

MEDAREX INC  
Form 10-Q  
November 02, 2007

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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## FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2007

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

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**MEDAREX, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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**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**

Indicate by check  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  whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer       Accelerated filer       Non-accelerated filer

Indicate by check  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 October 31, 2007
Common Stock, \$.01 par value	127,271,314

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MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

(Unaudited)

	September 30, 2007	December 31, 2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 33,725	\$ 34,511
Marketable securities	360,872	304,983
Marketable securities - Genmab		150,000
Prepaid expenses and other current assets	23,266	22,271
Total current assets	417,863	511,765
Property, buildings and equipment:		
Land	6,780	6,780
Buildings and leasehold improvements	86,677	85,123
Machinery and equipment	64,537	61,076
Furniture and fixtures	5,073	5,025
	163,067	158,004
Less accumulated depreciation and amortization	(84,330)	(73,663)
	78,737	84,341
Marketable securities - Genmab	296,957	344,382
Investments in, and advances to, other partners	6,041	8,141
Segregated cash	1,479	1,477
Other assets	3,672	4,587
Total assets	\$ 804,749	\$ 954,693
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Trade accounts payable	\$ 3,346	\$ 7,154
Accrued liabilities	50,411	42,250
Deferred contract revenue - current	27,754	21,032
Total current liabilities	81,511	70,436
Deferred contract revenue - long-term	86,042	94,115
Other long-term liabilities	3,612	3,689
2.25% Convertible senior notes due May 15, 2011	143,024	141,581
Minority interest	157	4,699
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; 127,218,463 shares issued and 127,184,623 outstanding at September 30, 2007 and 124,288,191 shares issued and 124,244,059 outstanding shares outstanding at December 31, 2006	1,272	1,243
Capital in excess of par value	1,138,053	1,107,487
Treasury stock, at cost 33,840 shares in 2007 and 44,132 shares in 2006	(85)	(111)

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Accumulated other comprehensive income	297,061	495,208
Accumulated deficit	(945,898)	(963,654)
Total shareholders' equity	490,403	640,173
Total liabilities and shareholders' equity	\$ 804,749	\$ 954,693

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 September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Contract and license revenues	\$ 6,758	\$ 6,347	\$ 19,054	\$ 20,362
Contract and license revenues from Genmab	215	375	1,717	1,158
Reimbursement of development costs	5,454	5,714	14,990	15,800
Total revenues	12,427	12,436	35,761	37,320
Costs and expenses:				
Research and development	49,165	48,350	141,460	142,324
General and administrative	13,149	15,451	35,020	35,127
Acquisition of in-process technology	6,900		6,900	
Total costs and expenses	69,214	63,801	183,380	177,451
Operating loss	(56,787)	(51,365)	(147,619)	(140,131)
Equity in net loss of affiliate				(1,037)
Interest and dividend income	5,176	4,841	15,460	12,677
Gain on sale of Genmab stock			152,143	
Impairment loss on investments in partners			(2,141)	
Interest expense	(1,541)	(1,055)	(4,622)	(3,166)
Minority interest - Celldex	1,602	1,675	4,542	4,781
Non-cash gain on loss of significant influence in Genmab				3,202
Income (loss) before provision for income taxes	(51,550)	(45,904)	17,763	(123,674)
Provision for income taxes	5	37	7	321
Net income (loss)	\$ (51,555)	\$ (45,941)	\$ 17,756	\$ (123,995)
Net income (loss) per share:				
- basic	\$ (0.41)	\$ (0.37)	\$ 0.14	\$ (1.04)
- diluted	\$ (0.41)	\$ (0.37)	\$ 0.14	\$ (1.04)
Weighted average number of common shares outstanding				
- basic	127,125	124,555	126,200	119,698
- diluted	127,125	124,555	128,501	119,698

See notes to these unaudited consolidated financial statements.

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2007	2006
<b>Operating activities:</b>		
Net income (loss)	\$ 17,756	\$ (123,995)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10,158	9,822
Amortization	2,489	2,478
Net bond (discount)/premium amortization	(1,570)	(2,527)
Stock options and awards to employees	15,821	14,099
Non cash revenue		(1,339)
Non-cash gain on loss of significant influence in Genmab		(3,202)
Equity in net loss of Genmab		1,037
Gain on sale of Genmab	(152,143)	
Impairment losses on investments in partners and other assets	2,141	
Minority interest in net loss	(4,542)	(4,781)
License fees purchased with stock	330	
Changes in operating assets and liabilities		
Other current assets	(995)	5,405
Trade accounts payable	(3,808)	726
Accrued liabilities	9,265	17,573
Deferred contract revenue	(1,351)	(10,138)
Net cash used in operating activities	(106,449)	(94,842)
<b>Investing activities:</b>		
Purchase of property and equipment	(5,063)	(9,527)
Investment in partner		(500)
Proceeds from sale of Genmab	152,143	
Proceeds from sale of Land		16
Increase in segregated cash	(2)	(26)
Purchase of marketable securities	(152,143)	(192,005)
Sales and maturities of marketable securities	96,224	113,095
Net cash provided by (used in) investing activities	91,159	(88,947)
<b>Financing activities:</b>		
Cash received from sales of securities and exercise of stock options, net	13,178	133,451
Principal payments under capital lease obligations	(22)	(20)
Net cash provided by financing activities	13,156	133,431
Effect of exchange rate differences on cash and cash equivalents	837	1,624
Net (decrease) increase in cash and cash equivalents	(1,297)	(48,734)
Cash and cash equivalents at beginning of period	34,511	90,602
Cash and cash equivalents at end of period	\$ 33,214	\$ 41,868
<b>Non-cash investing and financing activities:</b>		
Unrealized gain (loss) on investment in Genmab	\$ (45,281)	\$ 306,860

Supplemental disclosures of cash flow information

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Cash paid during period for:			
Income taxes	\$	35	\$ 313
Interest	\$	1,691	\$ 1,697

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 September 30, 2007 and 2006.

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 60% of the outstanding common stock of Celldex Therapeutics, Inc. (Celldex) (see Note 4).

Effective February 1, 2006, the Company ceased accounting for its investment in Genmab A/S (Genmab) under the equity method of accounting due to a reduction in ownership and a corresponding loss of significant influence (see Note 2). The Company currently accounts for its investment in Genmab in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*.

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, 2006 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, 2006 filed with the Securities and Exchange Commission, or SEC.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the following: (i) the reported amounts of assets and liabilities, (ii) the disclosure of contingent liabilities at the dates of the financial statements and (iii) the reported amounts of revenues and expenses during the reporting periods. 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 the Financial Accounting Standards Board ( FASB ) SFAS No. 128, *Earnings per Share*. Basic net income (loss) per share is based upon the number of weighted average shares of common stock outstanding. Diluted net income (loss) per share is based upon the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding. Potential shares of common stock result from the assumed exercise of outstanding stock options, with exercise prices less than the average market price of the Company's common stock during the

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nine month period ended September 30, 2007, which are included under the treasury stock method, as well as the assumed conversion of convertible senior notes. Potentially dilutive securities have been excluded from the computation of diluted net loss per share for the three month period ended September 30, 2007 and the three and nine month periods ended September 30, 2006, as their effect is antidilutive. Convertible senior notes have been excluded from the computation of diluted income per share for the nine month period ended September 30, 2007 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 nine months ended September 30, 2007:

<b>Income (Numerator):</b>	
Net income for basic and diluted income per share	\$ 17,756
<b>Shares (Denominator):</b>	
Weighted average shares for basic income per share	126,200,394
Effect of dilutive securities (stock options)	2,300,942
Weighted average shares for diluted income per share	128,501,336
Basic income per share	\$ 0.14
Diluted income per share	\$ 0.14

The following table sets forth potential shares of common stock that would be issued if all of the convertible notes were converted to common stock and all of the outstanding stock options were exercised, without regard to whether the convertible notes or outstanding stock options were in the money. These potential shares of common stock are not included in the computation of diluted net loss per share for the three months ended September 30, 2007 and three and nine months ended September 30, 2006 because to do so would be antidilutive.

