

MEDAREX INC  
Form 10-Q  
May 12, 2008

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

---

## FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2008

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_ ..

Commission File No. 0-19312

---

## MEDAREX, INC.

(Exact Name of Registrant as Specified in Its Charter)

**New Jersey**  
(State or Other Jurisdiction of Incorporation or Organization)

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

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

**08540**  
(Zip Code)

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

Edgar Filing: MEDAREX INC - Form 10-Q

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

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check x whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Indicate the number of shares of each of the issuer's classes of common stock, as of the latest practicable date:

Class	Outstanding at April 30, 2008
Common Stock, \$.01 par value	127,623,252

TABLE OF CONTENTS

	Page
<b>PART I FINANCIAL INFORMATION</b>	
Item 1.	
	3
	4
	5
	6
Item 2.	22
Item 3.	36
Item 4.	37
<b>PART II OTHER INFORMATION</b>	
Item 1.	38
Item 1A.	38
Item 6.	63
	65

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share data)

	March 31, 2008	December 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 153,297	\$ 37,335
Marketable securities	311,180	311,437
Marketable securities - Genmab		152,000
Prepaid expenses and other current assets	15,818	29,013
Total current assets	480,295	529,785
Property, buildings and equipment:		
Land	6,780	6,780
Buildings and leasehold improvements	85,521	87,217
Machinery and equipment	67,911	68,729
Furniture and fixtures	4,903	5,122
	165,115	167,848
Less accumulated depreciation and amortization	(89,149)	(87,923)
	75,966	79,925
Marketable securities - Genmab	115,587	139,165
Investment in AVANT	9,381	
Investments in, and advances to, other partners	6,040	6,040
Segregated securities	1,300	1,530
Other assets	2,206	3,415
Total assets	\$ 690,775	\$ 759,860
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Trade accounts payable	\$ 7,130	\$ 7,579
Accrued liabilities	30,184	47,194
Deferred contract revenue - current	27,005	26,872
Total current liabilities	64,319	81,645
Deferred contract revenue - long-term	82,151	85,103
Other long-term liabilities	4,019	4,351
2.25% Convertible senior notes due May 15, 2011	143,986	143,505
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; 127,574,311 shares issued and 127,540,471 shares outstanding at March 31, 2008 and 127,453,308 shares issued and 127,419,468 shares outstanding at December 31, 2007	1,276	1,275
Capital in excess of par value	1,166,202	1,145,453
Treasury stock, at cost 33,840 shares in 2008 and 2007	(85)	(85)
Accumulated other comprehensive income	116,316	289,334
Accumulated deficit	(887,409)	(990,721)

Edgar Filing: MEDAREX INC - Form 10-Q

Total shareholders' equity		396,300		445,256
Total liabilities and shareholders' equity	\$	690,775	\$	759,860

See notes to these unaudited consolidated financial statements.

**MEDAREX, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

(In thousands, except per share data)

	Three Months Ended March 31,	
	2008	2007
Contract and license revenues	\$ 7,110	\$ 5,914
Contract and license revenues from Genmab	874	1,084
Reimbursement of development costs	4,019	4,541
Total revenues	12,003	11,539
Costs and expenses:		
Research and development	49,292	47,022
General and administrative	12,409	11,302
Total costs and expenses	61,701	58,324
Operating loss	(49,698)	(46,785)
Equity in net loss of affiliate	(1,785)	
Interest and dividend income	4,528	4,799
Gain on sale of Genmab stock	151,834	152,143
Interest expense	(1,544)	(1,541)
Minority interest - Celldex		1,651
Income before provision for income taxes	103,335	110,267
Provision for income taxes	23	2
Net income	\$ 103,312	\$ 110,265
Basic and diluted net income per share:		
basic	\$ 0.81	\$ 0.88
diluted	\$ 0.76	\$ 0.80
Weighted average number of common shares outstanding:		
basic	127,643	124,690
diluted	138,580	140,144

See notes to these unaudited consolidated financial statements.

**MEDAREX, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2008	2007
<b>Operating activities:</b>		
Net income	\$ 103,312	\$ 110,265
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation	3,434	3,626
Amortization	726	592
Amortization of net bond premium/discount	(740)	
Stock based compensation and vesting of restricted stock units	5,113	3,952
Equity in net loss of AVANT	1,785	
Gain on sale of Genmab stock	(151,834)	(152,143)
Minority interest - Celldex		(1,651)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	9,292	(881)
Trade accounts payable	684	(2,530)
Accrued liabilities	(15,430)	(217)
Deferred contract revenue	(1,711)	(182)
Net cash used in operating activities	(45,369)	(39,169)
<b>Investing activities:</b>		
Purchase of property and equipment	(1,278)	(1,923)
Proceeds from sale of Genmab stock	151,834	152,143
Decrease in segregated cash	49	
Purchase of marketable securities	(35,872)	(115,053)
Sales and maturities of marketable securities	42,000	37,534
Net cash provided by (used in) investing activities	156,733	72,701
<b>Financing activities:</b>		
Cash received from sales of securities and exercise of stock options, net	1,046	3,578
Principal payments under capital lease obligations	(12)	(7)
Net cash provided by financing activities	1,034	3,571
Effect of exchange rate differences on cash and cash equivalents	(20)	(13)
Effect of change in accounting from consolidation to equity method	3,584	
Net increase (decrease) in cash and cash equivalents	115,962	37,090
Cash and cash equivalents at beginning of period	37,335	34,511
Cash and cash equivalents at end of period	\$ 153,297	\$ 71,601
<b>Non-cash investing and financing activities:</b>		
Unrealized gain (loss) on investment in Genmab	\$	\$
<b>Supplemental disclosures of cash flow information</b>		
Cash paid during period for:		
Income taxes	\$	\$ 22
Interest	\$	\$

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 consolidated financial statements are unaudited and 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. The consolidated interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results for the interim periods ended March 31, 2008 and 2007.

The Company's financial statements consolidate all of its subsidiaries, including those that it controls and those in which it holds a majority voting interest. Medarex currently owns approximately 35.6% of the outstanding common stock of AVANT Immunotherapeutics, Inc. (AVANT) as a result of the merger of AVANT with Celldex Therapeutics, Inc. (Celldex). Prior to this merger, Medarex owned approximately 60% of the outstanding common stock of Celldex (see Note 2).

The Company accounts for its investment in Genmab A/S (Genmab) in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (see Note 4).

The unaudited consolidated results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. The unaudited consolidated balance sheet at December 31, 2007 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. These consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto, which are contained in the Company's annual report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission, or SEC.

The preparation of the financial statements and related disclosures in conformity with accounting principles generally accepted in the United States requires management to make estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's consolidated balance sheets and the amounts of revenues and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but

## Edgar Filing: MEDAREX INC - Form 10-Q

not limited to, the accounting for revenue recognition, stock-based compensation, income taxes, loss contingencies and accounting for research and development costs. Actual results could differ from those estimates.

### *Net Income (Loss) per Share*

Basic and diluted net income (loss) per share are computed in accordance with SFAS No. 128, *Earnings*

## MEDAREX, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

*per Share.* Basic net income per share is based upon the number of weighted average shares of common stock outstanding. Diluted net income 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, with exercise prices less than the average market price of the Company's common stock during the three month period ended March 31, 2007, which are included under the treasury stock method, as well as the assumed conversion of convertible senior notes. Stock options have been excluded from the computation of diluted net income per share for the three month period ended March 31, 2008 as their effect is antidilutive. A summary of such potentially dilutive securities is as follows:

The following table sets forth the computation of basic and diluted income per share for the three month periods ended March 31, 2008 and 2007:

	Three Months Ended March 31,	
	2008	2007
Income (Numerator):		
Net income for basic and diluted income per share	\$ 103,312	\$ 110,265
Adjustment for interest expense on convertible notes	1,491	1,491
Income for diluted income per share	\$ 104,803	\$ 111,756
Shares (Denominator):		
Weighted average shares for basic income per share	127,642,821	124,690,194
Effect of dilutive securities (stock options)		4,516,670
Effect of convertible notes, after assumed conversion	10,936,935	10,936,935
Weighted average shares for diluted income per share	138,579,756	140,143,799
Basic net income per share	\$ 0.81	\$ 0.88
Diluted net income per share	\$ 0.76	\$ 0.80

Potential shares of common stock that would be issued if all outstanding stock options were exercised (19,389,418 shares), without regard to whether the outstanding stock options were in the money are not included in the computation of diluted net income per share for the three months ended March 31, 2008 because to do so would be antidilutive.

**Marketable Securities and Long-Term Non-Marketable Investments**

## Edgar Filing: MEDAREX INC - Form 10-Q

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* ( SFAS No. 115 ), 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

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

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 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 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 no impairment charges related to investments in partners whose securities are publicly traded for the three month periods ended March 31, 2008 and 2007. The Company recorded no impairment charges related to investments in partners whose securities are privately held for the three month periods ended March 31, 2008 and 2007. If the Company deems any of its investments to be impaired at the end of any future period, it may incur impairment charges on these investments.

***Estimated Fair Value of Financial Instruments***

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, (Statement No. 157). Statement No. 157 defines and establishes a framework for measuring fair value and expands disclosures about fair value instruments. In accordance with SFAS No. 157, the Company has categorized its financial assets, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. The Company does not have any financial liabilities that are required to be measured at fair value on a recurring basis. If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial assets recorded on the consolidated balance sheets are categorized based on the inputs to the valuation techniques as follows:

- *Level 1* Financial assets whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the company has the ability to access at the measurement date (examples include active exchange-traded equity securities and most U.S.

Government and agency securities).

- *Level 2* Financial assets whose value are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.
- *Level 3* Financial assets whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

reflect management's own assumptions about the assumptions a market participant would use in pricing the asset. The Company does not currently have any Level 3 financial assets.

	<b>Level 1</b>	<b>Level 2</b>	<b>Total</b>
Money Market Funds	\$ 156,115	\$	\$ 156,115
U.S. Treasury Obligations	90,574		90,574
U.S. Corporate Debt Securities		161,060	161,060
Mortgage-Backed Securities		47,323	47,323
Equity Securities	6,501		6,501
Equity Securities - Genmab	115,587		115,587
<b>Total</b>	<b>\$ 368,777</b>	<b>\$ 208,383</b>	<b>\$ 577,160</b>

***Revenue Recognition***





## Edgar Filing: MEDAREX INC - Form 10-Q

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 reported as deferred revenue until they are recognizable as revenue. The Company follows the following principles in recognizing revenue:

- Fees received from the licensing of the Company's proprietary technologies for research and development performed by its customers and partners are recognized generally on a straight line basis 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, the consideration is allocated among the separate units of accounting based on their 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.

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

- 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.
- 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.

***Income Taxes***

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statement amounts and their respective tax bases. The Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109* (FIN 48) to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement and classification of amounts relating to uncertain tax positions, accounting for and disclosure of interest and penalties, accounting in interim periods, disclosures and transition relating to the adoption of the new accounting standard. The Company adopted FIN 48 as of January 1, 2007, as required and determined that the adoption of FIN 48 did not have a material impact on the Company's financial position and results of operations. The Company did not recognize interest or penalties related to income tax during the three month periods ended March 31, 2008 and 2007 and did not accrue for interest or penalties as of March 31, 2008 or December 31, 2007. The Company does not have an accrual for uncertain tax positions as of March 31, 2008 or December 31, 2007. Tax returns for years 2002 and thereafter are subject to future examination by tax authorities.

