effectiveness. None of these products employed our core fully human antibody technology. In addition, we have determined not to continue the development of one late-stage product candidate due to both a lack of effectiveness and unforeseen safety issues that arose in clinical testing. This product did not employ our core fully human antibody technology.

Generally, our clinical trials, including our melanoma trials, are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. The most common adverse events associated with our melanoma trials have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related autoimmune adverse events, such as dermatitis and colitis, ranging from mild in most cases to severe in a very small number of instances. Almost all of these adverse events responded to medical therapy. In a very small number of instances, fatalities have occurred during the course of these trials such fatalities may or may not be attributable to our product. We believe that these adverse events will not materially affect our ability to continue with clinical

trials of this product as planned. We cannot assure you that additional safety issues will not arise with respect to our products in the future.

To date, we have experienced slower than expected rates of patient recruitment in certain of our clinical trials. As a result, in certain instances, we have experienced delays in our product development and clinical

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

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

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

In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. For example, the FDA is in the process of moving several product categories currently regulated by the agency s Center for Biologics Evaluation and Research, or CBER, to the agency s Center for Drug Evaluation and Research, or CDER. These product categories include 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, controversial subjects which have received adverse publicity from animal rights activists and various other interest groups. Such adverse publicity could decrease market acceptance of products employing our technology.

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 may experience pressure to lower the prices of any prescription pharmaceutical products we are able to obtain approval for because of new and/or proposed federal legislation.

New federal legislation, enacted in December 2003, has added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations may increase pressures to lower prices. While the new law specifically prohibits the United States government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the United States government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating de facto price controls on prescription drugs. In addition, the new law contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include some sorts of limitations on prescription drug prices. Our results of operations could be materially harmed by the Medicare prescription drug coverage legislation, by the potential effect of such legislation on amounts that private insurers will pay for our products and by other healthcare reforms that may be enacted or adopted in the future.

We may face increased competition from products imported from Canada or other countries.

Any products we are able to commercialize may be subject to competition from lower priced versions of such products and competing products from Canada, Mexico, and other countries where there are government price controls or other market dynamics that make the products lower priced. The ability of patients and other customers to obtain these lower priced imports has grown significantly as a result of the Internet, an expansion of pharmacies in Canada and elsewhere targeted to American purchasers, the increase in U.S.-based businesses affiliated with Canadian pharmacies marketing to American purchasers, and other factors. Many of these foreign imports are illegal under current law. However, the volume of imports continues to rise due to the limited enforcement resources of the FDA and the U.S. Customs Service, and the pressure in the current political environment to permit the imports as a mechanism for expanding access to lower priced medicines.

In addition, in December 2003, federal legislation was enacted to change United States import laws and expand the ability to import lower priced versions of our and competing products from Canada, where there are

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government price controls. These changes to the import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The current Secretary of Health and Human Services has indicated that there is not a basis to make such a certification at this time. However, it is possible that this Secretary or a subsequent Secretary could make the certification in the future. In addition, legislative proposals have been made to implement the changes to the import laws without any certification, and to broaden permissible imports in other ways. Even if the changes to the import laws do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the Customs Service, and other government agencies. For example, state and local governments have suggested that they may import drugs from Canada for employees covered by state health plans or others, and some have already put such plans in place.

The importation of foreign products could adversely affect our profitability. This potential impact could become more significant in the future, and the impact could be even greater if there is a further change in the law or if state or local governments take further steps to import products from abroad.

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

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

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

We may also encounter problems with the following:

- production yields;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with FDA regulations, including the demonstration of purity and potency;
- changes in FDA requirements;
- production costs; and/or
- development of advanced manufacturing techniques and process controls.

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. We are currently pursuing late-stage clinical and commercial supply agreements with cGMP-compliant third-party manufacturers with available capacity to meet our internal production timetables. In September 2003, we entered into a clinical supply agreement with Lonza Group Ltd. with respect to MDX-010, and discussions are ongoing with respect to terms of a commercial supply agreement. We do not currently have the capability to manufacture our products under development in large commercial quantities and have no experience in commercial-scale manufacturing. 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 such companies for clinical and/or commercial supply on acceptable terms or in a timely manner, if at all. Moreover, even if we are able to enter into clinical and/or commercial supply manufacturing arrangements with cGMP-compliant third-party manufacturers, we cannot

assure you that such manufacturers will be able to produce products that are substantially equivalent to the product candidates that we have produced in our own facilities and used in our clinical trials. If such companies are not able to produce products that are substantially equivalent to our product candidates, the progress of our clinical trials and/or commercialization of our products may be delayed and our business, financial condition and results of operations may be materially harmed.

