MEDAREX INC
Form 10-Q
August 09, 2005

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2005

OR

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

For the transition period from to .

Commission File No. 0-19312

MEDAREX, INC.

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

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

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

Indicate by check ý 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 ý No o

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

Yes ý No o

The number of shares of common stock, $.01 par value, outstanding as of July 29, 2005 was 111,033,341 shares.

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31, 2004	June 30, 2005 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 64,843	$ 56,551
Marketable securities	309,664	306,518
Segregated cash	12,301	
Prepaid expenses and other current assets	6,708	22,925
Total current assets	393,516	385,994
Property, buildings and equipment:		
Land	6,795	6,795
Buildings and leasehold improvements	77,995	78,670
Machinery and equipment	43,077	44,949
Furniture and fixtures	4,290	4,345
Construction in progress	2,821	4,143
	134,978	138,902
Less accumulated depreciation and amortization	(45,098)	(52,356)
	89,880	86,546
Investment in Genmab	1,657	
Investment in IDM	41,206	11,940
Investments in, and advances to, other partners	10,482	10,482
Segregated cash	1,700	1,700
Other assets	10,904	7,585
Total assets	$ 549,345	$ 504,247
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Trade accounts payable	$ 4,998	$ 1,603
Accrued liabilities	32,148	19,103
Deferred contract revenue - current	15,260	17,473
Total current liabilities	52,406	38,179
Deferred contract revenue - long-term	86,691	111,798
Other long-term liabilities	5,873	2,785
4.25% Convertible senior notes due August 15, 2010	146,986	
2.25% Convertible senior notes due May 15, 2011	150,000	150,000
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; 85,865,333 shares issued and 85,673,693 outstanding at December 31, 2004 and 111,098,958 shares issued and 110,993,076 shares outstanding at June 30, 2005	859	1,111

Capital in excess of par value	699,380	871,283
Treasury stock, at cost 191,640 shares at December 31, 2004 and 105,882 shares at June 30, 2005	(482)	(266)
Deferred compensation	372	181
Accumulated other comprehensive income	6,649	6,261
Accumulated deficit	(599,389)	(677,085)
Total shareholders equity	107,389	201,485
Total liabilities and shareholders equity	$ 549,345	$ 504,247

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 June 30,		Six Months Ended June 30,	
	2004	2005	2004	2005
Contract and license revenues	$ 1,203	$ 10,208	$ 2,309	$ 16,140
Contract and license revenues from Genmab	707	1,508	1,530	2,108
Reimbursement of development costs		6,821		8,800
Total revenues	1,910	18,537	3,839	27,048
Costs and expenses:				
Research and development	30,124	35,751	53,112	64,877
General and administrative	5,495	6,117	11,303	11,852
Total costs and expenses	35,619	41,868	64,415	76,729
Operating loss	(33,709)	(23,331)	(60,576)	(49,681)
Equity in net loss of affiliate	(5,606)		(10,372)	(1,657)
Interest and dividend income	1,881	2,722	6,185	5,161
Impairment loss on investments in partners		(9,001)	(316)	(29,265)
Additional receipts related to asset acquisitions				69
Interest expense	(3,951)	(1,052)	(7,586)	(2,127)
Net loss on extinguishment of debt	(2,165)		(1,839)	
Pre tax loss	(43,550)	(30,662)	(74,504)	(77,500)
Provision for income taxes	3	138	9	196
Net loss	$ (43,553)	$ (30,800)	$ (74,513)	$ (77,696)
Basic and diluted net loss per share:	$ (0.55)	$ (0.28)	$ (0.94)	$ (0.71)
Weighted average number of common shares outstanding				
- basic and diluted	79,523	111,059	79,514	109,052

See notes to these unaudited consolidated financial statements.

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	For the Six Months Ended June 30,	
	2004	2005
Operating activities:		
Net loss	$ (74,513)	$ (77,696)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,810	6,367
Amortization	2,329	3,534
Loss on extinguishment of debt	2,165	
Loss on sale of equipment	105	
Stock options and awards to employees and non-employees	176	169
Non-cash revenue - Genmab	(1,000)	
Equity in net loss of Genmab	10,372	1,657
Impairment loss on investments in partners	316	29,266
Gain on exchange of convertible debt	(325)	
Gain on sale of equity securities	(1,664)	
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	1,930	(16,217)
Trade accounts payable	209	(3,290)
Accrued liabilities	3,928	(16,187)
Deferred contract revenue	(265)	27,320
Net cash used in operating activities	(50,427)	(45,077)
Investing activities:		
Purchase of property and equipment	(3,626)	(3,203)
Proceeds from sale of equipment	600	
Purchase of marketable securities	(78,374)	(56,108)
Increase in segregated cash	(79,317)	
Sales of marketable securities	109,547	69,517
Net cash (used in) provided by investing activities	(51,170)	10,206
Financing activities:		
Cash received from sales of securities and exercise of stock options, net	668	26,981
Proceeds from sale of 2.25% convertible senior notes, net	145,222	
Debt repurchase	(66,848)	
Deferred offering costs - Celldex	(437)	(399)
Debt exchange costs	(100)	
Principal payments under lease obligations	(78)	(3)
Net cash provided by financing activities	78,427	26,579
Net decrease in cash and cash equivalents	(23,170)	(8,292)
Cash and cash equivalents at beginning of period	72,998	64,843
Cash and cash equivalents at end of period	$ 49,828	$ 56,551
Supplemental disclosures of cash flow information		
Cash paid during period for:		
Income taxes	$	$ 120
Interest	$ 4,109	$ 4,031

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 its subsidiaries (collectively, the Company) in accordance with U.S. generally accepted accounting principles 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 U.S. generally accepted accounting principles 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, 2004 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, 2004.

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, as well as the assumed conversion of convertible senior notes. Potentially dilutive securities have been excluded from the computation of diluted net loss per share for all periods presented, 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. These investments are accounted for under the cost basis. Because these securities are not publicly traded, the Company values these investments by using information acquired from industry trends, management

of these companies, such companies financial statements, and other external sources. Specifically, the Company s determination of any potential impairment of the value of the securities of privately held companies includes an analysis of the following for each such privately held company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financings and potential strategic alternatives. 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.

The Company recorded impairment charges of $0, $0.2 million, $0 and $0 related to investments in partners whose securities are publicly traded for the three and six month periods ended June 30, 2004 and the three and six month periods ended June 30, 2005, respectively. In addition, the Company recorded impairment charges of $0, $0.1 million, $7.2 million and $27.4 million in partners whose securities are privately held for the three and six month periods ended June 30, 2004 and the three and six month periods ended June 30, 2005, respectively. The impairment charge for the three and six month periods ended June 30, 2005 related entirely to the Company s investment in IDM. The amount of the impairment charge was calculated as the difference between (i) the estimated per share value expected to be received by IDM shareholders upon completion of its merger with Epimmune, Inc., publicly announced on March 16, 2005, and (ii) the Company s carrying value. According to IDM and Epimmune, the transaction is expected to close in the third quarter of 2005. If the Company deems these investments to be further impaired at the end of any future period, it may incur additional impairment charges on these investments.

Revenue Recognition

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

The Company sells antibodies primarily to partners in the United States and overseas. Revenue from these sales is recognized when the antibodies are shipped and the Company has no further obligations related to the development of the antibodies.

Fees received from the licensing of the Company s proprietary technologies for research and development performed by its customers and partners is recognized generally over the term of the respective license period beginning after both the license period has begun and the technology has been delivered.

Fees received for product development services are recognized ratably over the period during which the services are performed.

Milestone payments are recognized as revenue upon the achievement of mutually agreed milestones, provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there are no continuing performance obligations associated with the milestone payment.

Revenue arrangements that include multiple deliverables, are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, consideration is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.