***Recently Issued Accounting Pronouncements***

In December 2007, the EITF reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with

## Edgar Filing: MEDAREX INC - Form 10-Q

collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15,

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company is currently evaluating the requirements of EITF 07-1; however it does not believe that its adoption will have a significant impact on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (R), *Business Combinations* (Statement No. 141 (R)), which replaces SFAS No. 141, *Business Combinations*, and requires an acquirer to recognize the assets acquired, the liabilities assumed and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. Statement No. 141 (R) also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. Statement No. 141 (R) makes various other amendments to authoritative literature intended to provide additional guidance or conform the guidance in that literature to that provided in Statement No. 141 (R). Statement No. 141 (R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company does not expect that the adoption of Statement No. 141 (R) will have a significant impact on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* (Statement No. 160), which amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to improve the relevance, comparability and transparency of the financial information that a reporting entity provides in its consolidated financial statements. Statement No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries not held by the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent's equity. Statement No. 160 also requires the amount of consolidated net income attributable to the parent and to the non-controlling interest to be clearly identified and presented on the face of the consolidated statement of operations. Changes in a parent's ownership interest while the parent retains its controlling financial interest must be accounted for consistently, and when a subsidiary is deconsolidated, any retained non-controlling equity investment in the former subsidiary must be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any non-controlling equity investment. Statement No. 160 also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. Statement No. 160 applies prospectively to all entities that prepare consolidated financial statements and applies prospectively for all fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The Company is currently evaluating the requirements of Statement No. 160; however it does not believe that its adoption will have a significant impact on its consolidated financial statements.

***Recently Adopted Accounting Pronouncements***

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. The Company adopted EITF 07-3 on January 1, 2008. Adoption of EITF 07-3 did not have a material impact on the Company's consolidated financial position or results of operations.



**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, (Statement No. 157). Statement No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. See *Estimated Fair Value of Financial Instruments* above for further information about the adoption of the required provisions of Statement No. 157.

In February 2008, the FASB issued FASB Staff Position (FSP) No. 157-2, *Effective Date of FASB Statement No. 157* (FSP No. 157-2). FSP No. 157-2 delays the effective date of Statement No. 157 for one full year for all nonfinancial assets and nonfinancial liabilities, except for certain items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The Company has elected a partial deferral of Statement No. 157 under the provisions of FSP No. 157-2 related to the measurement of fair value used when evaluating intangible assets and other long-lived assets for impairment and valuing asset retirement obligations and liabilities for exit or disposal activities. The Company is currently evaluating the impact of Statement No. 157 on its consolidated financial statements for items within the scope of FSP 157-2, which will become effective beginning with the first quarter of 2009.

**2. Investment in Celldex Therapeutics, Inc./AVANT Immunotherapeutics, Inc.**

In March 2004, the Company assigned or licensed to Celldex certain intellectual property related to the Company's vaccine technology, including the rights to CDX-1307 (previously known as 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.

To complement its technology and its internal clinical pipeline, in October 2005, Celldex completed the acquisition of all of the issued and outstanding shares of capital stock of Lorantis Limited (Lorantis), a privately held biotechnology company based in Cambridge, U.K. and substantially all of the assets of Alteris Therapeutics, Inc. (Alteris), a privately held biotechnology company based in Philadelphia, PA.

The purchase price of Lorantis consisted of 6.8 million shares of Celldex Class A common stock (valued at \$34.0 million).

The purchase price for substantially all of the Alteris assets consisted of 1.2 million shares of Celldex common stock (valued at \$6.0 million) and approximately \$1.6 million in cash. Celldex may be required to pay Alteris up to \$5.0 million upon obtaining the first approval for commercial sale of an EGFRvIII product. As a result of the Lorantis stock acquisition and the Alteris asset acquisition, the Company's ownership percentage of Celldex was reduced from 100% to approximately 60%.

## Edgar Filing: MEDAREX INC - Form 10-Q

In October 2007, the Company's minority interest in the equity of Celldex was reduced to zero and accordingly, the company (as the majority shareholder) was required to record 100% of Celldex's losses for the final three months of 2007.

On March 7, 2008, AVANT Immunotherapeutics, Inc. and Celldex merged with the combined company named AVANT Immunotherapeutics, Inc. ( AVANT ) and trades under the NASDAQ ticker symbol AVAN.

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

Under the terms of the merger agreement, Celldex shareholders received approximately 4.96 shares of AVANT common stock in exchange for each share of Celldex stock they owned. In connection with the merger, AVANT's board of directors approved a 1-for-12 reverse stock split of AVANT's common stock which became effective on March 7, 2008. The Company received a total of 5,312,539 shares of AVANT representing approximately 35.6% of the total post split outstanding shares of AVANT.

For the period from January 1, 2008 through March 6, 2008, the Company (as the majority shareholder) continued to record 100% of Celldex's losses which amounted to approximately \$2.3 million.

As a result of the merger with AVANT and the corresponding reduction in the Company's ownership from approximately 60% to approximately 35.6%, the Company ceased consolidating the operations of Celldex as of March 6, 2008 and began to account for its investment in AVANT under the equity method of accounting in accordance with APB No. 18, *The Equity Method of Accounting for Investments in Common Stock*. The Company recorded a non-cash change in interest gain of approximately \$18.5 million during the three month period ended March 31, 2008 associated with the change from the consolidation basis to the equity method of accounting. Because of the uncertainty surrounding the ultimate realizability of the gain, the gain was recorded as an increase to capital in excess of par value, a component of shareholders' equity.

A member of the Company's board of directors is also the chairman of AVANT's board of directors. As of March 31, 2008, the market value of the Company's investment in AVANT was approximately \$52.1 million.

Summary financial information for AVANT is as follows as of March 31, 2008 and for the period from March 7, 2008 through March 31, 2008:

Current Assets	\$	22,733
Non-Current Assets		17,820
Current Liabilities		11,260
Non-Current Liabilities		1,162
Revenue		1,514
Gross Profit		1,514
Net Loss		(5,013)



**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

**3. Equity-Based Compensation**

The Company's equity awards are governed by its 2005 Equity Incentive Plan, as amended (the Plan). The purchase price of stock options under the Plan is determined in accordance with the Company's Equity Grant Policy as approved by the Board of Directors of the Company. The term is fixed by the Compensation and Organization Committee of the Board of Directors, but no incentive stock option is exercisable after 10 years from the date of grant. Stock options generally vest over a four year period. As of March 31, 2008, a total of 2,587,568 shares were available for future grants under the Plan.

On January 1, 2006, the Company adopted the fair value recognition provisions of Statement No. 123(R), using the modified prospective transition method. Under the modified prospective transition method, compensation expense is recognized in the financial statements on a prospective basis for (i) all share based payments granted prior to, but not vested as of January 1, 2006, based upon the grant date fair value estimated in accordance with the original provisions of Statement No. 123, and (ii) share based payments granted on or subsequent to January 1, 2006, based upon the grant date fair value estimated in accordance with the provisions of Statement No. 123(R). The grant date fair value of awards expected to vest is expensed on a straight line basis over the vesting periods of the related awards. Under the modified prospective transition method, results for prior periods are not restated.

Total stock based compensation expense of approximately \$5.3 million for the three month period ended March 31, 2008 has been included in the consolidated statement of operations within research and development expenses (\$2.0 million) and general and administrative expenses (\$3.3 million).

Total stock based compensation expense of approximately \$3.9 million for the three month period ended March 31, 2007 has been included in the consolidated statement of operations within research and development expenses (\$2.5 million) and general and administrative expenses (\$1.4 million).

The following summarizes all stock option transactions for the Company under the Plan for the period from January 1, 2008 through March 31, 2008.

## MEDAREX, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

	Common Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2008	17,078,740	\$ 10.67		
Granted	2,495,900	\$ 9.07		
Exercised	(71,640)	\$ 6.43		
Canceled	(2,206)	\$ 14.29		
Forfeited	(111,376)	\$ 11.90		
Outstanding at March 31, 2008	19,389,418	\$ 10.47	6.7 years	\$ 18,424
Exercisable at end of period	11,797,481	\$ 9.68	5.2 years	\$ 17,857
Vested and unvested expected to vest at March 31, 2008	18,708,287	\$ 10.43	6.7 years	\$ 18,376

The weighted-average grant-date fair value of options granted during the three month periods ended March 31, 2008 and 2007 were \$6.54 and \$9.90, respectively. The aggregate intrinsic value of options exercised during these same periods was \$0.3 million and \$5.3 million, respectively. The grant-date fair value of shares which vested during the three month periods ended March 31, 2008 and 2007 was \$3.2 million and \$7.6 million, respectively. Cash proceeds from stock options exercised during the three month periods ended March 31, 2008 and 2007 totaled \$0.5 million and \$3.6 million, respectively.

The fair value of each option grant is estimated using the Black-Scholes option pricing method. The fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period (generally 4 years). Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. To estimate the grant date fair value, option pricing models require the use of estimates and assumptions as to (i) the expected term of the option, (ii) the expected volatility of the price of the underlying stock, (iii) the risk free interest rate for the expected term of the option and (iv) pre-vesting forfeiture rates. The expected term of the option is based upon the contractual term, taking into account expected employee exercise and expected post-vesting termination behavior. The expected volatility of the price of the underlying stock is based on the historical volatility of the Company's common stock. The risk free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected life assumed on the date of grant. Pre-vesting forfeiture rates are estimated based on past voluntary termination behavior, as well as an analysis of actual option forfeitures. The following table sets forth the assumptions used to calculate the fair value of options granted for the three month periods ended March 31, 2008 and 2007:

## MEDAREX, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

	<b>Three Months Ended March 31</b>	
	<b>2008</b>	<b>2007</b>
Expected stock price volatility	81.5%	82.2%
Risk-free interest rate	2.57%	4.55%
Expected life of options (years)	6.40	6.00
Expected dividend yield	0%	0%

As of March 31, 2008, the total unrecognized compensation cost related to non-vested stock options was approximately \$46.0 million. This cost is expected to be recognized over a weighted average period of 2.8 years.

Deferred Compensation

The Company maintains deferred compensation programs, under which each of the Company's executive officers elected to have a portion of their bonuses, which were otherwise payable in cash, converted to restricted stock units representing shares of the Company's common stock. Participants in the deferred compensation programs could elect to defer up to 50% of their respective bonuses. The number of restricted stock units awarded upon such conversion was determined by dividing (i) the amount of the bonus to be converted by (ii) the fair market value of the Company's common stock on the grant date. Participants in the deferred compensation programs elected to defer receipt of the common stock portion of their bonuses until the earlier of three years from the grant date or the participant's termination from the Company. The bonus portion deferred by each of the participants is matched on a 1:1 basis by the Company and 25% of the match is vested as of the respective grant dates. So long as a participant remains employed by the Company, an additional 25% of the Company's matching contribution vests on each anniversary of the respective grant dates for the next three years. All benefits under each of the deferred compensation programs are distributed in a single payment and will be paid exclusively in the form of shares of the Company's common stock. The Company's matching contribution was approximately \$0.1 million and \$0.1 million for the three month periods ended March 31, 2008 and 2007, respectively.

**4. Investments in Genmab**

As a result of a series of transactions, including an initial public offering by Genmab of its ordinary shares in October 2000, the Company owned an approximate 18.5% interest in Genmab as of December 31, 2006.

## Edgar Filing: MEDAREX INC - Form 10-Q

In February 2007, the Company completed the sale of 2,578,500 shares of Genmab through a block trade. The Company received net proceeds of approximately \$152.1 million from this sale resulting in a realized gain of approximately \$152.1 million as the Company's cost basis for these shares was zero. As a result of this transaction, the Company's ownership in Genmab was reduced to approximately 10.8%.