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

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

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

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

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

- our partners have significant discretion whether to pursue planned activities;
- we cannot control the quantity and nature of the resources our partners may devote to product candidates;
- our partners may not develop products generated using our antibody technology as expected; and

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

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

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

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

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

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

significantly increase our need for capital; and/or

place additional strain on management s time.

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

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

Due to the size of our interest in Genmab, we are currently required to account for our equity interest in Genmab under the equity method of accounting, which provides that we must include a portion of Genmab s income and losses equal to our percentage equity interest in Genmab in our consolidated financial statements. For the years ended December 31, 2001, 2002 and 2003, our share of Genmab s losses were approximately $7.3 million, $19.6 million and $15.0 million, respectively. For the three month period ended March 31, 2004, our share of Genmab s net loss was $4.8 million. We expect that during the second half of 2004, the remaining basis of our investment in Genmab will be reduced to zero and, accordingly, recognition of our share of Genmab s net losses will be suspended.

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 and Tularik, and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. On March 29, 2004, Tularik announced a merger with Amgen, Inc. whereby Tularik will become a wholly owned subsidiary of Amgen. The parties expect the transaction to close in the second half of 2004. 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 year ended December 31, 2003, no impairment charges were recorded related to the value of our investments in publicly traded companies. For the three month period ended March 31, 2004, we recorded an impairment charge of $0.2 million on investments in partners whose securities are publicly traded. 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 years ended December 31, 2002 and 2003, we recorded impairment charges of approximately $2.4 million and $1.4 million, respectively, on our investments in privately-held companies. For the three month period ended March 31, 2004, we recorded an impairment charge of $0.1 million on investments in partners whose securities are privately held. 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, J.D., Ph.D., our President and Chief Executive Officer; Nils Lonberg, Ph.D., our Senior Vice President and Scientific Director; and Geoffrey M. Nichol, M.D., MBA., our Senior Vice President, Product Development. We maintain a key man life insurance policy for Dr. Drakeman in the amount of $2.0 million and are in the process of applying for key man life insurance policies in the amount of $1.0 million for each of Dr. Lonberg and Dr. Nichol. We have entered into employment agreements with Dr. Drakeman and all of our other executive officers, which expire in January, 2007. Thereafter, all of these agreements are automatically renewed for successive one (1) year terms unless we or the employee elect not to renew.

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, sales and marketing, relevant law 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:

- apply for, obtain, protect and enforce patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

in-license certain technologies.

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.

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

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

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

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

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

Moreover, other parties could have blocking patent rights to products made using HuMAb-Mouse technology, such as antibodies, and their production and uses, for instance 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 and patent applications owned by third parties that pertain to monoclonal antibodies against CTLA-4, such as MDX-010, and their uses. We are also aware of certain United States and foreign patents and patent applications held by third parties relating to anti-CD4 antibodies, such as HuMax-CD4, anti-CD30 antibodies, such as MDX-060, anti-EGFr antibodies, such as HuMax-EGFr, and anti-PSMA antibodies, such as MDX-070, as well as other antibody products under development by us.

We are also aware of a United States patent owned by Genentech, Inc., relating to the production of recombinant antibodies in host cells. We currently produce certain of our products and our partners products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in this patent, then we may need to obtain a license, should one be available. If we are unable to obtain a license on commercially reasonable terms, we may be restricted in our ability to make recombinant antibodies using Genentech s techniques. In addition to the 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 that 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 that, 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 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 do not have exclusive access to the patents underlying the HuMAb-Mouse. In March 1997, prior to our acquisition of GenPharm International, Inc., GenPharm entered into a cross-license and settlement agreement with Abgenix, Inc., Cell Genesys, Inc., Xenotech, L.P. and Japan Tobacco, Inc., pursuant to which Abgenix and these entities paid us a total of approximately $38.6 million 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, as well as if any of these entities breach the cross-license and settlement agreement.