	<b>Three Months Ended September 30, 2007</b>	<b>Three and Nine Months Ended September 30, 2006</b>
Convertible notes	10,936,935	10,936,935
Outstanding stock options	17,538,288	17,786,823
	28,475,223	28,723,758

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

Marketable securities consist of fixed income investments with a maturity of greater than three months and other highly liquid investments that can be readily purchased or sold using established markets. Under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, these investments are classified as available-for-sale and are reported at fair value on the Company's consolidated balance sheet. Unrealized holding gains and losses are reported within accumulated other comprehensive income as a separate component

of shareholders' equity. Under the Company's accounting policy, a decline in the fair value of marketable securities is deemed to be other than temporary and such marketable securities are generally considered to be impaired if their fair value is less than the Company's cost basis for more than six months, or some other period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of a marketable security below the Company's cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge.

In addition, the Company has investments in several of its partners whose securities are not publicly traded. These investments are accounted for under the cost basis. Because these securities are not publicly traded, the Company values these investments by using information acquired from industry trends, management of these companies, such companies' financial statements, and other external sources. Specifically, the Company's determination of any potential impairment of the value of the 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 and nine month periods ended September 30, 2007 and 2006. The Company recorded impairment charges of \$0 and \$2.1 million in partners whose securities are privately held for the three and nine month periods ended September 30, 2007. The Company recorded no impairment charges related to investments in partners whose securities are privately held for the three and nine month periods ended September 30, 2006. If the Company deems any of its investments to be further impaired at the end of any future period, it may incur additional impairment charges on these investments.

#### ***Revenue Recognition***



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The Company receives payments from customers and partners, for licenses to its proprietary technology for product development, for services and from the achievement of product development milestones and from the sale of antibodies. 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 partners are recognized generally over the term of the respective license period beginning after both the license period has begun and the technology has been delivered.

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

Milestone payments are recognized as revenue upon the achievement of mutually agreed milestones, provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the

inception of the agreement, and (ii) there are no continuing performance obligations associated with the milestone payment.

Revenue arrangements that include multiple deliverables are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, or the residual method if the fair value of the undelivered element is the only element with determinable fair value, 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.

Revenue from sales of antibodies to partners in the United States and overseas 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 statements 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 has 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

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three and nine month periods ended September 30, 2007 or 2006 and did not



accrue for interest or penalties as of September 30, 2007 or December 31, 2006. The Company does not have an accrual for uncertain tax positions as of September 30, 2007 or December 31, 2006. Tax returns for all years 2000 and thereafter are subject to future examination by tax authorities.

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

In June 2007, the Emerging Issues Task Force reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2007, and earlier application is not permitted. This consensus is to be applied prospectively for new contracts entered into on or after the effective date. The Company is evaluating the potential impact of this consensus and does not expect it to have a material effect on its consolidated financial statements.

## **2. 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 22.2% interest in Genmab as of December 31, 2005.

During the three month period ended March 31, 2006, the Company's investment in Genmab was adjusted to reflect its share (22.2%) of Genmab's net loss (\$1.0 million) prior to Genmab's February 1, 2006 private placement.

On February 1, 2006, Genmab completed the private placement of 5.75 million shares of its stock. As a result of this private placement, the Company's ownership percentage of Genmab was reduced to approximately 18.9%. As a result of a decrease in the Company's ownership below 20%, on February 1, 2006 the Company began accounting for its investment in Genmab as a marketable security in accordance with SFAS No. 115 *Accounting for Certain Investments in Debt and Equity Securities*.

In addition, the Company recorded a non-cash gain on loss of significant influence in Genmab for the six month period ended June 30, 2006 of \$3.2 million in accordance with FASB Staff Position APB 18-1, *Accounting by an Investor for Its Proportionate Share of Accumulated Other Comprehensive Income of an Investee Accounted for under the Equity Method in Accordance with APB Opinion No. 18 upon a Loss of Significant Influence (FSP APB 18-1)*. The Company's net foreign translation gains of approximately \$5.4 million associated with its investment in Genmab and reflected in accumulated other comprehensive income as of December 31, 2005 was first offset against the remaining carrying value of its investment in Genmab (\$2.2 million) reducing the Company's investment in Genmab to zero with the remaining balance (\$3.2 million) recorded as a non-cash gain in the consolidated statement of operations for the six month period ended June 30, 2006.

On February 17, 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%.

### 3. **Equity-Based Compensation**

The Company's stock awards are governed by its 2005 Equity Incentive Plan, as amended (the Plan). The exercise price of stock options under the Plan is determined by the Compensation and Organization Committee of the Board of Directors of the Company (the Committee). The term is fixed by the Committee, but no incentive stock option is exercisable after 10 years from the grant date. Stock options generally vest over a four year period. As of September 30, 2007, a total of 5,355,753 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.

The total stock based compensation cost relating to Statement 123(R) for the three month period ended September 30, 2007 has been included in the consolidated statement of operations within research and development expenses (\$2.7 million) and general and administrative expenses (\$4.0 million). The total stock-based compensation cost relating to Statement 123(R) for the nine month period ended September 30, 2007 has been included in the consolidated statement of operations within research and development expenses (\$7.5 million) and general and administrative expenses (\$7.8 million).

The total stock based compensation cost relating to Statement 123(R) for the three month period ended September 30, 2006 has been included in the consolidated statement of operations within research and development expenses (\$2.9 million) and general and administrative expenses (\$2.1 million). The total stock based compensation cost relating to Statement 123(R) for the nine month period ended September 30, 2006 has been included in the consolidated statement of operations within research and development expenses (\$7.7 million) and general and administrative expenses (\$6.4 million).

The following summarizes all stock option transactions for the Company under the Plan for the period from January 1, 2007 through September 30, 2007.