Revenues derived from reimbursements of costs associated with the development of product candidates are recorded in compliance with EITF Issue 99-19, Reporting Revenue Gross as a Principal Versus Net as an Agent (EITF 99-19). According to the criteria established by EITF 99-19, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company believes it has met the criteria to record revenue for the gross amount of the reimbursements.

Grant revenues are recognized as the Company provides the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

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. 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 June 30		Six Months Ended June 30	
	2004	2005	2004	2005
Net loss, as reported	$ (43,553)	$ (30,800)	$ (74,513)	$ (77,696)
Add: Non-cash employee compensation	49	84	100	169
Deduct: Total stock-based employee compensation expense determined under fair value method	(3,237)	(3,393)	(6,432)	(7,169)
Pro forma net loss	$ (46,741)	$ (34,109)	$ (80,845)	$ (84,696)
Loss per share:				
Basic and diluted, as reported	$ (0.55)	$ (0.28)	$ (0.94)	$ (0.71)
Basic and diluted, pro forma	$ (0.59)	$ (0.31)	$ (1.02)	$ (0.78)

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 June 30		Six Months Ended June 30	
	2004	2005	2004	2005
Expected stock price volatility	59.5%	98.8%	59.5%	98.8%
Risk-free interest rate	3.63%	3.96%	3.63%	3.96%
Expected life of options	5 years	6.25 years	5 years	6.25 years
Expected dividend yield	0%	0%	0%	0%

Reclassifications

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

Recently Issued Accounting Pronouncements

In December 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends Statement No. 95, *Statement of Cash Flows.* Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Historically, in accordance with SFAS 123 and SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, the Company has elected to follow the disclosure only provisions of Statement No. 123 and, accordingly, continues to account for share based compensation under the recognition and measurement principles of APB Opinion No. 25 and related interpretations. Under APB 25, when stock options are issued with an exercise price equal to the market price of the underlying stock on the date of grant, no compensation expense is recognized in the financial statements, and compensation expense is only disclosed in the footnotes to the financial statements. The Company will be required to adopt Statement No. 123(R) beginning January 1, 2006. The Company is currently in the process of evaluating the option valuation methods and adoption transition alternatives available under Statement 123(R). Although the Company has not yet determined the impact of Statement 123(R), it may be significant to its consolidated results of operations.

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 31.8% interest in Genmab as of December 31, 2003.

In July 2004, Genmab completed a private placement of 5.6 million shares of its stock. As a result of this private placement, the Company s ownership percentage in Genmab was reduced to approximately 24.7%. The difference between the Company s proportionate share of the additional equity raised and its carrying value at the time the private placement was completed was approximately $9.7 million and was accounted for in accordance with APB Opinion No.18, *The Equity Method of Accounting for Investment in Common Stock*, and

Staff Accounting Bulletin No. 51, *Accounting for Sales of Stock by a Subsidiary.* This transaction was accounted for as an increase to capital in excess of par value at the time the private placement was completed.

During the three and six month periods ended June 30, 2004, the value of the Company s investment in Genmab was adjusted to reflect the Company s share of Genmab s net loss ($5.6 million) and ($10.4 million), respectively, and an unrealized loss of $36 thousand and an unrealized gain of $0.5 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. During the six month period ended June 30, 2005, the value of the Company s investment in Genmab was further adjusted to reflect the Company s share of Genmab s net loss ($1.7 million). During the first quarter of 2005, the remaining basis of the Company s investment in Genmab was reduced to zero, and accordingly, recognition of the Company s share in Genmab s net losses has been suspended indefinitely.

3. Proposed Public Offering of Celldex Therapeutics, Inc. Common Stock

The Company s wholly-owned subsidiary Celldex Therapeutics, Inc. (Celldex) has filed a registration statement with the Securities and Exchange Commission related to a proposed initial public offering of a portion of its common stock. The Company has assigned or licensed to Celldex certain intellectual property related to the Company s 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 (IND), associated with this product candidate which became effective in February 2004. If the initial public offering is completed, the Company anticipates that it would continue to hold approximately 70% of the outstanding shares of common stock of Celldex.

4. Debt Redemption/Conversion

In January 2005, the Company completed the provisional redemption of all of its outstanding $146.986 million 4.25% Convertible Senior Notes due August 15, 2010 (the 4.25% Notes). Prior to the redemption date, holders of all of the outstanding 4.25% Notes converted their notes into a total of 21,875,353 shares of the Company s common stock. In connection with the redemption, the Company paid approximately $12.5 million in cash representing primarily a make-whole payment of $10.2 million, as well as accrued interest of $2.3 million. The make-whole payment was equal to $130.10 per $1,000 principal amount of 4.25% Notes redeemed, less the amount of any interest actually paid and any interest accrued and unpaid before the provisional redemption date. The Company accrued the $10.2 million make-whole payment in the quarter ended December 31, 2004, at the time the redemption was announced. In connection with the completion of this transaction, unamortized debt issuance costs of approximately $3.2 million were reclassified to capital in excess of par value at the time the 4.25% Notes were converted to common stock.

5. Bristol-Myers Squibb Collaboration

In January 2005, the Company announced the closing of a collaboration and co-promotion agreement and a related securities purchase agreement with Bristol-Myers Squibb Company (BMS), pursuant to which the Company and BMS each granted the other certain intellectual property licenses and product rights on a worldwide basis in order to enable the parties to collaborate in research and development of certain therapeutic antibody-based product candidates for the treatment of cancer and other diseases, and, in the event that further development work is successful, to commercialize any resulting products. In particular, the collaboration

includes a grant by the Company to BMS of a license to commercialize MDX-010, a fully human antibody product developed using the Company s UltiMAb Human Antibody Development System®, that is antagonistic to cytotoxic T-lymphocyte antigen 4 (CTLA-4). MDX-010 is currently under investigation for the treatment of a broad range of cancers. The collaboration also includes the grant by the Company to BMS of a license to MDX-1379, a gp100 peptide vaccine, for use with MDX-010 for the treatment of metastatic melanoma.

As part of the collaboration, the two companies committed to an initial multi-year budget of approximately $192.0 million to fund the development of MDX-010 as a potential treatment for a broad range of cancers. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the United States and Europe, with the remaining 35% to be paid by the Company. The parties will share equally the costs of any clinical trials of product candidates intended solely for regulatory approval in the United States, and BMS will be fully responsible for all development efforts that relate solely to regulatory approval in Europe and other parts of the world. Approximately $6.4 million and $8.4 million of the Company s revenue for the three and six month periods ended June 30, 2005 represented the reimbursement of the Company s costs associated with the development of MDX-010 recorded in compliance with EITF 99-19.

Under the terms of the collaboration, the Company could receive up to $205.0 million from BMS if all regulatory milestones are met, plus up to an additional $275.0 million in sales-related milestones. The Company will also have the option to co-promote any products in the United States, and, if the Company elects to exercise this option and has participated in the funding of the applicable Phase III clinical trial(s), the Company will receive 45% of any profits from commercial sales. In the event the Company chooses not to exercise its co-promotion rights, BMS will have exclusive commercial rights in the United States and will pay the Company royalties on any commercial sales. Outside the United States, BMS will have exclusive commercial rights and will pay the Company royalties on any commercial sales.

Pursuant to these agreements, BMS made an initial cash payment to the Company of $25.0 million, which has been recorded as deferred revenue. In addition, BMS purchased a total of 2,879,223 unregistered shares of the Company s common stock at a purchase price equal to $8.6829 per share for an aggregate purchase price of $25.0 million. The purchase price represented a small premium to the market price on the date the Company signed the collaboration agreement.