We are not the exclusive owner of the technology underlying the KM-Mouse. Effective September 4, 2002, we entered into a Collaboration and License Agreement with Kirin Brewery Co., Ltd., which provides for us to exchange certain cross-licenses for each other s technology for the development and commercialization of human antibody products made using the HuMAb-Mouse, the KM-Mouse and certain other antibody-generating mice. Kirin has certain rights to distribute and use such mice throughout the world. Our business may suffer as a consequence of competition from Kirin or if the Collaboration and License Agreement were breached or terminated for any reason.

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

The administration of drugs to humans, in clinical trials or after commercialization, may expose us to product liability claims. Consumers, healthcare producers or persons selling products based on our technology may be able to bring claims against us based on the use of our products in clinical trials and the sale of products based on our technology. Product liability claims may be expensive to defend and may result in large judgments against us. We have obtained limited product liability coverage for our clinical trials, under which coverage limits are $10 million per occurrence and $10 million in the aggregate. Although we believe these coverage limits are adequate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. We intend to increase our coverage limits as we progress into additional late-stage clinical trials and to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for products in development. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

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

Generally, our clinical trials, including our melanoma trials, are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some, cases our product is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. The most common adverse events associated with our melanoma trials have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related autoimmune adverse events, such as dermatitis and colitis, ranging from mild in most cases to severe in a very small number of instances. Almost all of these adverse events responded to medical therapy. In a very small number of instances, fatalities have occurred during the course of these trials such fatalities may or may not be attributable to our product. We believe that these adverse events will not materially affect our ability to continue with clinical trials of this product as planned. Any of these events could result in a product liability claim. Any such claims against us, regardless of their merit, could result in significant awards against us, which could materially harm our business, financial condition and results of operations.

We face intense competition and rapid technological change.

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

We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapeutics. Some of these companies have commenced clinical trials of antibody products or have successfully commercialized antibody products. Many of these companies are addressing the same diseases and disease indications as we and our partners. Also, we compete with companies that offer antibody generation services to other companies that have disease related target antigens. These competitors have specific expertise or technology related to monoclonal antibody development. We compete

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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 transgenic mouse 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 Cambridge Antibody Technology Group plc, Dyax Corp., Genetastix Corporation and MorphoSys AG to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, MedImmune, Inc., Amgen, Biogen Idec, Novartis, Genentech, Inc., Protein Design Labs, Inc., Wyeth, Abbott and Corixa Corporation have generated therapeutic products that are currently on the market and that are derived from recombinant DNA that comprise human antibody components.

Other technologies can also be applied to the treatment of the diseases that we or our partners are pursuing. For example, immunoconjugates monoclonal antibodies linked to toxins or radioactive isotopes are being developed by others. In addition, the application of recombinant DNA technology to develop potential products consisting of proteins (such as growth factors, hormones, enzymes, receptor fragments and fusion proteins, or cytokines) that do not occur normally in the body, or occur only in small amounts, has been underway for some time. Included in this group are interleukins such as IL-2 and IL-11, interferons alpha, beta and gamma, colony stimulating factors such as G-CSF and GM-CSF, clotting factors, growth hormones, erythropoeitin, DNAse, tPA, glucocerebrosidase, PDGF, and a number of other biological 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 from these institutions. These competitors, either alone or with their partners, may succeed in developing or licensing 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 Service 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 and risk 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 and maintain regulatory authorization to conduct clinical trials. 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 an equivalent application 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 comply with current good manufacturing practices requirements, 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 current good manufacturing practices, or cGMP, requirements 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

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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, manufacturing, and labeling 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.

If we are able to obtain approvals for our products, the law or FDA policy could change and expose us to competition from generic or follow-on versions of our products.

Under current U.S. law and FDA policy, generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, may be approved through an abbreviated approval process. In general terms, the generic applicant references an approved innovator product for which full clinical data demonstrating safety and effectiveness exist for the approved conditions of use. The generic applicant in turn need only demonstrate that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as the referenced innovator drug, and that the generic product is absorbed in the body at the same rate and to the same extent as the referenced innovator drug (this is known as bioequivalence). In addition, the generic application must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the referenced innovator drug.