On February 1, 2008, the Company completed the sale of 2,500,000 shares of Genmab through a block trade. The Company received net proceeds of approximately \$151.8 million from such block trade. As a result

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

of this transaction, the Company's ownership percentage in Genmab was reduced to approximately 5.1%.

**5. Bristol-Myers Squibb Collaboration**



## Edgar Filing: MEDAREX INC - Form 10-Q

In January 2005, the Company entered into 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 to enable the parties to collaborate in research and development of certain 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 ipilimumab, a fully human antibody product developed using the Company's UltiMA<sup>®</sup> technology, that is antagonistic to cytotoxic T-lymphocyte antigen 4 (CTLA-4). Ipilimumab is currently under investigation for the treatment of a broad range of cancers.

As part of the collaboration, BMS is 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 products 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 \$3.5 million and \$4.0 million of the Company's revenue for the three month periods ended March 31, 2008 and 2007, represented the reimbursement of 65% of the Company's costs associated with the development of ipilimumab recorded in accordance with EITF 99-19. The Company's share of the BMS development costs for the three month periods ended March 31, 2008 and 2007 was approximately \$5.3 million and \$5.2 million.

Under the terms of the collaboration, the Company has the option to co-promote any product in the U.S. If the Company exercises a co-promotion option with respect to a product for use in the first cancer indication for which an initial regulatory approval filing is accepted by the FDA, the Company will have the right and obligation to co-promote such product for use in all cancer indications, even if such indications are the subject of additional filings or approvals, and even if the Company opted-out of the development of any such indication. Even if the Company elects to co-promote a product for cancer indications, however, the Company would need to exercise a separate option to co-promote that product with respect to any indication other than cancer. If the Company does not exercise its co-promotion option with respect to a product for use in the first cancer indication for which an initial regulatory approval filing is accepted by the FDA, then the Company will not have the right or obligation to co-promote such product for any cancer indications, unless the filing for that first cancer indication is not approved by the FDA.

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. In addition, if the Company exercises its co-promotion option with respect to ipilimumab for the metastatic melanoma indication, and regulatory approval is obtained, the Company would receive 45% of any profits from commercial sales of such product in the U.S. In the event the Company chooses not to exercise its co-promotion rights with respect to a product, BMS will have exclusive commercial rights in the U.S. and will pay the Company royalties on commercial sales. Regardless of whether or not the Company exercises its co-promotion option outside the U.S., BMS will have exclusive commercial rights for products and will pay the Company royalties on commercial sales.

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

As part of the collaboration, BMS made a cash payment to us on January 21, 2005 of \$25.0 million and also purchased 2,879,223 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 Company determined that all elements under the collaboration and co-promotion agreement should be accounted for as a single unit of accounting under EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ( EITF 00-21 ). In accordance with SAB No. 104 (Topic 13, *Revenue Recognition*), deferral of revenue is appropriate regarding nonrefundable, upfront fees received in single unit of accounting arrangements. As the Company has continuing obligations under the collaboration and co-promotion agreement, and as significant development risk remains, the Company recorded the \$25.0 million upfront fee as deferred revenue and the Company is recognizing this amount over the enforceable term of the technology sublicensed to BMS under the collaboration and co-promotion agreement of approximately 11 years, as well as the technology and know-how to be delivered in connection therewith.

The BMS collaboration became effective in January 2005, and unless terminated earlier, will continue for as long as development and/or commercialization of any collaboration product continues. BMS, however, may terminate the collaboration on a country-by-country basis at any time and, under certain conditions, on a product-by-product basis, resulting in the return of all rights to the Company with respect to such country and/or product. In addition, BMS may terminate the Company's co-promotion rights in the U.S. in the event that the Company fails to satisfy certain performance criteria. The Company may terminate the BMS collaboration in the event of certain specified material breaches by BMS (in which case product rights would revert to the Company), and the Company may terminate BMS's co-promotion rights in the event that BMS fails to satisfy certain performance criteria.

**6. Legal Proceedings**

The SEC is conducting an informal inquiry into the Company's historical stock option granting practices and related accounting and disclosures. In addition, the United States Attorney's Office for the District of New Jersey is conducting a grand jury investigation relating to the same matters. At the conclusion of the SEC's informal inquiry and the U.S. Attorney's Office investigation, the Company could be subject to criminal or civil charges and fines or penalties or other contingent liabilities; however, no outcome is determinable at this time.

In June 2006, two derivative actions relating to the Company's historical stock option granting practices were filed in New Jersey state court by shareholders purporting to act on behalf of Medarex, naming Medarex as a nominal defendant and certain current and former directors as defendants. The state actions were consolidated in August 2006, and an amended consolidated complaint was filed in October 2007. In November 2006 and January 2007, three additional derivative complaints were filed in the United States District Court for the District of New Jersey, containing nearly identical factual allegations concerning Medarex's historical stock option granting practices. The federal actions were



## Edgar Filing: MEDAREX INC - Form 10-Q

consolidated in April 2007, and an amended consolidated complaint was filed in June 2007. The complaints allege, among other things, that certain of Medarex's officers and directors breached their fiduciary duties to the Company and violated federal securities laws in connection with public statements made in SEC filings relating to the Company's historical stock option granting practices and related accounting. The complaints seek unspecified damages and equitable relief. We could be required to pay significant damages in connection with this litigation.

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

The Company is unable to reasonably estimate any possible range of loss or liability associated with the stock option inquiry or derivative suits due to their uncertain resolution.

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

**7. Contingencies**

***Kirin Brewery Co., Ltd.***

In 2002, the Company entered into a collaboration and license agreement with Kirin Brewery Co., Ltd. ( Kirin ) which cross-licenses certain of the Company's and Kirin's technologies for the development and commercialization of human antibody products. Under the collaboration and license agreement, the Company and Kirin developed the KM-Mouse<sup>®</sup>, a unique crossbred mouse which combines the traits of the Company's HuMAb-Mouse<sup>®</sup> with Kirin's TC Mouse and exchanged cross-licenses with respect to the KM-Mouse and other antibody-generating mice. In addition, each of the cross-licenses granted under the collaboration and license agreement are subject to certain license, milestone and royalty payments by each party to the other.

Through March 31, 2008, the Company has not made any milestone payments to Kirin. However, approximately \$2.8 million has been paid to Kirin as of March 31, 2008 representing a payment due Kirin as a result of the Company's collaboration with Pfizer. Based on products the Company is developing, which use or the Company believes may use Kirin technology and that (i) are currently in clinical trials, or (ii) the Company anticipates may enter clinical trials through the end of 2009, the Company may be required to make milestone payments to Kirin aggregating up to approximately \$8.5 million with respect to such products. The Company's 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;

## Edgar Filing: MEDAREX INC - Form 10-Q

- 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.

Whether the Company may be obligated to make milestone payments to Kirin in the future is subject to the success of its efforts with respect to products the Company or its partners are developing that utilize the Kirin technology and, accordingly, is inherently uncertain.

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

Unless terminated earlier, the collaboration and license agreement expires on December 31, 2014. The collaboration and license agreement can be terminated by either party in the event of a material breach by the other party if the breach is not cured during a specified cure period. In addition, either party may terminate any commercial license with respect to a specific biologic target granted to it by the other party under the agreement at any time.

***Other Contingent Arrangements***

The Company has entered into a number of other agreements that contain in-licenses of third-party technology (in addition to Kirin) which may be used together with the Company's own platform technologies for the generation, development and/or manufacture of its antibody products. In addition, the Company has entered into other third-party agreements that contain in-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 the Company's products currently under development trigger such milestone payments. Through March 31, 2008, the Company has made milestone payments under these agreements of approximately \$1.7 million. In addition, under the agreements the Company currently has in place (other than with Kirin), based on a total of 11 products the Company is developing for which milestones are potentially due and that (i) are now in clinical trials, or (ii) which the Company anticipates may enter clinical trials before the end of 2009, the Company may be obligated to make future milestone payments aggregating up to approximately \$63.9 million with respect to such products. In general, potential milestone payments for antibody product candidates 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 milestone payments per product include:

- submission of IND(s) or foreign equivalents;
- commencement of Phase 1, Phase 2 and/or Phase 3 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 the Company's products. Whether the Company will be obligated to make milestone or royalty payments in the future is subject to the success of its product development efforts and, accordingly, is inherently uncertain.

*Stock Option Grant Practices*

In conjunction with the review of the Company's stock option grant practices, the Company has also evaluated the related tax issues to determine if the Company may be subject to additional tax liability as a result of the matters under review. In addition, due to revision of measurement dates, certain stock options that were previously treated as incentive stock options may not actually qualify for such treatment and may be treated as non-statutory stock options. Accordingly, the Company may be subject to fines, penalties or both relating to the tax treatment of such stock options. While the Company believes that its accrual for additional tax liabilities associated with the matters under review is appropriate under the circumstances, it is possible that additional liabilities exist and the amount of such additional liabilities could be material.

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

**8. Comprehensive Income (Loss)**

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

	<b>Three Months Ended March 31</b>	
	<b>2008</b>	<b>2007</b>
Net income	\$ 103,312	\$ 110,265
Unrealized loss on securities	(18,612)	(49,422)
Unrealized gain (loss) on foreign exchange	(2,572)	85
Total comprehensive income	\$ 82,128	\$ 60,928

**9. Segment Information**

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

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

	<b>Three Months Ended March 31</b>	
<b>Customer</b>	<b>2008</b>	<b>2007</b>
Bristol-Myers Squibb	36%	41%
Pfizer	24%	21%

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

*Certain statements made in this Quarterly Report on Form 10-Q are forward-looking statements that are subject to risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include information concerning our future financial performance, business strategy, plans, goals and objectives. Statements preceded by, followed by or that otherwise include the words believes, expects, anticipates, intends, estimates, plans, forecasts, is likely to, projected and similar expressions or future conditional verbs such as should, would, may, and could are generally forward-looking in nature and not historical facts. You should not place undue reliance on any such forward-looking statements as such statements speak only as of the date on which they are made, and we might not update them to reflect changes that occur after the date they are made.*

**Overview**

We are a biopharmaceutical company focused on the discovery, development and commercialization of fully human antibody-based therapeutic products. We believe that our UltiMAB<sup>®</sup> technology platform 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.

Medarex is committed to building value by developing a diverse pipeline of antibody products to address major unmet healthcare needs in the world. Currently, over 40 antibody product candidates generated from our UltiMAB<sup>®</sup> technology are in human clinical trials, or have had regulatory applications submitted for such trials(1). Seven of the most advanced product candidates in which Medarex has an economic interest through co-promotion/profit sharing rights, royalties and/or equity ownership are in Phase 3 clinical trials or are the subject of regulatory applications for marketing authorization. These late-stage product candidates were generated through the use of our UltiMAB<sup>®</sup> technology.

In addition to the antibody product candidates currently in Phase 3 trials, multiple product candidates in Phase 2, Phase 1 and preclinical testing are being developed either by Medarex alone or by Medarex jointly with our partners, or separately by our partners. These partners include Amgen, Inc., Bristol-Myers Squibb Company, Centocor, Inc., Eli Lilly and Company, Genmab A/S, ImClone Systems Incorporated, MedImmune, Inc., and Novartis Pharma AG. We believe that through the broad use of our UltiMAB<sup>®</sup> technology, we are leveraging our efforts and our partners' efforts to create, develop and potentially commercialize innovative treatments for a wide range of diseases.

In addition to our UltiMAB<sup>®</sup> technology, we have considerable experience in preclinical and clinical development as well as in manufacturing antibodies for clinical trials. Our existing manufacturing facility in Annandale, New Jersey currently has the capacity to undertake multiple antibody projects concurrently for clinical development purposes, meeting our near-term production demands. We have assembled a team of experienced scientific, production, clinical and regulatory personnel to facilitate the discovery and development of antibody-based products for us and for certain of our partners.