6. Contingencies

In August 2004, the Company completed the acquisition of all of the outstanding capital stock not already owned by the Company of Ability Biomedical Corporation. Pursuant to this transaction, the Company acquired Ability Biomedical s intellectual property related to IP-10, a protein believed to be associated with a variety of immune disorders, including multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, chronic obstructive pulmonary disease and type I diabetes.

Upon achievement of certain development milestones with respect to the Company s anti-IP-10 antibody program, but no later than September 4, 2007, the Company may be required to pay the former shareholders of Ability Biomedical approximately $3.68 million in cash and/or common stock, subject to fluctuations in currency exchange rates. In lieu of such additional payment, the Company also has the option to revert to the original joint collaboration agreement with the former shareholders of Ability Biomedical whereby each party would be responsible for 50% of the costs associated with the anti-IP-10 antibody program.

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 June 30, 2005.

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.

7. 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 primarily relates to the Company s equity position in Genmab. The following table sets forth the components of comprehensive income (loss):

	Three Months Ended June 30		Six Months Ended June 30	
	2004	2005	2004	2005
Net loss	$ (43,553)	$ (30,800)	$ (74,513)	$ (77,696)
Unrealized (loss) gain on securities	(2,254)	904	(3,589)	(393)
Unrealized (loss) gain on foreign exchange	(36)		522	5
Total comprehensive loss	$ (45,843)	$ (29,896)	$ (77,580)	$ (78,084)

8. Segment Information

The Company is a biopharmaceutical company focused on the discovery, development and potential commercialization of fully human antibody-based therapeutic products. 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 June 30		Six Months Ended June 30	
Customer	2004	2005	2004	2005
Centocor, Inc.		22%		15%
Genmab A/S	37%	8%	43%	8%
Novartis Pharma AG			13%	2%
Bristol-Myers Squibb Co.	26%	39%	13%	36%
Pfizer, Inc.	11%	13%	6%	17%

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No other single customer accounted for more than 10% of the Company s total revenues for the three and six month periods ended June 30, 2004 and 2005, respectively.

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. Statements that are not historical facts, including statements preceded by, followed by, or that include the words potential ; believe ; anticipate ; intend ; plan ; expect ; estimate ; could ; may ; or similar statements are forward-looking statements. R uncertainties include risks associated with product discovery and development, uncertainties related to the outcome of clinical trials, unforeseen safety issues resulting from the administration of product candidates in patients, uncertainties associated with the collaborative process and uncertainties related to product manufacturing, as well as risks detailed from time to time in our periodic reports and registration statements filed with the Securities and Exchange Commission. There can be no assurance that our product development efforts will succeed, that developed products will receive the required regulatory clearance or that, even if such regulatory clearance were received, such products would ultimately achieve commercial success. 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 of Part II below. References to our product candidates, 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, development and potential commercialization of fully human antibody-based therapeutic products. We believe that our UltiMAb Human Antibody Development System® enables us to rapidly create and develop such products for a wide range of diseases, including cancer, inflammation, autoimmune disorders and other life-threatening and debilitating diseases.

Currently, 24 antibody product candidates generated from our UltiMAb Human Antibody Development System are in human clinical trials for the treatment of a wide range of diseases, such as cancer, rheumatoid arthritis and other inflammatory, autoimmune and infectious diseases(1). Eight of these product candidates are in Phase II or Phase III clinical trials. The most advanced of these product candidates is MDX-010 (Phase III, Phase II and Phase I clinical trials), which we are developing jointly with Bristol-Myers Squibb Company, or BMS, for the treatment of metastatic melanoma and other cancers. Five of these product candidates are fully owned by us and our affiliates: MDX-060 for lymphomas (Phase II clinical trial), MDX-070 for prostate cancer (Phase II clinical trial), MDX-214 for cancer (Phase I/II clinical trial), MDX-1307 for genitourinary and breast cancers (Phase I clinical trial) and MDX-1100 for ulcerative colitis (Phase I clinical trial). We are developing MDX-066 (Phase I clinical trial) jointly with The Massachusetts Biologic Laboratories of the University of Massachusetts Medical School, or MBL, for the treatment of *Clostridium difficile* associated diarrhea. We are developing Valortim (Phase I clinical trial) jointly with PharmAthene, Inc. for inhalation anthrax. Another product candidate, MDX-018 (Phase I/II clinical trial), is being jointly developed with Genmab A/S for autoimmune disease. Three additional product candidates are being developed separately by Genmab: HuMax -CD4 (Phase III and Phase II clinical trials) for T-cell lymphomas, HuMax-EGFr (Phase I/II clinical trial) for head and neck cancer and HuMax-CD20 (Phase I/II clinical trial) for lymphomas. Genmab and Amgen, Inc. are developing AMG 714 (Phase II clinical trial) for rheumatoid arthritis. Additionally, other of our licensing partners, including Novartis Pharma AG, Eli Lilly and Company, and Centocor, Inc. (a subsidiary

(1) Information regarding the clinical status of third-party antibody products is based on publicly available information.

of Johnson & Johnson), are developing a total of ten product candidates, for inflammatory and/or autoimmune diseases and cancer, that are currently in clinical trials. Human Genome Sciences, Inc. has also announced the initiation of a Phase I trial of one anticancer product candidate developed pursuant to a licensing agreement with our partner Kirin Brewery Co., Ltd. We and our partners also have a number of UltiMAb® product candidates in preclinical development.

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 candidate if the product receives approval from the U.S. Food and Drug Administration, or FDA, and equivalent foreign agencies. In general, we are also entitled to receive royalties on product sales. Additional revenue may be earned from the sales of antibodies 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 that 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 June 30, 2005, we had an accumulated deficit of approximately $677.1 million. Over the next several years, we expect to incur substantial expenses as we continue to identify, develop and manufacture our product candidates, invest in research, move forward with the development and prepare to commercialize our product candidates. Our commitment of resources to research and the continued development and potential commercialization 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 product candidates are selected for clinical 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 product candidates 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 raise additional funds through debt or equity financings or 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 generally 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 and the Company has no further obligations related to the development of the antibodies.

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 period 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 Investigational New Drug Application, or IND, commencement of Phase I, II or III clinical trials, submission of a Biologic License Application, or 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.

Revenue arrangements that include multiple deliverables, are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.

Revenues derived from reimbursements of costs associated with the development of product candidates are recorded in compliance with EITF Issue 99-19, Reporting Revenue Gross as a Principal Versus Net as an Agent (EITF 99-19). According to the criteria established by EITF 99-19, in transaction where we act as a principal, with discretion to choose suppliers, bear the credit risk and perform part of the services required in the transaction, we believe we have met the criteria to record revenue for the gross amount of the reimbursements.

Grant revenues are recognized as we provide the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

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 0.9% and 0.8% of total marketable securities as of December 31, 2004 and June 30, 2005, 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 $22.4 million as of June 30, 2005. These securities are carried at original investment cost and adjusted for other than temporary impairment charges, if any. 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, management of these companies, such companies financial statements, and other external sources. Specifically, our determination of any potential impairment of the value of the securities of privately held companies includes an analysis of the following for each such privately held company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financings and potential strategic alternatives. 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.

Results of Operations

Three months ended June 30, 2004 and 2005

Contract and License Revenues

Contract and license revenues totaled $1.2 million and $10.2 million for the three month periods ended June 30, 2004 and 2005, respectively, an increase of $9.0 million, or 749%. This increase relates principally to $4.0 million in milestone payments received from our contract and licensing business and a total of approximately $3.9 million of increased revenue recognized from our collaboration with Bristol-Myers Squibb Company, or BMS, which became effective in January 2005, our collaboration with Pfizer, Inc., or Pfizer, and the National Institutes of Health, or NIH, in accordance with a grant we received in 2004. Because contract and license revenues depend to a large extent on the product development efforts of our partners and licensees, our period-to-period contract and license revenues can fluctuate significantly and are inherently difficult to predict.