There is no such abbreviated approval process under current law for biological products approved under the Public Health Service Act through a BLA, such as monoclonal antibodies, cytokines, growth factors, enzymes, interferons and certain other proteins. However, various proposals have been made to establish an abbreviated approval process to permit approval of generic or follow-on versions of these types of biological products. The proposals include proposals for legislation, and proposals for FDA to extend its existing authority to this area.

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For example, some have proposed that FDA allow a generic or follow-on copy of certain therapeutic biologics to be approved under an existing mechanism known as a 505(b)(2) application. A 505(b)(2) application is a form of a New Drug Application, or NDA, where the applicant does not have a right to reference some of the data being relied upon for approval. Under current regulations, 505(b)(2) applications can be used where the applicant is relying in part on published literature or on findings of safety or effectiveness in another company s NDA.

505(b)(2) has not been used to date for therapeutic biologic products. In addition, the use of 505(b)(2) applications even for conventional chemical drug products is the subject of an ongoing legal challenge. It is thus not clear what the permitted use of a 505(b)(2) application might be in the future for biologics products, or whether any other proposals on generic or follow-on biologics will be adopted. However, if the law is changed or if FDA somehow extends its existing authority in new ways, and third parties are permitted to obtain approvals of versions of our products through an abbreviated approval mechanism, and without conducting full clinical studies of their own, it could adversely effect our business. Such products would be significantly less costly than ours to bring to market, and could lead to the existence of multiple lower priced competitive products. This would substantially limit our ability to obtain a return on the investments we have made in those products.

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 may be substantial. Our business activities involve the controlled use of hazardous materials and we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources and may materially harm our business, financial condition and results of operations.

Our stock price may be volatile.

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

- fluctuations in our operating results;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- published reports by securities analysts;
- progress with clinical trials;
- governmental regulation;
- developments in patent or other proprietary rights;
- developments in our relationship with collaborative partners;

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

general market conditions.

During the two-year period ended March 31, 2004, the sale prices of our common stock ranged between $2.69 and $16.83. 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 April 30, 2004, we had 11,718,545 shares of common stock reserved for issuance pursuant to options and other stock based awards which had been granted under our stock option plans having a weighted average exercise price of $8.32 per share and we had reserved 3,285,533 shares of common stock for issuance pursuant to future grants of options under our stock option plans. We have filed registration statements on Form S-8 covering all of these shares. Shares issued pursuant to these plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

In addition, as of that date, there were 384,207 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 three years. We have filed a registration statement on Form S-8 covering those shares. Shares issued pursuant to this plan, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

As of April 30, 2004, we had reserved 677,063 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 177,063 of those shares. The remaining 500,000 shares have not yet been registered but we intend to file a registration statement covering these shares prior to issuance under this plan. Upon the effectiveness of such registration statement, all shares issued under this plan, other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

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

As of April 30, 2004, we had 2,647,816 shares of common stock reserved for issuance pursuant to the conversion of the approximately $76.4 million aggregate principal amount of our 4.50% Convertible Subordinated Notes due 2006. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 34.6789 shares per each $1,000 principal amount of notes ($28.84 per share), subject to adjustment. Shares issued upon conversion of these notes will be freely tradable in the open market without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144.

As of April 30, 2004, we had 21,875,353 shares of common stock reserved for issuance pursuant to the conversion of the approximately $147.0 million aggregate principal amount of our outstanding 4.25% Convertible Senior Notes due August 15, 2010. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 148.8261 shares per each $1,000 principal amount of the notes ($6.72 per share), subject to adjustment.

As of April 30, 2004, we had 10,932,945 shares of common stock reserved for the issuance pursuant to the conversion of the $150.0 million aggregate principal amount of our outstanding 2.25% Convertible Senior Notes due May 15, 2011. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or redemption by us at a conversion rate of 72.9129 shares per each $1,000 principal amount of the notes ($13.72 per share), subject to adjustment.