A portion of our revenue is derived from licensing our fully human antibody technology to pharmaceutical and biotechnology companies. The terms of these license agreements typically include potential license fees and a series of potential milestone payments commencing upon the initiation of clinical trials and continuing through commercialization. These payments may total \$7 million to \$10 million per product if the antibody

---

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



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 to, and, in some cases, the manufacturing of antibodies for, our partners, as well as from government grants.

In April 2008, Pfizer, Inc., or Pfizer, announced the discontinuation of a Phase 3 clinical trial of tremelimumab (CP-675,206) in patients with advanced melanoma. According to Pfizer, additional studies of tremelimumab, alone and in combination with other therapies, are ongoing in patients with several types of cancer. We have a license agreement with Pfizer which provides for double-digit royalties on sales of this product, should commercialization occur.

In April 2008, Medarex and one of its partners, Bristol-Myers Squibb Company, announced that, after meeting with the FDA, the companies would delay the Biologics License Application (BLA) submission for ipilimumab, an investigational immunotherapy for patients with advanced metastatic melanoma, which FDA filing was previously expected to occur in 2008. The FDA requested additional overall survival (OS) data to further demonstrate the benefit of ipilimumab and the companies are working to develop the deadlines for the studies from which such data may be obtained.

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 March 31, 2008, we had an accumulated deficit of approximately \$887.4 million. Over the next several years, we expect to incur substantial expenses as we continue to identify, develop and manufacture our potential products, invest in research, move forward with our product development and prepare to commercialize our product(s). 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 potential 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 products progress towards commercialization. In the absence of substantial revenues from new corporate collaborations or other sources, we will incur substantial operating losses and may be required to raise additional funds through debt or equity financings or sales of stock of partners in which we have an equity ownership 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 reported as deferred revenue until they are recognizable as revenue. We follow the following principles in recognizing revenue:

- 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 on a straight-line basis 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, when collectibility of such milestone payment is assured and we have no future performance obligations relating to that event. 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 1, 2 or 3 clinical trials, submission of a Biologic License Application, or BLA, and regulatory approval of a product. Milestone payments are substantially at risk at the inception of an agreement.
- 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 transactions 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.
- We sell antibodies primarily to partners in the United States and overseas. Revenue from these sales is recognized when the antibodies are shipped and we have no further obligations related to the development of the antibodies.



- 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 (other than AVANT and Genmab) represented approximately 1.4% and 0.8% of total marketable securities as of March 31, 2008 and December 31, 2007.

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 fair value 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 a separate line item in our consolidated balance sheet entitled Investments in, and advances to, other partners and were approximately \$6.0 million as of March 31, 2008. 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, 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 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.

**Stock-Based Compensation Expense**

Prior to January 1, 2006, we accounted for our 2005 Equity Incentive Plan, or the Plan, as amended, under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB No. 25 and related Interpretations, as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*, or Statement No. 123. Compensation expense was recognized in the consolidated statement of operations for all stock option grants under the Plan that had an exercise price which was less than the fair market value of the underlying common stock on the grant date. However, no compensation expense was recorded in the financial statements for all stock options grants with an exercise price equal to the fair market value of the underlying common stock on the date of grant.

Effective January 1, 2006, we adopted the fair value recognition provisions of FASB Statement No. 123(R), *Share-Based Payment*, or Statement No. 123(R), using the modified prospective transition method. Under the modified prospective transition method, compensation expense is recognized in the financial statements on a prospective basis for (i) all share based payments granted prior to, but not vested as of January 1, 2006, based upon the grant date fair value estimated in accordance with the original provisions of Statement No. 123, and (ii) share based payments granted on or subsequent to January 1, 2006, based upon the grant date fair value estimated in accordance with the provisions of Statement No. 123(R). The grant date fair value of awards expected to vest is expensed on a straight line basis over the vesting periods of the related awards. Under the modified prospective transition method, results for prior periods are not restated.

The fair value of each option grant is estimated using the Black-Scholes option pricing method. The fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period (generally 4 years). Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. In order to estimate the grant date fair value, option pricing models require the use of estimates and assumptions as to (i) the expected term of the option, (ii) the expected volatility of the price of the underlying stock, (iii) the risk free interest rate for the expected term of the option and (iv) pre-vesting forfeiture rates. The expected term of the option is based upon the contractual term, taking into account expected employee exercise and expected post-vesting termination behavior. The expected volatility of the price of the underlying stock is based on the historical volatility of our common stock. The risk free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected life assumed on the date of grant. Pre-vesting forfeiture rates are estimated based on past voluntary termination behavior, as well as an analysis of actual option forfeitures. The following table sets forth the assumptions used to calculate the fair value of options granted for the three month periods ended March 31, 2008 and 2007:

	<b>Three Months Ended March 31</b>	
	<b>2008</b>	<b>2007</b>
Expected dividend yield	0%	0%
Expected stock price volatility	81.5%	82.2%
Risk free interest rate	2.57%	4.55%
Expected life of options (years)	6.4	6.0

Our results of operations for the three month periods ended March 31, 2008 and 2007 include incremental share based compensation expense of approximately \$5.3 million and \$3.9 million, respectively. As of March 31, 2008, the total unrecognized compensation cost related to non-vested stock options was approximately \$46.0 million. This cost is expected to be recognized over a weighted average period of 2.8 years.

*However, any significant awards granted during the remainder of the year, required changes in the estimated forfeiture rates, or significant changes in the market price of our stock could have an impact on this estimate.*





*Valuation of Long-Lived and Intangible Assets*

We assess the impairment of long-lived assets and identifiable intangible 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 long-lived assets or of intangible 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.

*Loss Contingencies and Litigation Reserves*

We assess potential losses in relation to legal proceedings and other pending or threatened legal or tax matters based upon the application of Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies*. If a loss is considered probable and the amount can be reasonably estimated, we recognize an expense for the estimated loss. If a loss is considered possible and the amount can be reasonably estimated, we disclose such loss if material. Litigation by its nature is uncertain and the determination of whether any particular case involves a probable loss or the amount thereof requires the exercise of considerable judgment, which is applied as of a certain date. Required reserves and estimates may change in the future due to new matters, developments in existing matters or if we determine to change our strategy with respect to any particular matter.

**Results of Operations**

*Three months ended March 31, 2008 and 2007*

*Contract and License Revenues*

Contract and license revenues totaled \$7.1 million and \$5.9 million for the three month periods ended March 31, 2008 and 2007, respectively, an increase of \$1.2 million, or 20%. The increase relates primarily to increased research licenses granted in 2008 as compared to 2007. 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 \$0.9 million and \$1.1 million for the three month periods ended March 31, 2008 and 2007, respectively, a decrease of \$0.2 million, or 19%.

**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. Reimbursement of development costs totaled \$4.0 million and \$4.5 million for the three month periods ended March 31, 2008 and 2007, respectively, a decrease of \$0.5 million, or 11% and related primarily to the development of ipilimumab with Bristol-Myers Squibb Company or BMS.

**Research and Development Expenses**

Research and development expenses for our products in development were \$49.3 million and \$47.0 million for the three month periods ended March 31, 2008 and 2007, respectively, an increase of \$2.3 million, or 5%. Historically, 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 track 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 the HuMAb-Mouse<sup>®</sup> and KM-Mouse<sup>®</sup>, 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 (including manufacturing). Such product development costs also include personnel costs, facilities (including depreciation), supply expense related to antibody manufacturing and clinical trial expenses.

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

	Three Months Ended	
	March 31,	
	2008	2007
Research	\$ 13,842	\$ 14,996
Product Development	35,450	32,026
Total	\$ 49,292	\$ 47,022

**Research Costs**

Research costs for the three month period ended March 31, 2008 decreased by \$1.2 million, or 8% as compared to the three month period ended March 31, 2007. The decrease in research costs primarily relates to the following:

## Edgar Filing: MEDAREX INC - Form 10-Q

- License and technology access fees for the three month period ended March 31, 2008 were \$0.8 million, a decrease of \$0.5 million, or 37%, as compared to the three month period ended March 31, 2007. Increases and decreases in license and technology access fees are primarily the result of the timing of the payments due under such agreements. These costs represent fees paid to certain partners and research

organizations in connection with certain of our collaboration and license agreements. Included in the 2007 costs are payments to certain companies and research and academic institutions and other entities for licenses to certain technologies for which no comparable payments were made in 2008.

**Product Development Costs**

Product development costs for the three month period ended March 31, 2008 increased by \$3.4 million, or 11% as compared to the three month period ended March 31, 2007. The increase in product development costs primarily relates to the following:

- Outside laboratory costs for the three month period ended March 31, 2008 were \$2.7 million, an increase of \$1.8 million, or 189%, as compared to the three month period ended March 31, 2007. This increase primarily reflects the cost of toxicology studies related to our antibody drug conjugate projects. We expect outside laboratory costs to continue to increase as we continue to increase our research activities.
- Contract manufacturing and outside labor costs for the three month period ended March 31, 2008 were \$2.4 million, an increase of \$1.4 million, or 142%, as compared to the three month period ended March 31, 2007. This increase in third party contract manufacturing costs primarily represents production and packaging expenses related to our antibody drug conjugate product candidates. The increase in outside labor costs primarily represents costs incurred related to the anticipated filing of a Biologics License Application or BLA for ipilimumab.
- Clinical research fees for the three month period ended March 31, 2008 were \$6.0 million, an increase of \$1.5 million, or 33%, as compared to the three month period ended March 31, 2007. This increase resulted primarily from increased clinical trial activity related to MDX-1100 and the initiation of Phase 1 clinical trials for MDX-1342. 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.

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. 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 1	1-2 Years
Phase 2	1-2 Years
Phase 3	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:

Edgar Filing: MEDAREX INC - Form 10-Q

- the length of time required to recruit qualified patients for clinical trials;
- the duration of patient dosing and follow-up in light of trial results;

- the number of clinical sites required for trials; and
- the number of patients that ultimately participate.

We continue to explore new collaborative arrangements that may affect future spending for research and development. As part of our partnering strategy, a significant portion of the research and development expenses incurred in connection with products using our technology is expected to be borne by our partners. We believe this allows us to participate in the research and development of substantially more potential product candidates than we could develop on our own if we bore the entire cost of development. Products using our technology are currently in various stages of development from preclinical to Phase 3. 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 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 \$12.4 million and \$11.3 million for the three month periods ended March 31, 2008 and 2007, respectively, an increase of \$1.1 million, or 10%. The increase is primarily attributable to approximately \$1.9 million in personnel costs and approximately \$1.9 million in non-cash stock based compensation expense offset in part by approximately \$2.5 million in lower legal and consulting fees.

#### ***Equity in Net Loss of Affiliate***

Equity in net loss of affiliate for the three month period ended March 31, 2008 of \$1.8 million represents our share of AVANT's net loss for the period from March 7, 2008 through March 31, 2008. Beginning on March 7, 2008 we began to account for our investment in AVANT under the equity method of accounting in accordance with APB No. 18, *The Equity Method of Accounting for Investments in Common Stock* (see Note 2 to the consolidated financial statements for further information). The recognition of our share of AVANT's net losses reduces the carrying value, or basis, of our investment in AVANT.

#### ***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 \$4.5 million and \$4.8 million for the three month periods ended March 31, 2008 and 2007, respectively, a decrease of \$0.3 million, or 6%. The decrease primarily reflects lower interest rates earned on our investment portfolio.