	Common Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at beginning of period	17,336,930	\$ 8.83		
Granted	2,993,789	15.93		
Exercised	(2,315,732)	5.91		
Canceled	(220,805)	39.16		
Forfeited	(810,963)	8.72		
Outstanding at end of period	16,983,219	10.62	6.8	\$ 80,175
Exercisable at end of period	10,887,011	9.63	5.6	\$ 64,070
Vested and unvested expected to vest at September 30, 2007	16,453,035	10.53	6.7	\$ 79,206

The weighted-average grant-date fair value of options granted during the nine month periods ended September 30, 2007 and 2006 were \$10.78 and \$7.29, respectively. The aggregate intrinsic value of options exercised during these same periods was \$17.9 million and \$6.5 million, respectively. The grant-date fair value of shares which vested during the nine month periods ended September 30, 2007 and 2006 was \$16.8 million and \$20.4 million, respectively. Cash proceeds from stock options exercised during the nine month periods ended September 30, 2007 and 2006 totaled \$13.7 million and \$4.5 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 the vesting period (generally 4 years). Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility was calculated based on the historical volatility of the Company's common stock. The average expected life was based on the contractual term of the option and expected employee exercise and post-vesting employment termination behavior. 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. Forfeitures are estimated based on voluntary termination behavior, as well as an analysis of actual option forfeitures. The weighted average assumptions used in the Black-Scholes option pricing model are as follows:

	Three Months Ended September 30		Nine Months Ended September 30	
	2007	2006	2007	2006
Expected stock price volatility	81.3%	82.7%	81.6%	82.8%
Risk-free interest rate	4.25%	4.59%	4.54%	4.62%
Expected life of options (years)	5.0	6.25	5.0	6.25
Expected dividend yield	0%	0%	0%	0%

As of September 30, 2007, the total unrecognized compensation cost related to non-vested stock options was approximately \$40.7 million. This cost is expected to be recognized over a weighted average period of 2.7 years.

#### Deferred Compensation

The Company maintains deferred compensation programs, under which certain 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 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 separate payments and will be paid exclusively in the form of shares of the Company's common stock. The expense associated with the Company's matching contribution was approximately \$0.1 million and \$0.1 million for the three month periods ended September 30, 2007 and 2006, respectively and \$0.2 million and \$0.4 million for the nine month periods ended September 30, 2007 and 2006, respectively.

#### **4. Celldex Therapeutics, 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 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, Pennsylvania.

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%.

5. **Bristol-Myers Squibb Collaboration**

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In January 2005, the Company announced the closing of a collaboration and co-promotion agreement and a related securities purchase agreement with Bristol-Myers Squibb Company ( BMS ), pursuant to which the Company and BMS each granted the other certain intellectual property licenses and product rights on a worldwide basis 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 candidate developed using the Company's UltiMab Human Antibody Development System, 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. The collaboration also includes the grant by the Company to BMS of a sub-license to MDX-1379, a gp100 peptide vaccine, for use with ipilimumab for the treatment of metastatic melanoma.

As part of the collaboration, the two companies committed to an initial multi-year budget of approximately \$192.0 million to fund the development of ipilimumab as a potential treatment for a broad range of cancers. 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 product candidates intended solely for regulatory approval in the United States, and BMS will be fully responsible for all development efforts that relate solely to regulatory approval in Europe and other parts of the world. Approximately \$4.7 million and \$3.9 million of the Company's revenue for the three month periods ended September 30, 2007 and 2006, respectively, and approximately \$12.5 million and \$11.7 million of the Company's revenue for the nine month periods ended September 30, 2007 and 2006, respectively, represented the reimbursement of the Company's costs associated with the development of ipilimumab recorded in compliance with EITF 99-19. The Company's share of the BMS development costs for the three month periods ended September 30, 2007 and 2006 was approximately \$7.6 million and \$5.7 million, respectively, and the Company's share of the BMS development costs for the nine-month periods ended September 30, 2007 and 2006 was approximately \$18.3 million and \$17.4 million, respectively, and is included as a component of research and development expense.

Under the terms of the collaboration, the Company could receive up to \$205.0 million from BMS if all regulatory milestones are met, plus up to an additional \$275.0 million in sales-related milestones. The Company will also have the option to co-promote any products in the United States, and, if the Company elects to exercise this option and has participated in the funding of the applicable Phase III clinical trial(s), the Company will receive up to 45% of any net profits, as defined, (and share in 45% of net losses, as defined) from commercial

sales in the U.S. less a small percentage of net sales, in certain circumstances. In the event the Company chooses not to exercise its co-promotion rights, BMS will have exclusive commercial rights in the United States and will pay the Company royalties on any commercial sales. Outside the United States, BMS will have exclusive commercial rights and will pay the Company royalties on any commercial sales.

In April 2007, in connection with BMS granting Pfizer a license under certain intellectual property owned by BMS, and an expansion of the scope of the Company's cross-license agreement with Pfizer, the Company and BMS amended certain royalty and profit sharing provisions of the Company's collaboration and co-promotion agreement with BMS.

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

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*. 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 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. The potential outcome of these actions, if any, are not determinable at this time. We could be required to pay significant damages in connection with this litigation.

The Company is unable to reasonably estimate any possible range of loss or liability associated with the stock option inquiry and/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. Acquisition of Ability Biomedical Corporation**

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

In August 2007, the Company agreed to pay the former shareholders of Ability Biomedical \$6.9 million, representing the final payment due under the original share purchase agreement. A payment of \$1.9 million was made to the former shareholders of Ability Biomedical in August 2007 and a final payment of \$5.0 million is due on or before November 30, 2007.

The \$6.9 million has been classified as in-process technology and was immediately written-off and included in the results of operations for the three and nine month periods ended September 30, 2007 since technological feasibility of the in-process technology had not yet been established and the technology had no alternative future use.

## 8. Contingencies

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

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

Through September 30, 2007, the Company has not made any milestone payments to Kirin. However, approximately \$2.8 million has been paid to Kirin as of September 30, 2007 representing a payment due Kirin as a result of the Company's collaboration with Pfizer. Based on a total of four product candidates 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 2008, the Company may be required to make milestone payments to Kirin aggregating up to approximately \$17.0 million with respect to such product candidates, or a maximum of approximately \$4.25 million per product candidate. 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;
- 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 is developing that utilize the Kirin technology and, accordingly, is inherently uncertain.

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 product candidates. In addition, the Company has entered into other third-party agreements that contain in-licenses associated with antibody product candidates that target specific antigens. Many of these agreements contain milestone payments that are due with respect to product candidates using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of the Company's product candidates currently under development trigger such milestone payments. Through September 30, 2007, the Company had made milestone payments under these agreements of approximately \$0.3 million. In addition, under the agreements the Company currently has in place (other than with Kirin), based on a total of nine product candidates 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 2008, the Company may be obligated to make future milestone payments aggregating up to approximately \$59.6 million with respect to such product candidates. 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 I, Phase II and/or Phase III clinical trials or foreign equivalents;

submission of BLA(s) or foreign equivalents; and

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

In addition, the licenses above may trigger royalty payments in connection with the commercialization of certain of 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 compensation 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 and/or penalties relating to the tax treatment of such stock options. While the Company believes that its accrual for additional compensation 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.

**9. Comprehensive Income (Loss)**

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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):

	Three Months Ended September 30		Nine Months Ended September 30	
	2007	2006	2007	2006
Net income (loss)	\$ (51,555)	\$ (45,941)	\$ 17,756	\$ (123,995)
Unrealized gain (loss) on securities	(12,489)	74,456	(46,938)	309,104
Unrealized (loss) gain on foreign exchange	(1,110)	502	935	(3,842)
Total comprehensive income (loss)	\$ (65,154)	\$ 29,017	\$ (28,247)	\$ 181,267

## 10. Segment Information

The Company is a biopharmaceutical company focused on the discovery, development and potential commercialization of fully human antibody-based therapeutic products. The operations of the Company and its subsidiaries constitute one business segment.