Contract and License Revenues from Genmab

Contract and license revenues from Genmab were $0.7 million and $1.5 million for the three month periods ended June 30, 2004 and 2005, respectively, an increase of $0.8 million, or 113%. This increase is primarily the result of fees received from Genmab for the licensing of European and Asian rights to antibodies raised against the CD4 antigen utilizing our UltiMAb technology, partially offset by a decrease in antibody exclusive licenses granted to Genmab in the second quarter of 2005 as compared to the second quarter of 2004.

Reimbursement of Development Costs

Revenues derived from the reimbursement of costs associated with the development of our product candidates are recorded in compliance with EITF Issue 99-19, Reporting Revenue Gross as a Principal Versus Net as an Agent (EITF 99-19). Reimbursement of development costs were $6.8 million for the three month period ended June 30, 2005 and related primarily to the development of MDX-010. There were no such reimbursements in the three month period ended June 30, 2004.

Research and Development Expenses

Research and development expenses for our products in development were $30.1 million and $35.8 million for the three month periods ended June 30, 2004 and June 30, 2005, respectively, an increase of $5.7 million, or 19%. Historically, due to the limited 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, namely, research and product development and by the types of costs as outlined below.

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 June 30,	
	2004	2005
Research	$ 8,871	$ 12,347
Product Development	21,253	23,404
Total	$ 30,124	$ 35,751

Research Costs

Research costs for the three month period ended June 30, 2005 increased by $3.5 million, or 39% as compared to the three month period ended June 30, 2004. The increase in research costs primarily relates to the following:

License and technology access fees for the three month period ended June 30, 2005 were $2.5 million, an increase of $2.4 million, or 3,591%, as compared to the three month period ended June 30, 2004. These costs represent fees paid to partners and research organizations in connection with certain of our collaboration and license agreements. Included in the 2005 costs are payments to 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.

Supply costs for the three month period ended June 30, 2005 were $1.7 million, an increase of $0.4 million, or 33%, as compared to the three month period ended June 30, 2004. Included in these costs are materials and small equipment. We expect these costs to increase as we continue to expand our research efforts.

Personnel costs for the three month period ended June 30, 2005 were $3.6 million, an increase of $0.3 million, or 8%, as compared to the three month period ended June 30, 2004. The increased personnel costs are primarily attributable to staff needed to support higher levels of new product development opportunities, the continued development of our UltiMAb system, and the performance of contract services for our collaborative partners. Personnel costs include primarily salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our research activities.

Product Development Costs

Product development costs for the three month period ended June 30, 2005 increased by $2.2 million, or 10% as compared to the three month period ended June 30, 2004. The increase in product development costs primarily relates to the following:

Clinical research fees for the three month period ended June 30, 2005 were $3.0 million, an increase of $1.7 million, or 137%, as compared to the three month period ended June 30, 2004. This increase resulted primarily from the continued enrollment of patients in the Phase III clinical trial for MDX-010 in combination with MDX-1379, which was initiated in the third quarter of 2004. Clinical research fees include clinical investigator site fees, external trial monitoring costs and data accumulation costs. We expect expenses related to clinical trials to increase in the future as we continue to develop our therapeutic product pipeline.

Personnel costs for the three month period ended June 30, 2005 were $6.4 million, an increase of $0.6 million, or 9%, as compared to the three month period ended June 30, 2004. This increase resulted primarily from the increased staff needed to support more extensive clinical trial activities for MDX-010. Personnel costs include salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our product development activities and progress our products through clinical trials.

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. Product candidates using our technology are currently in various stages of development from preclinical to Phase III. The successful development of these product candidates is dependent on many factors, including among other things, the efforts of our partners, unforeseen delays in, or expenditures relating to, preclinical development, clinical testing, manufacturing or regulatory approval, failure to receive market acceptance, the emergence of competitive products and the inability to produce or market our products due to third-party proprietary rights.

General and Administrative Expenses

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 $5.5 million and $6.1 million for the three month periods ended June 30, 2004 and 2005, respectively, an increase of $0.6 million, or 11%. This increase is primarily attributable to higher personnel costs of $0.2 million, increased shareholder expenses of $0.1 million and increased audit fees of $0.1 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 was $5.6 million and $0 for the three month periods ended June 30, 2004 and 2005, respectively, and represents our share of Genmab s net loss for the three month periods ended June 30, 2004 and 2005. 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. During the first quarter of 2005 the remaining basis of our investment in Genmab was reduced to zero and, accordingly, recognition of our share of Genmab s net losses was suspended indefinitely.

Interest and Dividend Income

Interest and dividend income consists primarily of interest earned from our cash, cash equivalents and marketable securities. Interest and dividend income was $1.9 million and $2.7 million for the three month periods ended June 30, 2004 and 2005, respectively, an increase of $0.8 million, or 45%. The increase reflects interest earned on higher average balances in our investment portfolio. We anticipate lower interest and dividend income in the future as we continue to fund our operations and capital expenditures from our cash reserves.

Impairment Loss on Investments in Partners

In the course of our business, we may make investments in companies (both public and private) as part of strategic collaborations. We recorded no impairment charges for the three month periods ended June 30, 2004 and 2005, related to investments in any of our partners whose securities are publicly traded.

In addition, we have investments in several partners whose securities are not publicly traded. Because these securities are not publicly traded, the value of these investments is inherently more difficult to estimate than investments in publicly traded companies. We recorded an impairment charge of $9.0 million for the three month period ended June 30, 2005, related entirely to our investment in IDM. The amount of the impairment charge was calculated as the difference between (i) the estimated per share value expected to be received by IDM shareholders upon completion of its merger with Epimmune, Inc., or Epimmune, publicly announced on March 16, 2005, and (ii) our carrying value. According to IDM and Epimmune, the transaction is expected to close in the third quarter of 2005. We recorded no impairment charges for the three month period ended June 30, 2004 related to investments in our partners whose securities are not publicly traded. If we deem these investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

Interest Expense

Interest expense was primarily related to interest and amortization of issuance costs on our 2.25% Convertible Senior Notes issued in May 2004, or the 2.25% Notes, and our 4.25% Convertible Senior Notes

issued in July 2003, or the 4.25% Notes. Interest expense was $4.0 million and $1.1 million for the three month periods ended June 30, 2004 and 2005, respectively, a decrease of $2.9 million, or 73%. This decrease reflects the January 2005 conversion of all of our 4.25% Notes ($146.986 million) into a total of 21,875,353 shares of our common stock. The 2.25% Notes are due in May 2011 and interest is payable semi-annually on May 15 and November 15 of each year. We expect interest expense to be less in 2005 as compared to 2004 as a result of the conversion of our 4.25% Notes.

Net Loss on Extinguishment of Debt

In connection with a private placement of $150.0 million of 2.25% Notes (see further discussion under the section entitled *Liquidity and Capital Resources*), in June 2004 we repurchased $65.6 million in aggregate principal amount of our 4.50% Convertible Subordinated Notes issued in June 2001, or the 4.50% Notes, for cancellation. As a result of this repurchase and cancellation we recorded a loss on the early extinguishment of debt of approximately $2.2 million for the three month period ended June 30, 2004. No such transactions occurred during the three month period ended June 30, 2005.

Six months ended June 30, 2004 and 2005

Contract and License Revenues

Contract and license revenues totaled $2.3 million and $16.1 million for the six month periods ended June 30, 2004 and 2005, respectively, an increase of $13.8 million, or 599%. This increase related principally to $4.0 million in milestone payments received from our contract and licensing business, and a total of approximately $7.7 million of increased revenue recognized from our collaboration with BMS, our collaboration with Pfizer, our collaboration with NovImmune S.A. and the NIH in accordance with a grant we received in 2004. Because contract and license revenues depend to a large extent on the product development efforts of our partners and licensees, our period-to-period contract and license revenues can fluctuate significantly and are inherently difficult to predict.