#### ***Gain on Sale of Genmab Stock***

In February 2008, we completed the sale of 2.5 million shares of Genmab through a block trade. We received net proceeds of approximately \$151.8 million from such block trade resulting in a realized gain of approximately \$151.8 million as our cost basis for these shares was zero. As a result of this transaction, our ownership percentage in Genmab was reduced to approximately 5.1%.



## Edgar Filing: MEDAREX INC - Form 10-Q

In February 2007, we received approximately \$152.1 million in net proceeds from the sale of approximately 2.6 million shares of Genmab stock resulting in a realized gain of approximately \$152.1 million as our cost basis for these shares was zero. The sale of the approximately 2.6 million shares of Genmab shares reduced our equity ownership in Genmab to approximately 10.8%.

### *Interest Expense*

Interest expense for the three month periods ended March 31, 2008 and 2007 relates primarily to interest and amortization of issuance costs on our 2.25% Convertible Senior Notes issued in May 2004, or the 2.25% notes. Interest expense was \$1.5 million and \$1.5 million for the three month periods ended March 31, 2008 and 2007, respectively.

### *Minority Interest Celldex*

Minority interest in loss of Celldex was \$0 and \$1.7 million for the three month periods ended March 31, 2008 and 2007, respectively. Minority interest in loss of Celldex for the three month period ended March 31, 2007 represents 40% of Celldex's net loss for such period. Celldex's results of operations for the three month period ended March 31, 2007 have been consolidated for reporting purposes and the \$1.7 million (the portion of Celldex's net loss not attributable to us) is recorded as a reduction of our expenses.

During October 2007, the minority interest in the equity of Celldex was reduced to zero and accordingly, we (as the majority shareholder) are required to record 100% of Celldex's net losses. We recorded 100% of Celldex's net loss for the period from January 1, 2008 through March 6, 2008. As a result of Celldex's merger with AVANT, beginning March 7, 2008 we began to account for our investment in AVANT under the equity method of accounting (see Note 2 to the consolidated financial statements for further information).

### **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, milestone payments and sales of our marketable securities (such as Genmab). We expect to continue to fund our cash requirements from these sources in the future.

At March 31, 2008 and 2007, we had \$464.5 million and \$457.0 million, respectively, in cash, cash equivalents and marketable securities (other than Genmab). Approximately \$11.3 million of cash and cash equivalents included in the March 31, 2007 balance sheet relates to Celldex and is consolidated for accounting purposes. We primarily invest our cash equivalents and marketable securities in highly liquid, interest-bearing, investment grade and government securities to preserve principal. In addition, as of March 31, 2008, the fair value of our investment in Genmab, which is classified as marketable securities, was approximately \$115.6 million.

In February 2008, we completed the sale of 2,500,000 shares of Genmab through a block trade. We received net proceeds of approximately \$151.8 million from such block trade. As a result of this transaction, our ownership percentage in Genmab was reduced to approximately 5.1%.



***Cash Used in Operating Activities***

Cash used in operating activities was \$45.4 million and \$39.2 million for the three month periods ended March 31, 2008 and 2007, respectively. This reflects an increase of \$6.2 million in 2008 as compared to the same period in 2007 and is primarily the result of increased research and development expenses as described in Results of Operations.

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

***Cash Provided by Investing Activities***

Net cash provided by investing activities was \$156.7 million and \$72.7 million for the three month periods ended March 31, 2008 and 2007, respectively. The increase in cash provided by investing activities was \$84.0 million and was primarily the result of the following factors:

- Proceeds from the sale of Genmab stock were \$151.8 million and \$152.1 million for the three month periods ended March 31, 2008 and 2007, respectively.
- Purchases of marketable securities totaled \$35.9 million and \$115.1 million for the three month periods ended March 31, 2008 and 2007, respectively. The 2008 and 2007 purchases were made with a portion of the net proceeds received from the respective sales of our Genmab stock.
- Sales and maturities of marketable securities were \$42.0 million and \$37.5 million for the three month periods ended March 31, 2008 and 2007, respectively. Proceeds from sales of marketable securities in 2008 and 2007 were primarily used to fund operations and capital expenditures.

***Cash Provided by Financing Activities***

Cash provided by financing activities was \$1.0 million and \$3.6 million for the three month periods ended March 31, 2008 and 2007, respectively. Cash provided by financing activities for the three month periods ended March 31, 2008 and 2007 primarily represents cash

received from the exercise of stock options.

*Other Liquidity Matters*

**BMS Collaboration**

In January 2005, we entered into a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. 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 products 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 ipilimumab, a fully human antibody product candidate developed using our UltiMAb® technology. Ipilimumab is currently under investigation for the treatment of a broad range of cancers.

As part of the collaboration, BMS is 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 products 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 have the option to co-promote any product in the U.S. If we exercise a co-promotion option with respect to a product for use in the first cancer indication for which an initial regulatory approval filing is accepted by the FDA, we will have the right and obligation to co-promote such product for use in all cancer indications, even if such indications are the subject of additional filings or approvals, and even if we opted-out of the development of any such indication. Even if we elect to co-promote a product for cancer indications, however, we would need to exercise a separate option to co-promote that product with respect to any indication other than cancer. If we do not exercise our co-promotion option with respect to a product for use in the first cancer indication for which an initial regulatory approval filing is accepted by the FDA, then we will not have the right or obligation to co-promote such product for any cancer indications, unless the filing for that first cancer indication is not approved by FDA.

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. In addition, if we exercise our co-promotion option with respect to ipilimumab for the metastatic melanoma indication, and regulatory approval is obtained, we would receive 45% of any profits from commercial sales of such product in the U.S. In the event we choose not to exercise our co-promotion rights with respect to a product, BMS will have exclusive commercial rights in the U.S. and will pay us royalties on commercial sales. Regardless of whether or not we exercise our co-promotion option outside the U.S., BMS will have exclusive commercial rights for products and will pay us royalties on commercial sales.

As part of the collaboration, BMS made a cash payment to us on January 21, 2005 of \$25.0 million and also purchased 2,879,223 shares of our common stock at a purchase price equal to \$8.6829 per share for an aggregate purchase price of \$25.0 million.

### **Convertible Senior Notes**

In May 2004, we sold \$150.0 million in aggregate principal amount of our 2.25% notes to qualified institutional investors. The 2.25% notes are initially convertible into shares of our common stock at the rate of 72.9129 shares per each \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$13.72 per share, subject to anti-dilution adjustments. Interest is payable on May 15 and November 15 of each year. The first interest payment was made on November 15, 2004.

The 2.25% notes mature on May 15, 2011 and are redeemable at our option on or after May 15, 2010. Holders of the 2.25% notes may require us to repurchase the notes if we undergo a change in control as defined in the indenture. We received net proceeds from the offering of the 2.25% notes of approximately \$145.2 million (after deducting the initial purchasers' discounts and offering expenses). The costs of issuance of the 2.25% notes of approximately \$4.8 million have been deferred and are being amortized over the term of the



2.25% notes. In May 2011, or earlier if we undergo a change in control, we may be required to use a significant portion of our cash to repay the remaining balance (\$150.0 million) of the 2.25% notes. If our cash is not sufficient to meet our obligations under the 2.25% notes, we would be required to seek additional financing.

***Financial Uncertainties Related to Potential Future Milestone Payments***

In 2002, we entered into a collaboration and license agreement with Kirin, which cross-licenses certain of each other's technologies for the development and commercialization of human antibody products. Under the collaboration and license agreement, we and Kirin developed the KM-Mouse<sup>®</sup>, a unique crossbred mouse that combines the traits of our HuMAb-Mouse<sup>®</sup> with Kirin's TC Mouse and exchanged cross-licenses with respect to the KM-Mouse<sup>®</sup> and other antibody-generating mice. In addition, certain of the cross-licenses granted under the collaboration and license agreement are subject to license, milestone and royalty payments by one party to the other.

Through March 31, 2008, we have not made any milestone payments to Kirin although approximately \$2.8 million has been paid to Kirin as of March 31, 2008 representing a payment due Kirin as a result of our collaboration with Pfizer. Based on 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 2009, we may be required to make milestone payments to Kirin aggregating up to approximately \$8.5 million with respect to such products. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

- whether or not a decision is made to request a license from Kirin;
- the type of license requested (research or commercial);
- the success and timing of development efforts and clinical trials of product candidates covered by any such licenses;
- the type of product developed, (payment obligations differ depending on whether a product is an *ex vivo* therapeutic, *in vivo* therapeutic, research reagent or diagnostic); and
- other financial provisions of the Kirin agreement that provide for variations in fee levels and netting of certain payments over specified periods of time that may impact the total amount potentially payable to Kirin for any particular license fee or milestone payment.

We have also entered into a number of other agreements that contain licenses of third-party technology which may be used together with our own platform technologies for the generation, development and/or manufacture of our antibody products. In addition, we have entered into other third-party agreements that contain licenses associated with antibody products that target specific antigens. Many of these agreements contain milestone payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of our products currently under development trigger such milestone payments. Through March 31, 2008, we have made milestone payments of approximately \$1.7 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of 11 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 2009, we may be obligated to make future milestone payments aggregating up to approximately \$63.9 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 1, Phase 2 and/or Phase 3 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 year 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, sales of stock of partners in which we have an equity ownership, 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 2007, the EITF reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company is currently evaluating the requirements of EITF 07-1; however it does not believe that its adoption will have a significant impact on its consolidated financial statements.

Edgar Filing: MEDAREX INC - Form 10-Q

In December 2007, the FASB issued SFAS No. 141 (R), *Business Combinations* (Statement No. 141 (R)), which replaces SFAS No. 141, *Business Combinations*, and requires an acquirer to recognize the assets

acquired, the liabilities assumed and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. Statement No. 141 (R) also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. Statement No. 141 (R) makes various other amendments to authoritative literature intended to provide additional guidance or conform the guidance in that literature to that provided in Statement No. 141 (R). Statement No. 141 (R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company does not expect that the adoption of Statement No. 141 (R) will have a significant impact on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* (Statement No. 160), which amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to improve the relevance, comparability and transparency of the financial information that a reporting entity provides in its consolidated financial statements. Statement No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries not held by the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent's equity. Statement No. 160 also requires the amount of consolidated net income attributable to the parent and to the non-controlling interest to be clearly identified and presented on the face of the consolidated statement of operations. Changes in a parent's ownership interest while the parent retains its controlling financial interest must be accounted for consistently, and when a subsidiary is deconsolidated, any retained non-controlling equity investment in the former subsidiary must be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any non-controlling equity investment. Statement No. 160 also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. Statement No. 160 applies prospectively to all entities that prepare consolidated financial statements and applies prospectively for all fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The Company is currently evaluating the requirements of Statement No. 160; however it does not believe that its adoption will have a significant impact on its consolidated financial statements.

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

We do not use derivative financial instruments in our 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 have exposure to market risks associated with changes in interest rates, as we have no variable interest rate debt outstanding. We do not believe we have any material exposure to market risks associated with interest rates, however, we may experience reinvestment risk as fixed income securities mature and are reinvested in securities bearing lower interest rates.

The recent and precipitous decline in the market value of certain securities backed by residential mortgage loans has led to a large liquidity crisis affecting the broader U.S. housing market, the financial services industry and global financial markets. Investors holding many of these and related securities have experienced substantial decreases in asset valuations and uncertain secondary market liquidity. Furthermore, credit rating authorities have, in many cases, been slow to respond to the rapid changes in the underlying value of certain securities and pervasive market illiquidity, regarding these securities.