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

Customer	Three Months Ended September 30		Nine Months Ended September 30	
	2007	2006	2007	2006
Bristol-Myers Squibb	44%	37%	42%	38%
Pfizer	20%	20%	22%	20%

## 11. Subsequent Event

On October 22, 2007 AVANT Immunotherapeutics, Inc. and Celldex announced the signing of a definitive merger agreement. The all-stock transaction, approved by both companies' Boards of Directors, will combine the two companies under the name AVANT, and is currently expected to close in the first quarter of 2008. Closing of the merger is contingent upon a vote of approval by AVANT's current shareholders at a special meeting of shareholders expected to take place in the first quarter of 2008. Upon successful completion of the merger, Celldex and AVANT shareholders will own 58% and 42% of the combined company on a fully diluted basis, respectively. It is expected that Medarex will own approximately 35% of the combined entity upon successful completion of the merger.

**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 potential commercialization of fully human antibody-based therapeutic products. We believe that our UltiMab Human Antibody Development System<sup>®</sup> enables us to rapidly create and develop such products for a wide range of diseases, including cancer, inflammation, autoimmune disorders and other life-threatening and debilitating diseases.

Currently, over 30 antibody product candidates generated from our UltiMab Human Antibody Development System are in human clinical trials, or have had regulatory applications submitted for such trials(1). Phase III clinical trials are currently underway relating to eight of the most advanced product candidates in which Medarex has an economic interest through co-promotion/profit sharing rights, royalties and/or equity ownership. Seven of the eight product candidates currently in Phase III trials were generated through the use of our UltiMab<sup>®</sup> technology and include:

ipilimumab (also known as MDX-010), which we are developing jointly with Bristol-Myers Squibb Company, or BMS, for the treatment of metastatic melanoma and other cancers;

golimumab (also known as CNTO 148) under development by Centocor, Inc. (a subsidiary of Johnson & Johnson), or Centocor, for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis;

CNTO 1275 for the treatment of psoriasis, also under development by Centocor;

zanolimumab (also known as HuMax-CD4<sup>®</sup>), being developed by Genmab A/S, or Genmab, for the treatment of T-cell lymphomas;

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ofatumumab (also known as HuMax-CD20), being developed by Genmab and GlaxoSmithKline for the treatment of follicular non-Hodgkin's lymphoma and chronic lymphocyte leukemia;

zalutumumab (also known as HuMax-EGFr), being development by Genmab for the treatment of head and neck cancer; and

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



Acz885, being developed by Novartis Pharma AG, or Novartis, for the treatment of Muckle Wells Syndrome.

The eighth product candidate currently in Phase III trials in which we have an economic interest is CP-675,206, which is being developed by Pfizer, Inc., or Pfizer, for the treatment of metastatic melanoma. We expect to receive double-digit royalties on sales of this product, should commercialization occur.

Medarex is committed to building value by developing a diverse pipeline of antibody products to address major unmet healthcare needs in the world. In addition to the antibody product candidates currently in Phase III trials, multiple product candidates in Phase II, Phase I and preclinical testing are being developed by either Medarex alone or by Medarex jointly with our partners, or separately by our partners. These partners include Amgen, Inc., BMS, Centocor, Eli Lilly and Company, Genmab, ImClone Systems Incorporated, or ImClone Systems, MedImmune, Inc. (a subsidiary of AstraZeneca PLC), Novartis and Novo Nordisk A/S. 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 Human Antibody Development System<sup>®</sup>, 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. We intend to add sales, marketing and additional manufacturing capabilities as needed.

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 candidate if the product receives approval from the U.S. Food and Drug Administration, or FDA, and equivalent foreign agencies. In general, we are also entitled to receive royalties on product sales. Additional revenue may be earned from the sales of antibodies to, and, in some cases, the manufacturing of antibodies for, our partners, as well as from government grants.

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

We have a history of operating losses and may not achieve profitability. As of September 30, 2007, we had an accumulated deficit of approximately \$945.9 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 product candidates are selected for clinical development and as some of our earlier stage product candidates move into later stage clinical development. In addition, we may incur significant milestone payment obligations as our product candidates progress towards commercialization. In the absence of substantial revenues from new corporate collaborations or other sources, we will incur substantial operating losses and may be required to raise additional funds through debt or equity financings or 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 licenses to our proprietary technology, for product development services, from the achievement of product development milestones and for the sale of antibodies. 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 partners. Revenue from these research fees is recognized generally over the term of the respective license period beginning only after both the license period has begun and the technology has been delivered.

We receive fees for product development services (including manufacturing) we perform for our 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 I, II or III 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, or the residual method if the fair value of the undelivered element is the only element with determinable

fair value, 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 in the current assets section of our consolidated balance sheets. The fair market value of investments in our partners whose securities are publicly traded (other than Genmab) was approximately 1.2% and 2.2% of total marketable securities as of September 30, 2007 and December 31, 2006, respectively.

Under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, our marketable securities are classified as available-for-sale securities and are carried at fair value. Marketable securities will include those securities of debt and publicly traded equity securities. These securities, including shares of Genmab, 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 September 30, 2007. These securities are carried at original investment cost and adjusted for other than temporary impairment charges, if any. Because these securities are

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not listed on a financial exchange, the value of these investments is inherently more difficult to estimate than investments in public companies. We value these investments by using information acquired from industry trends, management of these companies, such companies' financial

statements, and other external sources. Specifically, our determination of any potential impairment of the value of the securities of privately held companies includes an analysis of the following for each such privately held company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financings and potential strategic alternatives. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is other than temporary.

Future adverse changes in market conditions or adverse changes in financial condition and/or operating results of the companies in which we invest that may not be reflected in an investment's current carrying value may also require an impairment charge in the future.

### *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 stock options grants with an exercise price equal to the fair market value of the underlying common stock on the measurement date.

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.

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 weighted average assumptions used to calculate the fair value of options granted for the three and nine month periods ended September 30, 2007 and 2006:

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	Three Months Ended September 30		Nine Months Ended September 30	
	2007	2006	2007	2006
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	81.3%	82.7%	81.6%	82.8%
Risk free interest rate	4.25%	4.59%	4.54%	4.62%
Expected life of options (years)	5.0	6.25	5.0	6.25

Our results of operations for the three month periods ended September 30, 2007 and 2006 include share based compensation expense of approximately \$6.6 million and \$5.0 million, respectively. Our results of operations for the nine month periods ended September 30, 2007 and 2006 include share based compensation expense of approximately \$15.2 million and \$14.1 million, respectively. As of September 30, 2007, the total unrecognized compensation cost related to non-vested stock options was approximately \$40.7 million. This cost is expected to be recognized over a weighted average period of 2.7 years.

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





*Valuation of Long-Lived and Intangible Assets*

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

a significant underperformance relative to projected future results;

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

a significant negative industry or economic trend.

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

*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 September 30, 2007 and 2006*

#### *Contract and License Revenues*

Contract and license revenues totaled \$6.8 million and \$6.3 million for the three month periods ended September 30, 2007 and 2006, respectively, an increase of \$0.5 million, or 6%. 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 \$0.2 million and \$0.4 million for the three month periods ended September 30, 2007 and 2006, respectively.

#### *Reimbursement of Development Costs*

Revenues derived from the reimbursement of costs associated with the development of our product candidates are recorded in compliance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* ( EITF 99-19 ). Reimbursement of development costs totaled \$5.5 million and \$5.7 million for the three month periods ended September 30, 2007 and 2006, respectively, a decrease of \$0.2 million, or 5%.

#### *Research and Development Expenses*

Research and development expenses for our product candidates in development were \$49.2 million and \$48.4 million for the three month periods ended September 30, 2007 and 2006, respectively, an increase of \$0.8 million, or 2%. 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 have, historically, tracked our costs in the categories discussed below, namely, research and product development and by the types of costs as outlined below.