Contract and License Revenues from Genmab

Contract and license revenues from Genmab were $1.5 million and $2.1 million for the six month periods ended June 30, 2004 and 2005, respectively, an increase of $0.6 million, or 38%. This increase is primarily the result of fees received from Genmab for the licensing of European and Asian rights to utilize our UltiMAb technology to develop and commercialize antibodies raised against the CD4 antigen, partially offset by a decrease in antibody exclusive licenses granted to Genmab in the first half of 2005 as compared to the first half of 2004.

Reimbursement of Development Costs

Revenues derived from the reimbursement of costs associated with the development of our product candidates are recorded in compliance with EITF 99-19. Reimbursement of development costs were $8.8 million for the six month period ended June 30, 2005 and related primarily to the development of MDX-010. There were no such reimbursements in the six month period ended June 30, 2004.

Research and Development Expenses

Research and development expenses for our products in development were $53.1 million and $64.9 million for the six month periods ended June, 2004 and 2005, respectively, an increase of $11.8 million, or 22%. Historically, due to the limited 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, namely, research and product development and by the types of costs as outlined below.

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.

	Six Months Ended June 30,	
	2004	**2005**
Research	$ 18,034	$ 23,627
Product Development	35,078	41,250
Total	$ 53,112	$ 64,877

Research Costs

Research costs for the six month period ended June 30, 2005 increased by $5.6 million, or 31% as compared to the six month period ended June 30, 2004. The increase in research costs primarily relates to the following:

License and technology access fees for the six month period ended June 30, 2005 were $3.2 million, an increase of $2.7 million, or 579%, as compared to the six month period ended June 30, 2004. These costs represent fees paid to partners and research organizations in connection with certain of our collaboration and license agreements. Included in the 2005 costs are payments to 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.

Royalty expense for the six month period ended June 30, 2005 was $1.3 million, an increase of $1.3 million, as compared to the six month period ended June 30, 2004. This expense primarily represents an amount paid to Kirin as a result of our collaboration with Pfizer in accordance with a Collaboration and License Agreement with Kirin, which became effective in September 2002. No comparable amounts were accrued in the first half of 2004.

Supply costs for the six month period ended June 30, 2005 were $3.2 million, an increase of $0.7 million, or 29%, as compared to the six month period ended June 30, 2004. Included in these costs are materials and small equipment. We expect these costs to increase as we continue to expand our research efforts.

Personnel costs for the six month period ended June 30, 2005 were $7.3 million, an increase of $0.6 million, or 9%, as compared to the six month period ended June 30, 2004. The increased personnel costs are primarily attributable to staff needed to support higher levels of new product development opportunities, the continued development of our UltiMAb system, and the performance of contract services for our collaborative partners. Personnel costs include primarily salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our research activities.

Product Development Costs

Product development costs for the six month period ended June 30, 2005 increased by $6.2 million, or 18% as compared to the six month period ended June 30, 2004. The increase in product development costs primarily relates to the following:

Clinical research fees for the six month period ended June 30, 2005 were $4.3 million, an increase of $2.4 million, or 118%, as compared to the six month period ended June 30, 2004. This increase resulted primarily from the continued enrollment of patients in the Phase III clinical trial for MDX-010 in combination with MDX-1379, which was initiated in the third quarter of 2004. Clinical research fees include clinical investigator site fees, external trial monitoring costs and data accumulation costs. We expect expenses related to clinical trials to increase in the future as we continue to develop our therapeutic product pipeline.

Contract manufacturing costs for the six month period ended June 30, 2005 were $7.6 million, an increase of $2.0 million, or 36%, as compared to the six month period ended June 30, 2004. This increase in third party contract manufacturing costs primarily represents production and packaging expenses related to clinical trials of MDX-060.

Personnel costs for the six month period ended June 30, 2005 were $12.9 million, an increase of $1.5 million, or 14%, as compared to the six month period ended June 30, 2004. This increase resulted primarily from the increased staff needed to support more extensive clinical trial activities for MDX-010. Personnel costs include salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our product development activities and progress our products through clinical trials.

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

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 $11.3 million and $11.9 million for the six month periods ended June 30, 2004 and 2005, respectively, an increase of $0.6 million, or 5%. This increase is primarily attributable to higher personnel costs of $0.3 million and increased audit 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 was $10.4 million and $1.7 million for the six month periods ended June 30, 2004 and 2005, respectively, a decrease of $8.7 million, or 84% and represents our share of Genmab s net loss for the six month periods ended June 30, 2004 and 2005. This decrease reflects the write off of the remaining basis of our investment in Genmab as the result of our share in its net loss for the six month period ended June 30, 2005. 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. During the first quarter of 2005 the remaining basis of our investment in Genmab was reduced to zero and, accordingly, recognition of our share of Genmab s net losses will be suspended indefinitely.

Interest and Dividend Income

Interest and dividend income consists primarily of interest earned from our cash, cash equivalents and marketable securities. Interest and dividend income was $6.2 million and $5.2 million for the six month periods ended June 30, 2004 and 2005, respectively, a decrease of $1.0 million, or 17%. Included in interest and dividend income for the six month period ended June 30, 2004 is a gain on the sale of common stock of Protein Design Labs, Inc. of approximately $1.7 million. Excluding the impact of this gain, interest and other income would have increased by $0.7 million, or 16%, as compared to the six month period ended June 30, 2004. The increase reflects interest earned on higher average balances in our investment portfolio. We anticipate lower interest and dividend income in the future as we continue to fund our operations and capital expenditures from our cash reserves.

Impairment Loss on Investments in Partners

In the course of our business, we may make investments in companies (both public and private) as part of strategic collaborations. We recorded impairment charges of $0.2 million and $0 for the six month periods ended June 30, 2004 and 2005, respectively, related to investments in one of our partners whose securities are publicly traded.

In addition, we have investments in several partners whose securities are not publicly traded. Because these securities are not publicly traded, the value of these investments is inherently more difficult to estimate than investments in publicly traded companies. We recorded impairment charges of $0.1 million and $29.3 million for the six month periods ended June 30, 2004 and 2005, respectively, related to investments in certain of our partners whose securities are not publicly traded. The impairment charge for the six month period ended June 30, 2005 related entirely to our investment in IDM. The amount of the impairment charge was calculated as the difference between (i) the estimated per share value expected to be received by IDM shareholders upon completion of its merger with Epimmune, publicly announced on March 16, 2005, and (ii) our carrying value. According to IDM and Epimmune, the transaction is expected to close in the third quarter of 2005. If we deem these investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

Interest Expense

Interest expense was primarily related to interest and amortization of issuance costs on the 2.25% Notes and the 4.25% Notes. Interest expense was $7.6 million and $2.1 million for the six month periods ended June 30, 2004 and 2005, respectively, a decrease of $5.5 million, or 72%.

This decrease reflects the January 2005 conversion of all of our 4.25% Notes ($146.986 million) into a total of 21,875,353 shares of our common stock. The 2.25% Notes are due in May 2011 and interest is payable semi-annually on May 15 and November 15 of

each year. We expect interest expense to be less in 2005 as compared to 2004 as a result of the conversion of our 4.25% Notes.

Net Loss on Extinguishment of Debt

In connection with a private placement of $150.0 million of 2.25% Notes (see further discussion under the section entitled *Liquidity and Capital Resources*), we repurchased $65.6 million in aggregate principal amount of our 4.50% Notes for cancellation. As a result of this repurchase and cancellation we recorded a loss on the early extinguishment of debt of approximately $2.2 million for the three month period ended June 30, 2004.