As a result, this credit crisis may have a potential impact on the determination of the fair value of financial instruments or possibly require impairments in the future should the value of certain investments

suffer a decline in value which is determined to be other than temporary. We currently do not believe that any change in the market value of fixed income investments in our portfolio to be material or warrant a determination that there was any other than temporary impairment.

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

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

*Evaluation of Disclosure Controls and Procedures:* Our principal executive officer and principal financial officer reviewed and evaluated our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective in ensuring that all material information required to be included in this Quarterly Report on Form 10-Q has been made known to them in a timely fashion.

*Changes in Internal Controls Over Financial Reporting:* Such evaluation did not identify any significant changes in our internal controls over financial reporting that occurred during the quarter ended March 31, 2008 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

*Limitations on the effectiveness of controls:* 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. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected.

## Part II Other Information

### Item 1. Legal Proceedings

The SEC is conducting an informal inquiry into our historical stock option granting practices and related accounting and disclosures. In addition, we have received subpoenas from the U.S. Attorney's Office, District of New Jersey, relating to the same matters. At the conclusion of this inquiry and investigation, we could be subject to criminal or civil charges and significant fines or penalties.

In June 2006, two derivative actions were filed in New Jersey state court by shareholders purporting to act on behalf of Medarex, naming Medarex as a nominal defendant and certain current and former directors as defendants. The state actions were consolidated in August 2006, and an amended consolidated complaint was filed in October 2007. In November 2006 and January 2007, three additional derivative complaints were filed in the United States District Court for the District of New Jersey, containing nearly identical factual allegations concerning Medarex's historical stock option granting practices. The federal actions were consolidated in April 2007, and an amended consolidated complaint was filed in June 2007. The complaints allege, among other things, that certain of Medarex's officers and directors breached their fiduciary duties to the Company and violated federal securities laws in connection with public statements made in SEC filings relating to the Company's historical stock option granting practices and related accounting. The complaints seek unspecified damages and equitable relief. All of the defendants moved to dismiss the federal action in October 2007.

In addition to the proceedings described above, 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 ordinary course legal proceedings, individually or in the aggregate, will have a material adverse effect on our operations or financial condition.

### Item 1A. Risk Factors

**We have marked with an asterisk (\*) those risk factors that reflect substantive changes from the risk factors included in our Form 10-K filed on February 27, 2008 with the SEC for the year ended December 31, 2007.**

Additional factors that might affect future results include the following:

#### **Risks Related to Our Business and Industry**

**Successful development of our product candidates is uncertain.**



## Edgar Filing: MEDAREX INC - Form 10-Q

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 or been commercialized. Product candidates employing our human antibody technology may not advance beyond clinical development and may not demonstrate clinical safety and effectiveness sufficient to obtain marketing authorization.

Our development of current and future product candidates is subject to the risks of failure and delay inherent in the development of new pharmaceutical products and products based on new technologies. These risks include, but are not limited to:

- delays in product development, clinical testing or manufacturing;
- slower than expected patient enrollment;

- unplanned expenditures in product development, clinical testing or manufacturing;
- failure in clinical trials;
- failure to receive or delay in receipt of 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;
- failure to receive adequate coverage and reimbursement for our products from health care payors;
- changes in legal and regulatory requirements; and
- failure to achieve market acceptance.

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

**Our revenue and profit potential are unproven. No revenues have been generated from the commercial sale of our products and our products may not generate commercial revenues in the future.**

Because we and our partners have not begun commercial sales of our products, our revenue and profit potential are unproven, which 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. 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 a rapidly evolving biopharmaceutical industry.

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





## Edgar Filing: MEDAREX INC - Form 10-Q

We have incurred large operating losses, and we anticipate that these losses will continue for the foreseeable future. In particular, as of March 31, 2008, we had an accumulated deficit of approximately \$887.4 million. Our net loss was \$27.1 million for the year ended December 31, 2007. Our net loss for the year ended December 31, 2007 included a realized gain of approximately \$152.1 from the sale of a portion of our Genmab stock. Excluding this realized gain, our net loss for the year ended December 31, 2007 would have been \$179.2 million. Although we recorded net income of \$103.3 million for the three month period ended March 31, 2008 (which was the result of the sale of a portion of our Genmab stock) our operating loss for the period was \$49.7 million. Our losses have resulted principally from:

- research and development costs relating to the development of our technology and antibody product candidates;
- costs associated with the establishment of our 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;
- manufacturing clinical supplies of our antibody product candidates;
- establishing new collaborations; and
- new technologies.

In addition, we may be obligated to make milestone payments with respect to certain of our product candidates 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.**



## Edgar Filing: MEDAREX INC - Form 10-Q

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;
- delays in manufacturing;
- 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 are subject to an informal inquiry by the SEC and a grand jury investigation by the United States Attorney's Office for the District of New Jersey, relating to our stock option granting practices, and such governmental inquiry and investigation may result in charges filed against us and in fines or penalties.**

The SEC is conducting an informal inquiry into our historical stock option granting practices and related accounting and disclosures. In addition, the United States Attorney's Office for the District of New Jersey is conducting a grand jury investigation relating to the same matters. We understand that the governmental inquiry and investigation relate to the same subject matter underlying the investigation (the Investigation) conducted by a special investigation committee of our independent directors relating to our stock option grant practices from 1996 through June 30, 2006. Based upon the information obtained in the Investigation, through

July 2002, we had a practice, in many instances, of selecting dates for our stock option grants and restricted stock grants as of the date when the stock price was the lowest during the month of grant, without disclosing this practice in our public filings and without properly measuring the compensation expense on a date that the terms of the equity awards were finalized. Subsequent to July 2002, while this practice of selecting dates ceased by us in response to new legal and regulatory reporting requirements, there were two annual equity grants for rank and file employees for which the measurement dates differed from the grant dates recorded in our books and records, which the Investigation revealed were primarily a result of administrative delays, with no apparent intent to achieve favorable exercise prices. Based on the results of the Investigation, we restated our financial statements for the quarter ended March 31, 2006 and the years ended December 31, 2005, 2004 and 2003, respectively.

Criminal or civil charges could be filed against us and we could be required to pay significant fines or penalties in connection with either or both of the governmental inquiry and investigation or other governmental investigations. We have incurred, and continue to incur, substantial costs related to the governmental inquiry and investigation and they continue to cause a diversion of our management's time and attention which could have a material adverse effect on our financial condition and results of operations. Any criminal or civil charges by the SEC or the U.S. Attorney's Office or any fines or penalties imposed by either the SEC or the U.S. Attorney's Office or other governmental agency could materially harm our business, results of operations, financial position and cash flows.

**We have civil litigation pending that relates to our stock option granting practices, and we cannot predict the ultimate outcome of this litigation.**

In June 2006, two derivative actions were filed in New Jersey state court by shareholders purporting to act on behalf of Medarex, naming Medarex as a nominal defendant and certain current and former directors as defendants. The state actions were consolidated in August 2006, and an amended consolidated complaint was filed in October 2007. In November 2006 and January 2007, three additional derivative complaints were filed in the United States District Court for the District of New Jersey, containing nearly identical factual allegations concerning Medarex's historical stock option granting practices. The federal actions were consolidated in April 2007, and an amended consolidated complaint was filed in June 2007. The complaints allege, among other things, that certain of Medarex's officers and directors breached their fiduciary duties to the Company and violated federal securities laws in connection with public statements made in SEC filings relating to the Company's historical stock option granting practices and related accounting. The complaints seek unspecified damages and equitable relief. All of the defendants moved to dismiss the federal action in October 2007. We could be required to pay significant legal fees and damages in connection with this litigation.

**We are subject to the risks of additional lawsuits and regulatory actions in connection with our historical stock option granting practices, the resulting restatements, and the remedial measures we have taken.**

In addition to the possibilities that there may be additional governmental actions and shareholder lawsuits against us, we may be sued or taken to arbitration by current or former officers or employees in connection with their stock options or other matters. These governmental actions, lawsuits and arbitrations may be time consuming and expensive, and cause further distraction from the operation of our business. The adverse resolution of any specific action could have a material adverse effect on our business, financial condition and results of operations.

**We are at risk for additional tax liabilities.**

In connection with the investigation of our historical stock option grant practices, we evaluated the related tax issues to determine if we may be subject to additional tax liabilities. Due to revision of measurement dates for certain stock option grants, certain stock options that were previously treated as incentive stock options may not actually qualify for such treatment and may be treated as non-statutory stock options. As a result, we may be subject to fines or penalties relating to the tax treatment of such stock options. It is possible that additional tax liabilities exist arising out of our past stock option granting practices, and the amount of such additional tax liabilities could be material.

**We are at risk of securities class action litigation.**

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. The risk is relevant for us because our market price has experienced a decline due, in part, to the announcement of top-line results for registrational trials of ipilimumab on December 10, 2007. If we faced such litigation, while we would vigorously contest, it could result in substantial costs and a diversion of management's attention and resources, which could materially harm our business.

**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 technology platforms and conducting preclinical testing and clinical trials. Our future capital requirements will depend on a number of factors, including, for 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 commercial scale manufacturing capabilities, conducting commercialization activities and arrangements and in-licensing products.

## Edgar Filing: MEDAREX INC - Form 10-Q

We believe our current 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% 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, sale of assets, 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. 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.

**We have investments in financial instruments which could potentially decrease in value as a result of the credit crisis.**

Due to recent market developments, including a series of rating agency downgrades of sub-prime U.S. mortgage-related assets and insurers of long-term debt, the value of sub-prime-related investments and certain tax-exempt long-term debt has declined. This recent and precipitous decline in the market value of securities backed by residential mortgage loans and long-term debt insured by these bond insurers has led to a liquidity crisis affecting the financial services industry specifically and the global financial markets generally. As a result, investors in many industry sectors have experienced substantial decreases in asset valuations and uncertain market liquidity for their investments.

The resulting credit crisis may have an impact on the fair value of certain of our investments and may require future impairments if the value of those investments suffers a decline which is determined to be other than temporary. At present, no material change in the market value of our fixed income investments has occurred, however, a future decline in value of such investments which is determined to be other than temporary may require us to record a material impairment of the fair value of those investments.



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

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 product candidates 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. We rely on third parties, including our partners, academic institutions and clinical research organizations to conduct, supervise or monitor many of our clinical trials. We have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

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 in accordance with 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, or for some studies due to the data safety monitoring committee charged with overseeing the study as a whole; 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 our product candidates. In a number of instances, we have terminated the development of certain product candidates in the early stages of human clinical testing due to a lack of effectiveness.

## Edgar Filing: MEDAREX INC - Form 10-Q

Generally, our clinical trials, including our melanoma trials for ipilimumab, are conducted in patients with serious or life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product candidate 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 product candidates. In trials of ipilimumab, the most commonly reported drug-specific adverse events are primarily immune-related, ranging from mild in most cases to severe in a very few number of instances, and are consistent with the mechanism of action of CTLA-4 blockade. These events are organ-specific, principally involving the gastrointestinal tract (diarrhea or colitis), the skin (severe rash or pruritis), the endocrine glands (reduced pituitary function) and the liver (increased liver enzymes). Other than a very small number of fatalities not directly related to disease progression or complications of the disease being treated, representing approximately

1% of over 2,000 patients treated in all previous trials of ipilimumab, which may or may not be attributable to our product candidates, the majority of adverse events resolved or improved with treatment and without further significant complications. From our collective experience in treating over 2,000 patients with ipilimumab, treatment guidelines have been established to ensure proper management and most of these adverse events are manageable and resolve following withdrawal of ipilimumab or appropriate medical therapy, such as corticosteroids. In addition, we and BMS are exploring potential biomarkers that may be predictive of clinical responses. We cannot assure you that additional safety issues will not arise with respect to our products in the future.