Our research costs consist of costs associated with the breeding, care and continued development of our HuMAb-Mouse and KM-Mouse, as well as costs associated with research and testing of our product candidates prior to reaching the preclinical stage. Such research costs primarily include personnel costs, facilities (including depreciation), research supplies, funding of outside research and license and technology access fees.

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Our product development costs consist of costs of preclinical development (including manufacturing) and conducting and administering clinical trials. Such product development costs also include personnel costs, facilities (including depreciation), supply expense related to antibody manufacturing and clinical trial expenses.

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

	Three Months Ended September 30,			
		2007		2006
Research	\$	14,953	\$	16,516
Product Development		34,212		31,834
Total	\$	49,165	\$	48,350

#### *Research Costs*

Research costs for the three month period ended September 30, 2007 decreased by \$1.6 million, or 10% as compared to the three month period ended September 30, 2006. The decrease in research costs primarily relates to the following:

License and technology access fees for the three month period ended September 30, 2007 were \$1.2 million, a decrease of \$1.7 million, or 58%, as compared to the three month period ended September 30, 2006. 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 2006 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 2007.

#### *Product Development Costs*

Product development costs for the three month period ended September 30, 2007 increased by \$2.4 million, or 7% as compared to the three month period ended September 30, 2006. The decrease in product development costs primarily relates to the following:

Our share of partners' product development costs for the three month period ended September 30, 2007 was \$9.3 million, an increase of \$2.0 million, or 26%, as compared to the three month period ended September 30, 2006. These costs primarily represent our share (35%) of the BMS costs for the development of ipilimumab. We expect our 35% share of BMS's costs related to the development of ipilimumab to increase in the future as BMS continues to increase its development activities related to ipilimumab.

Patent costs for the three month period ended September 30, 2007 were \$1.8 million, an increase of \$1.3 million, or 305%, as compared to the three month period ended September 30, 2006. This increase primarily reflects the increasing number of our patents and the cost of maintaining our patent portfolio. We expect patent costs to continue to increase as we continue to increase our research activities.

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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:

<b>Clinical Phase</b>	<b>Estimated Completion Period</b>
Phase I	1-2 Years
Phase II	1-2 Years
Phase III	2-4 Years

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

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

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

the number of clinical sites required for trials; and

the number of patients that ultimately participate in clinical trials.

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 product candidates using our technology is expected to be borne by our partners. We believe this allows us to participate in the research and development of substantially more potential product candidates than we could develop on our own if we bore the entire cost of development. Product candidates using our technology are currently in various stages of development from preclinical to Phase III. The successful development of these product candidates is dependent on many factors, including among other things, the efforts of our partners, unforeseen delays in, or expenditures relating to, preclinical development, clinical testing, manufacturing or regulatory approval, failure to receive market acceptance, the emergence of competitive products and the inability to produce or market our products due to third-party proprietary rights.

#### ***General and Administrative Expenses***

General and administrative expenses include compensation, professional services, consulting, travel and facilities (including depreciation) and other expenses related to legal, business development, finance, information systems and investor relations. General and administrative expenses totaled \$13.1 million and \$15.5 million for the three month periods ended September 30, 2007 and 2006, respectively, a decrease of \$2.4 million, or 15%. Approximately \$4.7 million of the decrease is related to professional fees incurred in 2006 associated with an investigation of our stock option grant practices and was partially offset by an increase of \$2.0 million of stock based compensation expense. General and administrative expenses are expected to increase in the future as our product candidates are developed and we expand our business activities.

#### ***Acquisition of In-Process Technology***

Acquisition of in-process technology for the three month period ended September 30, 2007 of \$6.9 million represented the final payment due under the original share purchase agreement with the former shareholders of Ability Biomedical Corporation, or Ability Biomedical. The \$6.9 million was classified as in-process research and development. The in-process research and development was determined not be technologically feasible and had no alternative future use, and, as a result was charged to operations as acquisition of in-process technology during the three month period ended September 30, 2007.



***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 \$5.2 million and \$4.8 million for the three month periods ended September 30, 2007 and 2006, respectively, an increase of \$0.4 million, or 7%. The increase primarily reflects higher interest rates earned on our investment portfolio. In addition, we have higher interest and dividend income in 2007 as the result of higher average cash balances reflecting the proceeds received (approximately \$128.0 million) from our April 2006 public offering of 11.5 million shares of common stock and (approximately \$152.1 million) from our February 2007 sale of approximately 2.5 million shares of Genmab stock.

***Interest Expense***

Interest expense for the three month periods ended September 30, 2007 and 2006 relates primarily to interest and amortization of issuance costs on our 2.25% Convertible Senior Notes ( the 2.25% Notes ) issued in May 2004. Interest expense was \$1.5 million and \$1.1 million for the three month periods ended September 30, 2007 and 2006, respectively, an increase of \$0.4 million or 46%. The increase reflects the amortization of additional debt discount of approximately \$0.5 million for the three months ended September 30, 2007 associated with an increase in the fair value of the embedded conversion option of the 2.25% Notes which occurred in the fourth quarter of 2006.

***Minority Interest Celldex***

Minority interest in loss of Celldex represents 40% of Celldex's net loss for the three month periods ended September 30, 2007 and 2006. Minority interest in loss of Celldex was \$1.6 million and \$1.7 million the three month periods ended September 30, 2007 and 2006 respectively, a decrease of \$0.1 million, or 4%. Prior to October 12, 2005, we owned 100% of the outstanding capital stock of Celldex. As a result of certain acquisitions in October of 2005 by Celldex (see Note 4 to the consolidated financial statements), our ownership percentage was reduced from 100% to approximately 60%. Celldex's results of operations for 2007 and 2006 have been consolidated for reporting purposes, and the \$1.6 million and \$1.7 million (the portions of Celldex's net loss for the three month periods ended September 30, 2007 and 2006, respectively, not attributable to us) is recorded as a reduction of our expenses.

***Nine months ended September 30, 2007 and 2006***

***Contract and License Revenues***

Contract and license revenues totaled \$19.1 million and \$20.4 million for the nine month periods ended September 30, 2007 and 2006, respectively, a decrease of \$1.3 million, or 6%. Contract and licenses revenues for the nine month period ended September 30, 2006 includes revenue recognized from an existing collaboration for which there was no comparable revenue for the nine month period ended September 30, 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 \$1.7 million and \$1.2 million for the nine month periods ended September 30, 2007 and 2006, respectively, an increase of \$0.5 million, or 48%. This increase is primarily the result of an increase in antibody exclusive licenses granted to Genmab in the first nine months of 2007 as compared to the first nine months of 2006.

***Reimbursement of Development Costs***

Revenues derived from the reimbursement of costs associated with the development of our product candidates are recorded in compliance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* ( EITF 99-19 ). Reimbursement of development costs totaled \$15.0 million and \$15.8 million for the nine month periods ended September 30, 2007 and 2006, respectively, a decrease of \$0.8 million, or 5%.

***Research and Development Expenses***

Research and development expenses for our product candidates in development were \$141.5 million and \$142.3 million for the nine month periods ended September 30, 2007 and 2006, respectively, a decrease of \$0.8 million, or less than one percent. 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 have, historically, tracked our costs in the categories discussed below, namely, research and product development and by the types of costs as outlined below.