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 six month period ended June 30, 2004. We calculated the gain in accordance with EITF 96-19, *Debtor s Accounting for a Modification or Exchange of Debt Instruments.* EITF 96-19 requires that the gain on the early extinguishment of debt be computed using the fair value of the newly issued convertible debt which, at the time of the debt exchange, was trading at a premium to the principal amount of the notes. We classified the premium associated with the newly issued 4.25% notes of approximately $10.2 million as capital in excess of par value in accordance with APB 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants.*

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 June 30, 2005, we had $363.1 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 $50.4 million and $45.1 million for the six month periods ended June 30, 2004 and 2005, respectively. This reflects a decrease of $5.3 million in 2005 as compared to the same period in 2004. The decrease in net cash used in operating activities for the six month period ended June 30, 2005 was primarily due to the receipt of approximately $31.0 million from BMS, in accordance with our November 2004 Collaboration and Co-Promotion Agreement which became effective in January 2005. This was offset by increased operating expenses as well as a $10.2 million make-whole payment associated with the provisional redemption of our 4.25% Notes (see further discussion under Cash Provided by (Used in) Financing Activities). The increase in operating expenses relates primarily to the development of our product pipeline and includes personnel costs, expenses related to our facilities, third-party research and contract manufacturing costs, and the costs of clinical trials. All of these costs were higher as result of our increased clinical trial and product development activities.

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We have incurred and will continue to incur significant costs in the area of research and development, including preclinical and clinical trials, as our product candidates are developed. We plan to spend significant amounts to progress our current product candidates through the clinical trial and commercialization process as well as to develop additional product candidates on our own or with our partners. As our product candidates progress through the clinical trial process, we may be obligated to make significant milestone payments. 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 (Used in) Investing Activities

Net cash used in investing activities was $51.2 million for the six month period ended June 30, 2004 compared to net cash provided by investing activities of $10.2 million for the six month period ended June 30, 2005. The overall increase in cash provided by investing activities was $61.4 million and was primarily due to the following factors:

An increase of $79.3 million in segregated cash. This increase represents funds designated for the repurchase of the remaining principal amount of our 4.50% Subordinated Convertible Notes due 2006, which was completed on July 1, 2004, offset in part by

A decrease in net sales of marketable securities of $17.9 million for the six month period ended June 30, 2005 compared to the six month period ended June 30, 2004. This decrease was primarily due to decreased sales of marketable securities in 2005 to fund operations and capital expenditures. Operations and capital expenditures for the six month period ended June 30, 2005 were partially funded with the proceeds received from the BMS collaboration.

Cash Provided by Financing Activities

Cash provided by financing activities was $78.4 million and $26.6 million for the six month period ended June 30, 2004 and 2005 respectively. Cash provided by financing activities for the six month period ended June 30, 2004 resulted primarily from the net proceeds of approximately $145.2 million received from the private placement of $150.0 million of 2.25% Notes offset, in part, by cash used of approximately $66.8 million to repurchase a portion of our 4.50% Notes for cancellation. Cash provided by financing activities for the six month period ended June 30, 2005 was primarily due to the proceeds received ($25.0 million) from the sale of common stock to BMS in connection with our collaboration.

On January 14, 2005, we completed the provisional redemption of all of our 4.25% Notes which was previously announced in December 2004. Holders of all of the outstanding 4.25% Notes ($146.986 million) converted their notes into a total of 21,875,353 shares of our common stock prior to the redemption date. In connection with the redemption, we paid approximately $12.5 million in cash in January 2005 representing the make-whole payment of $10.2 million and accrued interest of $2.3 million. We accrued the $10.2 million make-whole payment in the quarter ended December 31, 2004, at the time the redemption was announced.

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 June 30, 2005. 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.

Our wholly-owned subsidiary Celldex Therapeutics, Inc. has filed a registration statement with the Securities and Exchange Commission related to a proposed initial public offering of a portion of its common stock. 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 candidate which became effective in February 2004. If the initial public offering is completed, we anticipate that we will continue to hold approximately 70% of the outstanding shares of common stock of Celldex. We cannot assure you that this transaction will be consummated.

In July 2004, we entered into an amendment to a collaboration and license agreement with Gilead Sciences, Inc., referred to herein as the Gilead Amendment. Under the terms of the Gilead Amendment, we agreed to pay Gilead a total of $8.5 million in eight equal quarterly installments of $1.063 million, payable at our election, in cash, registered shares of our common stock or a combination thereof, in exchange for (i) a reduction of certain future royalty payment obligations payable by us to Gilead, and (ii) an expansion of the scope of certain licenses from Gilead to us relating to certain intellectual property rights regarding anti-CTLA-4 products. The first of these payments was paid on August 2, 2004 through the issuance of 185,622 shares of our common stock to Gilead. The second (October 1, 2004), third (January 3, 2005), fourth (April 1, 2005) and fifth (July 1, 2005) payments were made in cash. The three remaining payments will be made on a quarterly basis, commencing on October 3, 2005 and ending on April 3, 2006. If we decide to make a quarterly installment payment in shares of our common stock, the number of shares of common stock subject to issuance for any installment will be determined by dividing (x) $1.063 million (less any cash paid in connection with the installment) by (y) the average of the closing sales prices of our common stock for each of the trading days during the five-trading-day period ending on (and including) the trading day that is two trading days immediately prior to the applicable date of issuance as publicly reported by NASDAQ. In the event that, during the 60-day period following the applicable date of issuance of such common stock, Gilead sells all of the shares of our common stock delivered as part of an installment payment under the Gilead License and the proceeds of such sale are less than $1.063 million (less any cash paid in connection with such installment), we must pay the difference to Gilead in cash. If such sale proceeds exceed $1.063 million (less any cash paid in connection with such installment), Gilead must pay us 50% of any such excess in cash. In the event that, during any such 60-day period, Gilead does not sell all of the shares of our common stock comprising the installment, there will be no such adjustment. In August 2004, we paid Gilead approximately $0.1 million representing the difference between the proceeds received by Gilead upon the sale of the 185,622 shares of common stock and the initial payment of $1.063 million.

In August 2004, we completed the acquisition of all of the outstanding capital stock not already owned by us of Ability Biomedical Corporation. Pursuant to this transaction, we acquired Ability Biomedical s intellectual property related to IP-10, a protein believed to be associated with a variety of immune disorders, including multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, chronic obstructive pulmonary disease and type I diabetes.

Upon achievement of certain development milestones with respect to our anti-IP-10 antibody program, but no later than September 4, 2007, we may be required to pay the former shareholders of Ability Biomedical approximately $3.68 million in cash and/or common stock, subject to fluctuations in currency exchange rates. In lieu of such additional payment, we also have the option to revert to the original joint collaboration agreement

with the former shareholders of Ability Biomedical whereby each party would be responsible for 50% of the costs associated with the anti-IP-10 antibody program.

In November 2004, we announced a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. This collaboration became effective in January 2005. Under the terms of the collaboration, we and BMS each granted the other certain intellectual property licenses and product rights on a worldwide basis in order to enable us to collaborate in research and development of certain therapeutic antibody-based product candidates for the treatment of cancer and other diseases, and, in the event that further development work is successful, to commercialize any resulting products. In particular, the collaboration includes a grant by us to BMS of a license to commercialize MDX-010, a fully human antibody product candidate developed using our UltiMAb Human Antibody Development System, that is antagonistic to CTLA-4. MDX-010 is currently under investigation for the treatment of a broad range of cancers. The collaboration also includes the grant by us to BMS of a sub-license to MDX-1379, a gp100 peptide vaccine licensed by us from the U.S. Public Health Service, for use with MDX-010 for the treatment of metastatic melanoma. We and BMS are currently conducting a Phase III clinical trial with MDX-010 and MDX-1379 combination therapy in Stage III and Stage IV metastatic melanoma patients at multiple sites within the U.S.