We have, at times, experienced slower than expected rates of patient recruitment in certain of our clinical trials. As a result, in certain instances, we may experience delays in our product development and clinical testing.

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 potential new drugs and biologics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and efficacy 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.

**Products employing our antibody technology may fail to gain market acceptance.**

Even if clinical trials demonstrate the safety and efficacy of product candidates developed by us or our partners using our technology and all regulatory approvals have been obtained, products 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 products employing our technology will depend on a number of factors, including, for example:

- establishment and demonstration of clinical efficacy 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 generally 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 will 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 government 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 to demonstrate the cost-effectiveness of our products. Such studies may require us to dedicate a significant amount of resources. Our product 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.

**The continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare may impair our future revenues and profitability.**

The pricing of our future products may be influenced in part by government controls and restrictions from private payors. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, measures have been put in place to attempt to reduce expenditures under the Medicare and Medicaid programs. In addition, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement more rigorous provisions relating to government payment levels. Private managed care organizations in the United States also seek to restrict the pharmaceutical products that doctors in those organizations can prescribe through the use of formularies, the lists of drugs which physicians are permitted to prescribe to patients in a managed care organization.

While we cannot predict whether the government will adopt any new legislative or regulatory proposals with respect to the pricing or reimbursement of medicines, the announcement or adoption of these proposals could have a material adverse effect on our business, results of operations, financial condition and cash flow. Managed care and other private payor exclusion of our pharmaceutical products from their formularies or demands for price concessions necessary to be included on formularies could also have a material adverse effect on our business, results of operations, financial condition and cash flow.

**Our manufacturing facilities may not continue to meet regulatory requirements and may 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 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 commercialization 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 with respect to ipilimumab and MDX-060. As part of our collaboration with BMS, we assigned to BMS the clinical supply agreement with respect to ipilimumab. Our partner BMS is responsible for securing commercial supply agreements for ipilimumab and is currently in negotiations with respect to such arrangements. BMS may not be able to successfully consummate such arrangements. We do not currently have the capability to manufacture our product candidates 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. Such manufacturers may encounter difficulties in production scale-up, including problems involving production yields, quality control and quality assurance and shortage of qualified personnel. Moreover, they may not perform as agreed or may not continue to manufacture our products for the time required by us to successfully market our products. These third parties may fail to deliver the required quantities of our products or product candidates on a timely basis and at commercially reasonable prices. 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, and provide periodic product listing information on the products manufactured at each registered facility. 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 or other regulatory authorities can impose regulatory sanctions including, among other

things, imposition of a shut down of manufacturing operations, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval.

**The development and commercialization of our lead product candidate, ipilimumab, is, in large part, dependent on the actions of BMS, which are outside of our control.**

We depend, in part, on our partners to support our business, including the development of product candidates 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, ipilimumab, to BMS for the treatment of all diseases. We have also granted to BMS a sub-license to MDX-1379 for use in combination with ipilimumab for the treatment of metastatic melanoma. The successful development and commercialization of ipilimumab 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 or to prioritize or devote sufficient resources to ipilimumab development and commercialization, or a change of control of BMS, may cause us to incur substantial additional costs in order to develop and commercialize ipilimumab, which could materially harm our business.

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

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 product candidates 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<sup>®</sup> 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 and may, instead, become one of our competitors. In April 2006, Abgenix and Amgen completed a merger that resulted in Amgen's ownership of Abgenix's Xenomouse<sup>®</sup> technology. As a result, Amgen may be less willing to continue its collaboration with us and may, through the use of the Xenomouse<sup>®</sup> technology, engage in direct competition with us in the area of generating fully human monoclonal antibodies for antibody-based therapeutics. 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 AVANT, we must include a portion of its income and losses in our financial statements.**

Due to the size of our equity interest in AVANT as a result of its merger with Celldex, we are currently (beginning March 7, 2008) required to account for our interest in AVANT under the equity method of accounting, which provides that we must include a portion of AVANT's income and losses equal to our percentage equity interest in AVANT in our consolidated financial statements. For the three month period ended March 31, 2008, our share of AVANT's net loss was approximately \$1.8 million.

**Our strategic equity investments in our partners 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 that 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. 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

## Edgar Filing: MEDAREX INC - Form 10-Q

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, 2006, we recorded an impairment charge of \$5.2 million on investments in partners whose securities are publicly traded. During the years ended December 31, 2007 and 2005, no impairment charges were recorded related to the value of our investments in publicly traded companies. 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. 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, 2007, 2006 and 2005, we recorded impairment charges of approximately \$2.1 million, \$0 and \$33.3 million, respectively, on our investments in privately-held companies. Approximately \$29.3 million of the 2005 impairment charge related to IDM Pharma prior to the share exchange with Epimmune, Inc., at which time IDM Pharma became a publicly-traded company. Future adverse changes in market conditions or adverse changes in operating results of these companies may also require an impairment charge in the future.

**Because competition for qualified personnel is intense, we may not be able to retain or recruit such qualified personnel, which could impact the research, development and commercialization of our products.**

For us to pursue product development 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 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 approval and during 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 product candidates 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 \$20.0 million per occurrence and \$20.0 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 product candidates in development. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

**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 competitors with similar technology to ours as well as distinctly different technologies. Second, the actual product candidates being developed by us or by our partners also face actual and potential competition. Developments by our competitors may render our human antibody technology or our products 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 product candidates or have successfully commercialized antibody products. Many of these companies are addressing the same disease indications as are 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. In the past, we competed directly with Abgenix, which merged with Amgen in April 2006, with respect to the generation of fully human antibodies from transgenic mice. Abgenix had offered potential partners the use of its XenoMouse<sup>®</sup> technology to generate fully human monoclonal antibodies. Regeneron has licensed its VelocImmune<sup>®</sup> monoclonal antibody generation technology to AstraZeneca, Astellas Pharma Inc. and Sanofi-aventis, potentially enabling such licensees to compete with us in the generation of therapeutic antibodies. Regeneron may also compete with us directly in the generation of therapeutic antibodies or may enter into additional licenses with other companies. AstraZeneca also has access to antibody generation technologies through its ownership of Cambridge Antibody Technology. In addition, we have entered into agreements with each of Kirin and Genmab, respectively, that grant these companies licenses to our proprietary transgenic mouse technology platform, enabling them to compete with us in offering antibody generation and development services in certain markets.

Xenerex and XTL have developed technologies 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 product candidates 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. XOMA and PDL BioPharma both offer technologies to convert mouse antibodies into antibodies closely resembling human antibodies. In addition, phage display technology is being used by companies, such as CAT, Dyax and MorphoSys to generate potentially therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, MedImmune (a subsidiary of AstraZeneca), Amgen, Biogen Idec, Novartis, Genentech, PDL BioPharma, Wyeth, BMS, Abbott Laboratories, Alexion Pharmaceuticals, Inc. and GlaxoSmithKline 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.

We have entered into license agreements with Pfizer, designed to give each party freedom to operate with respect to the development and commercialization of antibodies to CTLA-4. Among other things, these license agreements allow Pfizer to compete with us in such development and commercialization efforts, but Pfizer is obligated to make certain milestone and royalty payments to us based upon future sales of any Pfizer anti-CTLA-4 antibody product. Pfizer is developing tremelimumab, a fully human antibody generated by using transgenic mouse technology substantially similar to our HuMAb-Mouse<sup>®</sup> technology that targets the T-cell receptor CTLA-4. Although Pfizer announced the discontinuation of a Phase 3 clinical trial of tremelimumab



for metastatic melanoma in April 2008, it continues to conduct clinical trials of this product candidate in several types of cancer.

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

Accordingly, our competitors may obtain patent or regulatory 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 manufacturing, marketing and sales 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 in-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.

**Seeking orphan drug designation for eligible products is an uncertain process, and we may not receive any effective or competitive results from this competitive strategy.**

Our competitive strategy includes seeking orphan drug designation for eligible products (i.e., certain products for diseases with small patient populations). In the United States, the first drug with an orphan drug designation for a given disease to receive regulatory approval for such disease generally receives marketing exclusivity for the use of the drug for such disease for a period of seven years from approval. The orphan drug exclusivity bars others from obtaining approval for the same drug for the designated indication during the seven years, unless the

## Edgar Filing: MEDAREX INC - Form 10-Q

subsequent applicant can demonstrate that its product is clinically superior to the drug with exclusivity or the prior applicant is unable to provide adequate supply to meet medical need. Orphan drug exclusivity is also available in markets outside the United States on similar terms.

We have obtained orphan drug designation in the United States for ipilimumab and certain of our other product candidates in development, and therefore each is eligible for orphan drug exclusivity if approved first. The FDA's approach with respect to orphan drug status for antibody products is uncertain, particularly with respect to whether two antibody products against the same disease target would be considered to be the same for orphan drug purposes under current law and regulations. Furthermore, we are not aware of established FDA policies or precedent for how orphan drug exclusivity applies in circumstances where two or more compounds with orphan drug designations are approved for combination therapy. The FDA may not grant us exclusivity for ipilimumab, or may permit others to receive approval for differing combinations of similar compounds despite any orphan drug exclusivity we receive for different uses or for treating metastatic melanoma, depending on FDA's assessment of the chemical similarity of the other drugs to our products. Orphan drug exclusivity also does not prevent FDA from permitting others to market the same compound for different uses than the orphan use. We therefore may not receive any meaningful protection for ipilimumab or our other product candidates based on orphan drug exclusivity.

**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 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, and register our clinical trials in accordance with new legal requirements to register clinical trials on publicly available databases. We or our partners must obtain regulatory approval for each product candidate 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 medical 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, restrictions may be placed on our ability to market or distribute the product, or post-approval study or other requirements might be imposed, 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;
- limitations on previously approved marketing applications or licenses, or new post-approval requirements;
- 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 INDs with the FDA and to direct the regulatory approval process for product candidates 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.**

## Edgar Filing: MEDAREX INC - Form 10-Q

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our product candidates in the U.S. or in any foreign jurisdiction. We have only limited experience in filing and pursuing applications necessary to obtain regulatory approval. It is possible that none of our product candidates, including ipilimumab, will be approved for marketing. In April 2008, Medarex and one of its partners, Bristol-Myers Squibb Company, announced that, after meeting with the FDA, the companies would delay the BLA submission for the three registrational monotherapy trials for ipilimumab in metastatic melanoma (008, 022, 007), which FDA filing was previously expected to occur in 2008. The FDA requested additional overall survival (OS) data to further demonstrate the benefit of ipilimumab. Revised timelines are under development. Once submitted, the FDA may decide not to accept the BLA for filing and the FDA may never give its approval. We cannot guarantee that we will ever be able to produce commercially successful products.

**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 submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. New legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

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 cGMP requirements. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each 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. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. 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.

**New legal and regulatory requirements could make it more difficult for us to obtain approvals for our product candidates, and could limit or make more burdensome our ability to commercialize any approved products.**

Federal legislation known as the FDA Amendments Act of 2007 grants FDA extensive authority to impose post-approval clinical study and clinical trial requirements, require safety-related changes to product labeling, review advertising aimed at consumers, and require the adoption of risk management plans, referred to in the legislation as risk evaluation and mitigation strategies, or REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to healthcare professionals, and restrictions on distribution and use. For example, if the FDA makes the requisite findings, it might require that a new product be used only by physicians with certain specialized training, only in certain designated healthcare settings, or only in conjunction with special patient testing and monitoring. The legislation also includes requirements for providing the public information on ongoing clinical trials through a clinical trial registry and for disclosing clinical trial results to the public through a clinical trial database; renewed requirements for conducting trials to generate information on the use of products in pediatric patients; new requirements to pay the FDA a fee to obtain advisory review of certain consumer television advertisements; and new penalties, for example for false or misleading consumer advertisements. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements, and restrict sales and promotional activities. The FDA Amendments Act, and the additional proposals if enacted, may make it more

difficult or burdensome for us to obtain approval of our product candidates, any approvals we receive may be more restrictive or be subject to onerous post-approval requirements, our or our partners' ability to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

**If we are able to obtain approvals for our products, we could face 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 certain types of biological products. The proposals include proposals for legislation, and proposals for FDA to extend its existing authority to this area.