Our research costs consist of costs associated with the breeding, care and continued development of our HuMAb-Mouse and KM-Mouse, as well as costs associated with research and testing of our product candidates prior to reaching the preclinical stage. Such research costs primarily include personnel costs, facilities (including depreciation), research supplies, funding of outside research and license and technology access fees.

Our product development costs consist of costs of preclinical development (including manufacturing) and conducting and administering clinical trials. Such product development costs also include personnel costs, facilities (including depreciation), supply expense related to antibody manufacturing and clinical trial expenses.

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

	Nine Months Ended September 30,	
	2007	2006
Research	\$ 44,017	\$ 50,278
Product Development	97,443	92,046
Total	\$ 141,460	\$ 142,324

*Research Costs*

Research costs for the nine month period ended September 30, 2007 decreased by \$6.3 million, or 13% as compared to the nine month period ended September 30, 2006. The decrease in research costs primarily relates to the following:

License and technology access fees for the nine month period ended September 30, 2007 were \$2.5 million, a decrease of \$7.7 million, or 75%, as compared to the nine month period ended September 30, 2006. 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 2006 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 2007.

Personnel costs for the nine month period ended September 30, 2007 were \$17.6 million, an increase of \$1.3 million, or 8%, as compared to the nine month period ended September 30, 2006. The increase reflects additional staff needed to support higher levels of new product development opportunities, the continued development of our UltiMAB system, and the performance of contract services for our collaborative partners. Personnel costs include salary, benefits, stock based compensation, payroll taxes and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our research activities.

Facility costs for the nine month period ended September 30, 2007 were \$9.5 million, an increase of \$1.4 million, or 14%, as compared to the nine month period ended September 30, 2006. The increase in facility costs primarily relates to maintenance costs. Facility costs include depreciation, utilities, maintenance, property taxes and other related expenses. We expect to incur increased facility costs as a result of increased energy costs and continued capital expansion.

#### ***Product Development Costs***

Product development costs for the nine month period ended September 30, 2007 increased by \$5.4 million, or 6% as compared to the nine month period ended September 30, 2006. The increase in product development costs primarily relates to the following:

Clinical research fees for the nine month period ended September 30, 2007 were \$13.2 million, an increase of \$2.5 million, or 24%, as compared to the nine month period ended September 30, 2006. This increase resulted primarily from the continued enrollment of patients in the Phase III clinical trial for ipilimumab in combination with MDX-1379 and the initiation of additional sites for this trial. Sites participating in this trial are currently located in North America, Europe and Latin America. The continued enrollment of patients in the Phase III trial and the initiation of additional sites resulted in increased monitoring costs and increased investigator site fees. 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.

Patent costs for the nine month period ended September 30, 2007 were \$4.4 million, an increase of \$2.8 million, or 175%, as compared to the nine month period ended September 30, 2006. This increase primarily reflects

the increasing number of our patents and the cost of maintaining our patent portfolio. We expect patent costs to continue to increase as we continue to increase our research activities.

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

***General and Administrative Expenses***

General and administrative expenses include compensation, professional services, consulting, travel and facilities (including depreciation) and other expenses related to legal, business development, finance, information systems and investor relations. General and administrative expenses totaled \$35.0 million and \$35.1 million for the nine month period ended September 30, 2007 and 2006, respectively, a decrease of \$0.1 million, or less than one percent. Approximately \$3.2 million of the decrease is related to professional fees incurred in 2006 associated with an investigation of our historical stock option grant practices and was partially offset by an increase of \$1.7 million of stock based compensation expense. General and administrative expenses are expected to increase in the future as our product candidates are developed and we expand our business activities.

***Acquisition of In-Process Technology***

Acquisition of in-process technology for the nine month period ended September 30, 2007 of \$6.9 million represented the final payment due under the original share purchase agreement with the former shareholders of Ability Biomedical Corporation, or Ability Biomedical. The \$6.9 million was classified as in-process research and development. The in-process research and development was determined not be technologically feasible and had no alternative future use, and, as a result was charged to operations as acquisition of in-process technology during the nine month period ended September 30, 2007.

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

Equity in net loss of affiliate was \$0 and \$1.0 million for the nine month periods ended September 30, 2007 and 2006, respectively, a decrease of \$1.0 million. Equity in net loss of affiliate represents our share of Genmab's net loss for the nine month periods ended September 30, 2007 and 2006. The decrease was related to the suspension of our share of Genmab's net losses effective February 1, 2006. On February 1, 2006, Genmab completed the private placement of 5.75 million shares of its stock. As a result of this private placement, our ownership percentage of Genmab was reduced to approximately 18.9%. See Note 2 to the consolidated financial statements for further explanation. Beginning February 1, 2006 we began accounting for our investment in Genmab as a marketable security in accordance with SFAS No. 115.

***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 \$15.5 million and \$12.7 million for the nine month period ended September 30, 2007 and 2006, respectively, an increase of \$2.8 million, or 22%. The increase primarily reflects higher interest rates earned on our investment portfolio. In addition, we have higher interest and dividend income in 2007 as the result of higher average cash balances reflecting the proceeds received (approximately \$128.0 million) from our April 2006 public offering of 11.5 million shares of common stock and (approximately \$152.1 million) from our February 2007 sale of approximately 2.5 million shares of Genmab stock.

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

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In February 2007, we received approximately \$152.1 million in net proceeds from the sale of approximately 2.5 million shares of Genmab stock resulting in a realized gain of approximately \$152.1 million as our cost basis for these shares was zero. See Note 2 to the consolidated financial statements for further



explanation. The sale of the approximately 2.5 million shares of Genmab shares reduced our equity ownership in Genmab to approximately 10.8%.

#### ***Impairment Loss on Investments in Partners***

We have investments in several partners whose securities are not publicly traded. Because these securities are not publicly traded, the value of these investments is inherently more difficult to estimate than investments in publicly traded companies. We recorded impairment charges of \$2.1 million and \$0 for the nine month periods ended September 30, 2007 and 2006, respectively, related to investments in certain of our partners whose securities are not publicly traded. If we deem any of our investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

#### ***Interest Expense***

Interest expense for the nine month periods ended September 30, 2007 and 2006 relates to interest and amortization of issuance costs on the 2.25% Notes issued in May 2004. Interest expense was \$4.6 million and \$3.2 million for the nine month periods ended September 30, 2007 and 2006, respectively, an increase of \$1.4 million or 46%. The increase reflects the amortization of additional debt discount of approximately \$1.4 million for the nine months ended September 30, 2007 associated with an increase in the fair value of the embedded conversion option of the 2.25% Notes which occurred in the fourth quarter of 2006.

#### ***Minority Interest Celldex***

Minority interest in loss of Celldex represents 40% of Celldex's net loss for the nine month periods ended September 30, 2007 and 2006. Minority interest in loss of Celldex was \$4.5 million and \$4.8 million for the nine month periods ended September 30, 2007 and 2006 respectively, a decrease of \$0.3 million, or 5%. Prior to October 12, 2005, we owned 100% of the outstanding capital stock of Celldex. As a result of certain acquisitions in October of 2005 by Celldex (see Note 4 to the consolidated financial statements), our ownership percentage was reduced from 100% to approximately 60%. Celldex's results of operations for 2007 and 2006 have been consolidated for reporting purposes, and the \$4.5 million and \$4.8 million (the portions of Celldex's net loss for the nine month periods ended September 30, 2007 and 2006, respectively, not attributable to us) is recorded as a reduction of our expenses.