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

As of April 30, 2004, we had 79,103,639 shares of common stock outstanding, of which 1,407,667 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 filed a 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 $297.15 million of any of the following securities:

debt securities;

preferred stock;

common stock; or

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

We have also filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of our $125.0 million 4.25% Convertible Senior Notes due August 15, 2010, and up to 18,601,190 shares of our common stock which may be issued upon the conversion of the notes. These notes and 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 limitation of Rule 144. We also have filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of our $21.986 million 4.25% Convertible Senior Notes due August 15, 2010, and up to 3,271,727 shares of our common stock which may be issued upon the conversion of the notes. Upon the effectiveness of such registration statement, the notes and shares of common stock will be freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitation of Rule 144. In connection therewith, we have agreed to use our best efforts to keep these registration statements continuously effective until the earliest of (i) the sale of all outstanding registrable securities registered under the registration statements; (ii) the expiration of the period referred to in Rule 144(k) of the Securities Act with respect to the notes held by non-affiliates of us; (iii) all the registrable securities have ceased to be outstanding (whether as a result of redemption, repurchase, cancellation, conversion or otherwise); and (iv) two years after the respective effective dates of these registration statements.

Pursuant to the terms of a certain registration rights agreement, on or before August 2, 2004, we are required to file a registration statement on Form S-3 under the Securities Act relating to our $150.0 million convertible senior notes due May 15, 2011, and up to 10,932,945 shares of our common stock which may be issued upon conversion of the notes. Upon the effectiveness of the registration statement, the notes and the shares of common stock will be freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitation of Rule 144.

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 April 30, 2004, approximately $76.4 million aggregate principal amount of these notes was outstanding. In addition, in such event we will be required to offer to repurchase all of our outstanding 4.25% convertible senior notes due August 15, 2010. As of April 30, 2004, approximately $147.0 million aggregate principal amount of these notes was outstanding. Upon such change of control event, we are also required to offer to repurchase all of our

outstanding 2.25% convertible senior notes due May 11, 2011. As of April 30, 2004, $150.0 million aggregate principal amount of these notes was outstanding. In each instance, we may pay the repurchase price in cash or, at our option, in common stock. These change of control events include, without limitation, (i) the acquisition by any third party of at least 50% of our common stock; or (ii) our merger or consolidation with or into any other person, any merger or consolidation of another person into us or our sale or other disposal of all or substantially all of our assets, except in certain limited circumstances provided in the indentures relating to the notes. Such repurchase rights may be triggered at a time at which we do not have sufficient funds available to pay the repurchase price in cash or determine that payment in cash is otherwise inadvisable. In such event, the issuance of a significant number of additional shares of common stock in payment of the repurchase price may lower the market price of our common stock.

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

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

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

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

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

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

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

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

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

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

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

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

Item 6. Exhibits and reports on Form 8-K

(a) Reports on Form 8-K:

Form 8-K on January 7, 2004 relating to the retirement of Michael A. Appelbaum, Executive Vice President effective December 31, 2003.

Form 8-K on February 2, 2004 relating to the exchange and cancellation of $33,000,000 in aggregate principal amount of 4.50% Convertible Subordinated Notes due July 2006 for the issuance of $21,986,000 in aggregate principal amount of newly issued 4.25% Convertible Senior Notes due August 2010 in a limited number of privately negotiated transactions.

Form 8-K on February 18, 2004 relating to the Registration Statement on Form S-3 covering the resale by certain selling securityholders of the common stock issuable upon conversion of $125,000,000 aggregate principal amount of 4.25% Convertible Senior Notes issued in July 2003, which was declared effective by the Securities and Exchange Commission on February 17, 2004.

Form 8-K on February 26, 2004 relating to a press release of the Company s financial results for the year and quarter ended December 31, 2003.

(b) Exhibits:

Exhibit 3.1[1]	Restated Certificate of Incorporation.
Exhibit 31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Exhibit 31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
Exhibit 32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
Exhibit 32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

[1] Incorporated by reference to Exhibit Number 3.1 to the Company s Quarterly Report on Form 10-Q filed on August 12, 2003.

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 10, 2004

By: /s/ DONALD L. DRAKEMAN

Donald L. Drakeman

President and Chief

Executive Officer

(Principal Executive Officer)

Date: May 10, 2004

By: /s/ CHRISTIAN S. SCHADE

Christian S. Schade

Senior Vice President

Finance & Administration,

Chief Financial Officer

(Principal Financial and

Accounting Officer)