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 antibody products through an abbreviated approval mechanism, and without conducting full clinical studies of their own, it could materially harm 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.

**We are subject to federal, state, local and foreign laws and regulations, and complying with these may cause us to incur significant costs.**

We are subject to laws and regulations enforced by certain federal, state, local and foreign health and environmental authorities and other regulatory statutes including:

- the Occupational Safety and Health Act;
- the Environmental Protection Act;
- the Toxic Substances Control Act;
- the Federal Food, Drug and Cosmetic Act;
- the Resource Conservation and Recovery Act; and



- other current and potential federal, state, local or foreign laws and regulations.

In particular, with respect to environmental laws, our product development activities involve the use of hazardous materials, and we may incur significant costs as a result of the need to comply with these laws. Our research, development and manufacturing activities involve the controlled use of hazardous materials, chemicals, viruses and radioactive compounds. We are subject to federal, foreign, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste

products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts of terrorism, from these materials. In the event of an accident, we could be held liable for any damages that result, and any resulting liability could exceed our resources. We may also be required to incur significant costs to comply with environmental laws and regulations in the future.

### **Risks Related to Intellectual Property**

#### **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 or acquire 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. 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, if issued, may not be held enforceable. The products and product candidates currently being developed or considered for development are in the area of biotechnology, an area in which there are extensive patent filings. We rely on patent protection against use of our proprietary products and technologies by competitors. The patent position of biotechnology intellectual property generally is highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict with certainty the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents.

Patents, if issued, may be challenged, invalidated or circumvented. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire, or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. 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 which is not covered by an issued patent. 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 protect these secrets and know-how, in part, through confidentiality and proprietary information agreements.

## Edgar Filing: MEDAREX INC - Form 10-Q

We generally require our staff members, material consultants, scientific advisors and parties to collaboration and licensing agreement to execute confidentiality agreements upon the commencement of employment, the consulting relationship or the collaboration or licensing arrangement with us. 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.

**We do not have exclusive access to certain patents and therefore we may face increased competition from those entities that share access to these patents.**

Even though we own issued patents and pending applications and have received licenses pertaining to the HuMAb-Mouse<sup>®</sup> and the KM-Mouse<sup>®</sup> technologies, this does not mean that we and our licensees of the HuMAb-Mouse<sup>®</sup> and the KM-Mouse<sup>®</sup> 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 and applications covering the HuMAb-Mouse<sup>®</sup> and the KM-Mouse<sup>®</sup> technologies include patents and applications 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 the HuMAb-Mouse<sup>®</sup> or KM-Mouse<sup>®</sup> technology.

We do not have exclusive access to the patents underlying the HuMAb-Mouse<sup>®</sup>. 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 GenPharm 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 product candidates and business. These patents, patent applications, third party licenses and inventions form the basis of our HuMAb-Mouse<sup>®</sup> technology. Abgenix merged with Amgen in 2006. As a result, Amgen may have access to such patents, patent applications, third party licenses and inventions. Our business may suffer from the competition of these entities and their licensees and sublicensees.

We are not the exclusive owner of the technology underlying the KM-Mouse<sup>®</sup>. Our collaboration and license agreement with Kirin contains certain cross-licenses for certain of each other's technologies for the development and commercialization of human antibody products made using the HuMAb-Mouse<sup>®</sup>, the KM-Mouse<sup>®</sup> and certain other antibody-generating mice. Kirin has certain rights to distribute and use such mice throughout the world. Our business may be materially harmed as a consequence of competition from Kirin and its licensees and sublicensees or if the collaboration and license agreement were breached or terminated for any reason.

Moreover, other parties could have blocking patent rights to products made using the UltiMAB<sup>®</sup> technology, such as antibodies, and their production and uses, for instance because of a proprietary position covering the antibody or the antibody's target or the method of manufacturing or use of such antibody. For example, we are aware of certain U.S. and foreign patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets, and to the method of 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 antibody product candidates under development by us alone or with our collaborators.

**Third parties may allege our products or technologies 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.**

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 products or 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 or may be required to pay significant monetary damages or royalty rates to third parties. Such a result may materially harm our business, financial condition and results of operations.

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 that are covered by such intellectual property, which would materially harm our business.

With respect to third party patent rights, we are aware of a U.S. patent owned by Genentech, relating to the production of recombinant antibodies in host cells. The U.S. Patent and Trademark Office, or USPTO, has reexamined the patentability of this patent and has twice rejected the patentability of such claims. All of the claims were finally rejected, and although that finality has been withdrawn after Genentech filed a Request for Continued Examination, all claims remain rejected. Genentech has announced its intent to respond to the rejections and, if necessary, to appeal. Upon completion of any appeal that might take place, the rejection of the patentability of such claims could be reversed. The appeal processes could take several years to complete.

We currently produce our product candidates and our partners' product candidates using recombinant antibodies from host cells and may choose to produce additional product candidates in this manner. If any of our antibody product candidates are produced in the manner ultimately claimed in the Genentech patent, which claims survive the re-examination and any appeal processes, 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 (ipilimumab) 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 use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

In addition to this challenge to the validity of this Genentech patent through re-examination process at the USPTO, MedImmune, a licensee of the patent, has filed a complaint in Federal District Court alleging that the patent is invalid. MedImmune's standing to prosecute this complaint as a non-breaching licensee was challenged by Genentech, but a recent Supreme Court ruling on the matter has resulted in MedImmune's standing being upheld, and the case has been remanded for further consideration of the merits. As a result of this ruling, it may now be possible for licensees of our patents to challenge the validity of the patents that we have licensed to them.

In addition to Genentech's 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, including certain media preparations and their use for culturing CHO cells, and particular antibody formulations, any of which may be relevant to our current or future manufacturing techniques. If we determine that we need a license to these or other patents relating to methods of making antibodies and are unable to obtain licenses on commercially reasonable terms or at all, we may be restricted in our ability to use these methods to make antibodies or to import the antibodies into the United States.

If our antibody product candidates (or those antibody product candidates of our partners using our human antibody technology) or their commercial use or production are covered by any of the claims of the aforementioned patents or any other patents, or patents that may issue from the aforementioned patent



applications or any other 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 cannot assure you that our product candidates and/or actions in developing or selling human antibody product candidates will not infringe such patents. 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 product candidates. Our failure to obtain a license to any technology that we may require may materially harm our business, financial condition and results of operations.

### **Risks Related to Our Common Stock**

#### **Our stock price may be volatile.**

Historically, there has been significant volatility in the market prices of biotechnology companies' securities. During the two-year period ended March 31, 2008, the sale prices of our common stock ranged between \$7.70 and \$18.23. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- interim or final results of, or speculation about, clinical trials of and the regulatory filing schedule for our lead product candidate, ipilimumab;
- progress with clinical trials;
- fluctuations in our operating results;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- published reports by securities analysts;
- 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 product candidates or products;
- changes in our management;
- matters relating to the investigation of our past stock option grant practices; and
- general market conditions.



## Edgar Filing: MEDAREX INC - Form 10-Q

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these or other factors, including the sale or attempted sale of a large amount of our common stock into the market. Broad market fluctuations may also adversely affect the market price of our common stock.

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

As of April 30, 2008, we had 19,859,662 shares of common stock reserved for issuance pursuant to options and other stock based awards which had been granted under our equity incentive plans having a weighted average exercise price of \$10.12 per share and we had reserved 2,711,172 shares of common stock for issuance pursuant to future grants of options under our equity incentive 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.

As of April 30, 2008, we had reserved 516,688 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 Global 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 April 30, 2008, we had 10,936,935 shares of common stock reserved for 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.

**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 15, 2011. As of April 30, 2008, \$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 become 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 and New Jersey law 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, lead independent director, 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.**

**Item 6. Exhibits**

(a) Exhibits:

- 2.1 Certificate of Merger, dated June 15, 1989, including Plan of Merger, incorporated herein by reference to Exhibit 2.1 to Registrant's Registration Statement on Form S-1 (File No. 33-39956) filed April 12, 1991.
- 2.3 Amended and Restated Agreement and Plan of Reorganization among the Registrant, Medarex Acquisition Corp. and GenPharm International, Inc., dated as of May 5, 1997, together with Exhibits thereto, incorporated herein by reference to Exhibit 2.1 to Registrant's Current Report on Form 8-K filed June 17, 1997.
- 3.1 Restated Certificate of Incorporation of the Registrant, incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003.
- 3.2 Amended and Restated By-laws of the Registrant, incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed October 31, 2007.
- 4.1 Form of Specimen Common Stock Certificate, incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 33-39956) filed April 12, 1991.
- 4.2 Form of Rights Agreement (including Form of Rights Certificate), incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed May 25, 2001.
- 4.3 Amendment to Rights Agreement, dated November 6, 2007 between Registrant and Continental Stock Transfer & Trust Company, incorporated herein by reference to Registrant's Annual Report on Form 10-K filed February 27, 2008.
- 4.4 Indenture dated May 3, 2004 between the Registrant and Wilmington Trust Company, as trustee, incorporated herein by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K filed May 4, 2004.
- 4.5 First Supplemental Indenture dated October 4, 2006 among Registrant and Wilmington Trust Company, as trustee, incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed October 5, 2006.
- 10.1 Amendment No. 1 to Employment Agreement, effective as of January 1, 2008, between Christian S. Schade, Senior Vice President and Chief Financial Officer and Medarex, Inc, incorporated herein by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed January 24, 2008.
- 10.2 Amendment No. 1 to Employment Agreement, effective as of January 1, 2008, between Dr. Nils Lonberg, Senior Vice President and Scientific Director and Medarex, Inc, incorporated herein by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K filed January 24, 2008.
- 10.3 Amendment No. 1 to Employment Agreement, effective as of January 1, 2008, between Dr. Geoffrey M. Nichol, Senior Vice President, Product Development and Medarex, Inc, incorporated herein by reference to Exhibit 99.3 to the Registrant's Current Report on Form 8-K filed January 24, 2008.
- 10.4 Placing Agreement between Genpharm International, Inc. and Goldman Sachs International, dated January 28, 2008, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed February 1, 2008.

Edgar Filing: MEDAREX INC - Form 10-Q

- 10.5 Medarex, Inc. 2005 Equity Incentive Plan, as amended, incorporated herein by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K/A, filed November 2, 2007.
- 10.6 \* Form of Restricted Stock Unit Award Grant Notice, Restricted Stock Unit Award Agreement, Restricted Stock Unit Deferral Election Agreement and Restricted Stock Unit Subsequent Deferral Election under Registrant's 2005 Equity Incentive Plan, as amended.
- 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.
- 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.
- 32.1\* Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

---

Indicates management contract or compensatory plan.

\* Filed herewith.

Signatures

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

MEDAREX, INC.  
(Registrant)

Date: May 12, 2008

By: /s/

HOWARD H. PIEN  
**Howard H. Pien**  
**President and Chief**  
**Executive Officer**  
**(Principal Executive Officer)**

Date: May 12, 2008

By: /s/

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