#### ***Non-Cash Gain on Investment in Genmab***

Non-cash gain on investment in Genmab for the nine month period ended September 30, 2006 of \$3.2 million was recorded in accordance with FASB Staff Position APB 18-1, *Accounting by an Investor for Its Proportionate Share of Accumulated Other Comprehensive Income of an Investee Accounted for under the Equity Method in Accordance with APB Opinion No. 18 upon a Loss of Significant Influence (FSP APB 18-1)*. As a result of Genmab's private placement of 5.75 million shares of its common stock in February 2006 and the corresponding reduction of our ownership percentage below 20%, our accumulated other comprehensive income associated with our investment in Genmab was first offset against the remaining carrying value of our investment in Genmab (\$2.2 million) reducing our investment in Genmab to zero with the remaining balance (\$3.2 million) recorded as a non-cash gain in the consolidated statement of operations for the nine month period ended September 30, 2006.



## **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 product candidates for research purposes, development and manufacturing services, technology transfer and license fees and milestone payments. We expect to continue to fund our cash requirements from these sources in the future.

At September 30, 2007, we had \$394.6 million in cash, cash equivalents and marketable securities. Approximately \$8.7 million of cash and cash equivalents included in the September 30, 2007 balance 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 in order to preserve principal. In addition, as of September 30, 2007, the value of our investment in Genmab was approximately \$297.0 million.

### ***Cash Used in Operating Activities***

Cash used in operating activities was \$106.4 million and \$94.8 million for the nine month periods ended September 30, 2007 and 2006, respectively. This reflects an increase of \$11.6 million in 2007 as compared to the same period in 2006 and is primarily the result of increased research and development and general and administrative 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 product candidates are developed. We plan to spend significant amounts to progress our current product candidates through the clinical trial and commercialization process as well as to develop additional product candidates on our own or with our partners. As our product candidates progress through the clinical trial process, we may be obligated to make significant milestone payments. We also expect to incur future facility costs as a result of our continued capital expansion, renovations and replacements. We expect our general and administrative costs to increase as we expand our administrative and business development activities. Furthermore, we expect our investment income to decrease as we fund our future operations and capital expenditures from our cash reserves. We anticipate that our operating expenditures may be partially offset by revenues from partners for license fees, milestone payments, and development and manufacturing services.

### ***Cash Provided by (Used in) Investing Activities***

Net cash provided by investing activities was \$91.2 million for the nine month period ended September 30, 2007 and net cash used in investing activities was \$88.9 million for the nine month period ended September 30, 2006. The increase in cash provided by investing activities was \$180.1 million and was primarily the result of the following factors:

In February 2007, we completed the sale of 2,578,500 shares of Genmab through a block trade resulting in net proceeds of approximately \$152.1 million.

Purchases of marketable securities totaled \$152.1 and \$192.0 million for the nine month periods ended September 30, 2007 and 2006, respectively. The 2007 purchases were made with a portion of the net proceeds received from the sale of our Genmab stock.

Sales and maturities of marketable securities were \$96.2 million and \$113.1 million for the nine month periods ended September 30, 2007 and 2006, respectively. Proceeds from sales of marketable securities in 2007 and 2006 were primarily used to fund operations and capital expenditures.

*Cash Provided by Financing Activities*

Cash provided by financing activities was \$13.2 million and \$133.4 million for the nine month periods ended September 30, 2007 and 2006, respectively. Cash provided by financing activities for the nine month period ended September 30, 2007 primarily represents cash received from the exercise of stock options. Cash provided by financing activities for the nine month period ended September 30, 2006 was primarily due to proceeds received from a public offering of 11.5 million shares of our common stock at a public offering price of \$11.75 per share resulting in net proceeds of approximately \$128.0 million.

*Other Liquidity Matters*

In August 2007, we agreed to pay the former shareholders of Ability Biomedical \$6.9 million, representing the final payment due under the original share purchase agreement. A payment of \$1.9 million was made to the former shareholders of Ability Biomedical in August 2007 and a final payment of \$5.0 million is due on or before November 30, 2007.

In January 2005, we announced the closing of 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 product candidates for the treatment of cancer and other diseases, and, in the event that further development work is successful, to commercialize any resulting products. In particular, the collaboration includes a grant by us to BMS of a license to commercialize ipilimumab, a fully human antibody product candidate developed using our UltiMab Human Antibody Development System<sup>®</sup>. Ipilimumab is currently under investigation for the treatment of a broad range of cancers. The collaboration also includes the grant by us to BMS of a sub-license to MDX-1379, a gp100 peptide vaccine licensed by us from the U.S. Public Health Service, for use with ipilimumab for the treatment of metastatic melanoma. We and BMS are currently conducting three separate registrational studies of ipilimumab for metastatic melanoma under three separate Special Protocol Assessment agreements with the FDA. One is a monotherapy study of ipilimumab in second-line (previously treated with melanoma therapy other than ipilimumab) metastatic melanoma that completed enrollment in 2006. This monotherapy study is the subject of a potential BLA filing in early 2008. A Phase III clinical trial of ipilimumab used in combination with chemotherapy in first-line (previously untreated) patients with metastatic melanoma was initiated in June 2006 and is currently underway. The third study is an ongoing Phase III clinical trial with ipilimumab and MDX-1379 combination therapy in Stage III and Stage IV metastatic melanoma patients. Each of these trials is being conducted at multiple sites worldwide.

In April 2007, in connection with BMS granting Pfizer a license under certain intellectual property owned by BMS, and an expansion of the scope of our cross-license agreement with Pfizer, we and BMS amended certain royalty and profit sharing provisions of our collaboration and co-promotion agreement with BMS.

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As part of the collaboration, we and BMS committed to an initial multi-year budget of approximately \$192.0 million to fund the development of ipilimumab as a potential treatment for a broad range of cancers. 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 us. We and BMS 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 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. If we exercise our co-promotion option with respect to ipilimumab for the metastatic melanoma indication, and regulatory approval is obtained, we would receive up to 45% of any net profits, as defined, (and share in 45% of net losses, as defined) from commercial sales of such a collaboration product in the U.S. less a small percentage of net sales, in certain circumstances. 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 in the U.S., BMS will have exclusive commercial rights for products and will pay us royalties on commercial sales outside the U.S.

Pursuant to these agreements, BMS made an initial cash payment to us on January 21, 2005 of \$25.0 million. In addition, BMS purchased a total of 2,879,223 unregistered shares of our common stock at a purchase price equal to \$8.6829 per share for an aggregate purchase price of \$25.0 million. These shares were issued in a private placement pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933. The purchase price represented a small premium to the market price on the date we entered into the collaboration. BMS agreed to a two-year lock-up period with respect to any sales of such stock. The lock-up period expired in January 2007, and BMS may now sell such shares pursuant to the provisions of Rule 144 under the Securities Act. We have no future obligation to register such stock.

In October 2005, Celldex completed the acquisition of all of the issued and outstanding shares of capital stock of Lorantis Limited, or Lorantis, a privately held biotechnology company based in Cambridge, U.K. and substantially all of the assets of Alteris Therapeutics, Inc., or Alteris, a privately held biotechnology company based in Philadelphia, Pennsylvania.

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.