As part of the collaboration, we and BMS have committed to an initial multi-year budget of approximately $192.0 million to fund the development of MDX-010 as a potential treatment for a broad range of cancers. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the U.S. and Europe, with the remaining 35% to be paid by us. We and BMS will share equally the costs of any clinical trials of product candidates intended solely for regulatory approval in the U.S., and BMS will be fully responsible for all development costs that relate solely to regulatory approval in Europe and other parts of the world.

Under the terms of the collaboration, we could receive up to $205.0 million from BMS if all regulatory milestones are met, plus up to an additional $275.0 million in sales-related milestones. We will also have the option to co-promote any products in the U.S., and, if we elect to exercise this option and have participated in the funding of the applicable Phase III clinical trial(s), we will receive 45% of any profits from commercial sales. In the event we choose not to exercise our co-promotion rights, BMS will have exclusive commercial rights in the U.S. and will pay us royalties on commercial sales. Outside the U.S., BMS will have exclusive commercial rights and will pay us royalties on commercial sales.

Pursuant to these agreements, BMS made an initial cash payment to us on January 21, 2005 of $25.0 million. In addition, BMS purchased a total of 2,879,223 unregistered shares of our common stock at a purchase price equal to $8.6829 per share for an aggregate purchase price of $25.0 million. These shares were issued in a private placement pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933. The purchase price represented a small premium to the market price on the date we signed the collaboration agreement. BMS has agreed to a two-year lock-up period with respect to any sales of such stock. We have no future obligation to register such stock.

Financial Uncertainties Related to Potential Future Milestone Payments

Effective September 4, 2002, we entered into a collaboration and license agreement with Kirin, 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 that 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 June 30, 2005, we have not made any milestone payments to Kirin although approximately $2.8 million has been paid to Kirin as of June 30, 2005 representing a payment due Kirin as a result of our collaboration with Pfizer. In addition, based on a total of two 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 2006, we may be required to make milestone payments to Kirin aggregating up to approximately $8.5 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 June 30, 2005, we had made milestone payments of approximately $0.3 million 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 2006, we may be obligated to make future milestone payments aggregating up to approximately $22.5 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. To the extent our 2.25% Notes are converted into shares of our common stock on or before their maturity date, we will have use of that portion of the principal amount 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 December 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends Statement No. 95, *Statement of Cash Flows.* Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Historically, in accordance with SFAS 123 and SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, we have elected to follow the disclosure only provisions of Statement No. 123 and, accordingly, continue to account for share based compensation under the recognition and measurement principles of APB Opinion No. 25 and related interpretations. Under APB 25, when stock options are issued with an exercise price equal to the market price of the underlying stock price on the date of grant, no compensation expense is recognized in the financial statements, and compensation expense in only disclosed in the footnotes to the financial statements. We will be required to adopt Statement No. 123(R) beginning January 1, 2006. We are currently in the process of evaluating the option valuation methods and adoption transition alternatives available under Statement 123(R). Although we have not yet determined the impact of Statement 123(R), it may be significant to our consolidated results of operations.

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.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures: We maintain 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 our 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 our management, including our 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, our 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 our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2005. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2005, our disclosure controls and procedures were effective in ensuring that material information relating to our company is made known to the Chief Executive Officer and Chief Financial Officer by others within our company during the period in which this report was being prepared.

Changes in internal controls: There were no significant changes in our internal controls during the three months ended June 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 4. Submission of Matters to a Vote of Security Holders

At the Annual Meeting of Shareholders held on May 19, 2005, our shareholders elected two Class II Directors each to serve for a term to expire in 2008. Our shareholders also voted to approve our 2005 Equity Incentive Plan and to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for the 2005 fiscal year. Out of the 110,575,979 eligible votes, a total of 79,036,190 were cast at the meeting for Items Nos. 1 and 3 below either by proxies solicited in accordance with Section 14 of the Securities Exchange Act of 1934, as amended, and the regulations set forth thereunder, or by securities holders voting in person. In addition, a total of 47,712,295 votes were cast at the meeting either by proxies or in person for Item No. 2. There were 31,323,895 broker non-votes related to Item No. 2. In the case of directors, abstentions are treated as votes withheld and are included in the table. The tabulation of votes for each nominee is set forth under Item No. 1 below, the approval of the 2005 Equity Incentive Plan is set forth under Item No. 2 below and the ratification of the appointment of Ernst & Young LLP as independent registered public accounting firm for the 2005 fiscal year is set forth in Item No. 3 below:

Item No. 1

Nominees for Directors

Directors Class II	Votes For	Votes Withheld
Mr. Michael A. Appelbaum	74,832,845	4,203,345
Dr. Patricia M. Danzon	75,655,640	3,380,550

The following persons are incumbent directors whose terms of office continue after the Annual Meeting of Shareholders:

Class I Terms Expiring in 2006	Class III Terms Expiring in 2007
Dr. Donald L. Drakeman	Mr. Irwin Lerner
Dr. Ronald J. Saldarini	Dr. Julius A. Vida
Mr. Charles R. Schaller	

Item No. 2

Approval of our 2005 Equity Incentive Plan:

FOR	AGAINST	ABSTAIN
35,083,158	12,437,255	191,882

Item No. 3

Ratification of the selection of Ernst & Young LLP as Independent Registered Public Accounting Firm for the 2005 fiscal year:

FOR	AGAINST	ABSTAIN
77,414,151	1,509,828	112,211

Item 5. Other Information

Additional factors that might affect future results include the following:

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

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Active product candidates employing our human antibody technology have not moved beyond clinical development. Based on public disclosures, regulatory applications, including INDs, have been submitted to the FDA or comparable foreign authorities, for 24 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 clinical 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. This product did not employ 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 June 30, 2005, we had an accumulated deficit of approximately $677.1 million. Our net losses were $186.5 million and $77.7 million for the year ended December 31, 2004 and the six-month period ended June 30, 2005, 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 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. To the extent our 2.25% convertible senior notes due in 2011 are converted into shares of our common stock on or before their maturity date, we will have use of that portion of the principal amount 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 may be unable to raise sufficient funds to complete development of any of our product candidates, to continue operations or to repay our debt obligations at maturity. 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 $150.0 million in aggregate principal amount of our 2.25% convertible senior notes outstanding, which, unless converted to shares of our common stock or redeemed, will mature in 2011. Our ability to make payments on these notes and our other obligations 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;

the need or desire to modify our manufacturing processes;

slower than expected rates of patient recruitment;

modification of clinical trial protocols;

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. 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 trials of MDX-010 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 ABEs, such as diarrhea, rash,

reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. Other than a very small number of fatalities, which may or may not be attributable to our product candidate, most ABEs resolved with treatment. 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 has moved several product categories previously 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. FDA has also announced a planned reorganization within CDER to create a new consolidated office for the review of oncology therapies. Oncology therapies are currently reviewed by different offices within CDER. The effect that these reorganizations 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 U.S. 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.

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 U.S. government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the U.S. 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. The new legislation also modified the methodology used for reimbursement of physician administered and certain other drugs already covered under Medicare Part B. This new methodology would likely apply to certain of our products if and when commercialized. Experience with new reimbursement methodology is limited, and could be subject to change in the future. Our results of operations could be materially harmed by the different features of 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 is now significant 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 U.S. import laws and expand the ability to import lower priced versions of our and competing products from Canada, where there are 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 previous Secretary of Health and Human Services determined that there was not a basis to make such a certification at this time. However, it is possible that 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. We have entered into clinical supply agreements with Lonza Group Ltd. with respect to MDX-010 and MDX-060. As part of our collaboration with BMS, we assigned to BMS the clinical supply agreement with respect to MDX-010, and, together with BMS, we are pursuing ongoing discussions with respect to terms of a commercial supply agreement for MDX-010. 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. In particular, under the terms of our collaboration and co-promotion agreement with BMS, we have granted a license to commercialize our lead product candidate, MDX-010, to BMS for the treatment of a broad range of cancers. We have also granted to BMS a sub-license to MDX-1379 for use in combination with MDX-010 for the treatment of metastatic melanoma. The successful development and commercialization of MDX-010 is dependent, in large part, on the actions of BMS, which are outside of our control. The failure of BMS to act in accordance with its obligations under the collaboration and co-promotion agreement may cause us to incur substantial additional costs in order to develop and commercialize MDX-010, which could have a material adverse effect on our business.

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 be terminated, and we may not be able to establish additional partnerships.

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. 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 equity interest in Genmab, we are currently required to account for our 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, 2002, 2003 and 2004, our share of Genmab s losses were approximately $19.6 million (excluding the $31.0 million impairment charge discussed below), $15.0 million and $19.8 million, respectively. For the six-month period ended June 30, 2005, our share of Genmab s net loss was $1.7 million. As such, the current value of our equity interest in Genmab as determined by the equity method of accounting is zero and, accordingly, recognition of our share of Genmab s net losses is now suspended indefinitely.

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, and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. As these investments are the result of strategic alliances with our collaborative partners, we typically do not attempt to reduce or eliminate our market exposure of these types of strategic investments. Under SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, these investments are designated as available-for-sale and are reported at fair value on our consolidated balance sheet. Unrealized holding gains and losses on available-for-sale securities are generally excluded from earnings and reported within other comprehensive income which is a separate component of shareholders equity. Under our accounting policy, marketable equity securities are generally considered to be impaired if their fair value is less than our cost basis in such securities for more than six months, or some other period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of available-for-sale securities is considered to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. For the year ended December 31, 2002, we recorded impairment charges of approximately $40.5 million (of which approximately $31.0 million related to Genmab) on our strategic investments in publicly traded companies. During the year ended December 31, 2003, no impairment charges were recorded related to the value of our investments in publicly traded companies. For the year ended December 31, 2004, we recorded impairment charges of $0.2

million on investments in partners whose securities are publicly traded. No impairment charges were recorded on investments in partners whose securities are publicly traded for the three and six month periods ended June 30, 2005. 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. 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, management of these companies, financial statements, and other external sources. Specifically, our determination of any potential impairment of the value of privately held securities includes an analysis of the following for each company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financing and potential strategic alternatives. 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, 2003 and 2004, we recorded impairment charges of approximately $2.4 million, $1.4 million and $7.1 million, respectively, on our investments in privately-held companies. Approximately $7.0 million of the 2004 impairment charge related to IDM. For the three and six month periods ended June 30, 2005, we recorded impairment charges of $9.0 million and $29.3 million which related entirely to IDM. 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 maintain 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 U.S. 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 U.S. 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 U.S.

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 U.S. 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. We are also aware of certain U.S. 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-CD20 antibodies, such as HuMax-CD20, anti-EGFr antibodies, such as HuMax-EGFr, anti-PSMA antibodies, such as MDX-070,

anti-Type 1 IFN antibodies, such as MDX-1103, and antibody-antigen conjugates, such as MDX-1307/bHCG-VAC, as well as other antibody products under development by us.

We are also aware of a U.S. patent owned by Genentech, relating to the production of recombinant antibodies in host cells. We currently produce certain of our products and our partners products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in this patent, then we may need to obtain a license, should one be available. We have a license to this patent from Genentech for our anti-CTLA-4 product candidate (MDX-010) but currently do not have licenses for any of our other antibody product candidates. If we desire a license for any of our other antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, 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 U.S. 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 intend to seek 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, GenPharm entered into a cross-license and settlement agreement with Abgenix, 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, 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 developed by us or our partners.

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 $15 million per occurrence and $15 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 diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, 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. 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 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. We have also entered into license agreements with Pfizer which enable it to compete with us in the generation and development of antibodies to CTLA-4. 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, Amgen, Biogen Idec Inc., Novartis, Genentech, Protein Design Labs, Inc., Wyeth, Abbott Laboratories and Corixa have generated therapeutic products that are currently in development or 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 similar biological agents. Continuing development of new chemical entities and other drugs by large pharmaceutical companies carries with it the potential for discovery of agents for treating disease indications also targeted by drugs that we or our partners are developing.

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

developing products;

undertaking preclinical testing and clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing and marketing products.

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

We also face intense competition from other pharmaceutical and biotechnology companies to establish partnerships, as well as relationships with academic and research institutions, and to license proprietary technology 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, the U.S. Department of Justice, 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 U.S. 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 U.S. 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 U.S. 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 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, and the Veteran s Health Care Act of 1992, 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. For example, some have proposed that FDA allow a generic or follow-on copy of certain therapeutic biologics to be approved under the Public Health Service Act or 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 June 30, 2005, the sale prices of our common stock ranged between $4.37 and $11.55. 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 July 29, 2005, we had 13,986,188 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 $8.02 per share and we had reserved 7,405,227 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 under the Securities Act 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 102,915 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 under the Securities Act 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 July 29, 2005, we had reserved 894,129 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 under the Securities Act covering all of those shares. 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 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 July 29, 2005, we had 10,936,935 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 July 29, 2005, we had 111,033,341 shares of common stock outstanding, of which 9,374,318 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 shareholders. 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 $294.59 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 up to 18,601,190 shares of our common stock which were issued upon the conversion of our $125.0 million 4.25% Convertible Senior Notes due August 15, 2010 in connection with the provisional redemption of such notes in January 2005. 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 the resale limitations 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 up to 3,272,091 shares of our common stock which were issued on the conversion of all of our $21.986 million 4.25% Convertible Senior Notes due August 15, 2010, in connection with the provisional redemption of such notes in January 2005. 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 the resale limitations 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 repurchase or otherwise); and (iv) two years after the respective effective dates of these registration statements.

We have filed a registration statement on Form S-3 under the Securities Act relating to our $150.0 million 2.25% Convertible Senior Notes due May 15, 2011, and up to 10,936,935 shares of our common stock which may be issued upon conversion of the notes. The notes and the 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 the resale limitations of Rule 144.

We have filed a registration statement on Form S-4 under the Securities Act to register shares of our common stock having a maximum aggregate offering price of $12.0 million. Such shares are freely tradable without restriction or further registration under the Securities Act. On August 5, 2004 we issued 731,823 shares of such common stock, valued at approximately $4.3 million to satisfy a portion of the purchase price in connection with the acquisition of Ability Biomedical Corporation. This registration statement on Form S-4 under the Securities Act remains

available for the sale of up to $7.7 million 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 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 2.25% Convertible Senior Notes due May 11, 2011. As of July 29, 2005, $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, amended and restated 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 amended and restated 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 amended and restated 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 and potential new accounting pronouncements may impact our future financial position or results of operations.

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. 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.

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.

Item 6. Exhibits and reports on Form 8-K

(a) Reports on Form 8-K:

Form 8-K dated May 9, 2005 relating to a press release of the Company s financial results for the quarter ended March 31, 2005.

Form 8-K dated May 20, 2005 regarding the approval of the Company s 2005 Equity Incentive Plan and the election of directors.

Form 8-K dated July 29, 2005 relating to: (i) an amendment to the Company s 2005 Equity Incentive Plan, and (ii) an amendment to the Company s by-laws.

(b) Exhibits:

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

Signatures

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

MEDAREX, INC.
(Registrant)

Date: August 9, 2005 By: /s/ DONALD L. DRAKEMAN
Donald L. Drakeman
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 9, 2005 By: /s/ CHRISTIAN S. SCHADE
Christian S. Schade
Senior Vice President Finance & Administration, Chief Financial Officer
(Principal Financial and Accounting Officer)