*Financial Uncertainties Related to Potential Future Milestone Payments*

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

Through September 30, 2007, we have not made any milestone payments to Kirin although approximately \$2.8 million has been paid to Kirin as of September 30, 2007 representing a payment due Kirin as a result of our collaboration with Pfizer, Inc., or Pfizer. In addition, based on a total of four product candidates 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 2008, we may be required to make milestone payments to Kirin aggregating up to approximately \$17.0 million with respect to such product candidates, or a maximum of approximately \$4.25 million per product candidate. 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 product candidates. In addition, we have entered into other third-party agreements that contain licenses associated with antibody product candidates that target specific antigens. Many of these agreements contain milestone payments that are due with respect to product candidates using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of our product candidates currently under development trigger such milestone payments. Through September 30, 2007, we had made milestone payments of approximately \$0.3 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of nine product candidates 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 2008, we may be obligated to make future milestone payments aggregating up to approximately \$59.6 million with respect to such product candidates. In general, potential milestone payments for our 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 payments per product include:



submission of IND(s) or foreign equivalents;

commencement of Phase I, Phase II and/or Phase III clinical trials or foreign equivalents;  
submission of BLA(s) or foreign equivalents; and  
receipt of marketing approval(s) to sell products in a particular country or region.

In addition, the licenses above may trigger royalty payments in connection with the commercialization of certain of our products. To date, we have not made any royalty payments on sales of our products and believe we are at least 1 - 2 years away from selling any products that would require us to make any such royalty payments. Whether we will be obligated to make milestone or royalty payments in the future is subject to the success of our product development efforts and, accordingly, is inherently uncertain.

#### ***Future Liquidity Resources***

Our current sources of liquidity are our cash, cash equivalents and marketable securities, interest and dividends earned on such cash, cash equivalents and marketable securities, contract and licensing revenue and sales of our product candidates for research. We believe that such sources of liquidity will be sufficient to meet our operating, debt service, and capital requirements for at least the next 24 months. To the extent our 2.25% Notes are converted into shares of our common stock on or before their maturity date, we will have use of that portion of the principal amount of the notes to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our product candidates 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.

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

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

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

*Evaluation of Disclosure Controls and Procedures:* 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 (as defined in Rule 13a-15(f) of the Exchange Act) that

occurred during the quarter ended September 30, 2007 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-Q filed on August 6, 2007 with the SEC for the period ended June 30, 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.**



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Based on public disclosures, as of November 1, 2007, regulatory applications, including INDs, have been submitted to the FDA or comparable foreign authorities for over 30 product candidates derived from our UltiMab® platform. Neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA or comparable foreign authorities and/or commercialized. Product candidates employing our human antibody technology have not advanced, and may not advance, beyond clinical development and may not demonstrate clinical safety and effectiveness.

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 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.

In certain instances, we have experienced delays in our product development and clinical testing as a result of slower than anticipated patient recruitment. In a number of instances, we have terminated the development of certain product candidates in the early stages of human clinical testing due to a lack of effectiveness.

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

**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.**



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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.**



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We have incurred large operating losses, and we anticipate that these losses will continue for the foreseeable future. In particular, as of September 30, 2007, we had an accumulated deficit of approximately \$945.9 million. Our net loss was \$181.7 million for the year ended December 31, 2006. Although we recorded net income of \$17.8 million for the nine month period ended September 30, 2007 (which was the result of the sale of a portion of our Genmab stock) our operating loss for the period was \$147.6 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.**



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

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

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

delays in, or termination of, preclinical testing and clinical trials;

changes in regulatory requirements for clinical trials;

costs and expenses associated with preclinical testing and clinical trials;

the timing of regulatory approvals, if any;

sales and marketing expenses; and

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

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

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

**We 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 especially relevant for us because biotechnology companies have experienced greater than average price volatility in recent years and because we are currently subject to an SEC inquiry and a grand jury investigation relating to our historical stock option granting practices. If we faced such litigation, 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.**





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

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.**



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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.

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



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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. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

the inability to manufacture sufficient quantities of qualified materials under 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.

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. The most common adverse events associated with our trials of ipilimumab have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related immune-mediated events, such as diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. Other than a very small number of fatalities not directly related to progression or complications of the disease being treated, representing approximately 1% of over 1,000 patients treated in all previous trials, which may or may not be attributable to our product candidate, most events resolved with treatment. We cannot assure you that additional safety issues will not arise with respect to our products in the future.





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

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

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



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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.**



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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 may be materially harmed.

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





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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 in order to demonstrate the cost-effectiveness of our products. Such studies may require us to dedicate a significant amount of resources. Our project candidates may not be considered cost-effective. Third-party payors may not reimburse sales of products employing our human antibody technology, or enable us or our partners to sell them at profitable prices.

**The continuing efforts of governmental and third-party payers 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. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, 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. While we cannot predict whether the government will adopt any such legislative or regulatory proposals, the announcement or adoption of these proposals could 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.**



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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. If such companies are not able to produce products that are substantially equivalent to our product candidates, the progress of our clinical trials and/or commercialization of our products may be delayed and our business, financial condition and results of operations may be materially harmed.

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

**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.**



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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/or 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

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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 Celldex Therapeutics, Inc., we must consolidate the results of its operations in our financial statements.**

We currently own approximately 60% of the outstanding common stock of Celldex Therapeutics, Inc., a privately held biopharmaceutical company. Due to the size of our equity interest in Celldex, we are currently required to consolidate the operations of Celldex in our financial statements, which results in the inclusion of their losses in our financial statements. We are unable to predict what such losses will be. For the year ended December 31, 2006 and the nine month period ended September 30, 2007, our share, net of minority interest, of Celldex's net loss included in our financial statements was approximately \$10.3 million and \$6.8 million, respectively.

**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.**



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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 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 years ended December 31, 2006 and 2004, we recorded impairment charges of \$5.2 million and \$0.2 million on investments in partners whose securities are publicly traded. During the year ended December 31, 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, 2006, 2005 and 2004, we recorded impairment charges of approximately \$0, \$33.3 million and \$7.1 million, respectively, on our investments in privately-held companies. Approximately \$7.0 million of the 2004 impairment charge related to IDM Pharma. 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.**



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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.**





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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.

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

Generally, our clinical trials, including our melanoma trials for ipilimumab, are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product 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.

The most common adverse events associated with our melanoma trials of ipilimumab have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related immune-mediated adverse events, such as diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. Almost all of these adverse events responded to medical therapy. In a very small number of instances (approximately 1% of over 1,000 patients treated), fatalities not directly related to disease progression or complications have occurred during the course of these trials such fatalities may or may not be attributable to our product candidate. Any of these events or any other adverse events in any of our other clinical trials could result in a product liability claim. Any such claims against us, regardless of their merit, could result in significant awards against us, which could materially harm our business, financial condition and results of operations.

**We face intense competition and rapid technological change.**



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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. As a result of the merger, Amgen owns Abgenix's XenoMous<sup>®</sup> technology and may engage in direct competition with us in the area of generating fully human monoclonal antibodies for antibody-based therapeutics. Regeneron has licensed its VelocImmune<sup>®</sup> monoclonal antibody generation technology to each of AstraZeneca and Astellas Pharma Inc., respectively, potentially enabling AstraZeneca and Astellas 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.

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 CP-675,206, 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. According to publicly available information, Pfizer is conducting a first line Phase III clinical trial comparing CP-675,206 alone to chemotherapy alone for metastatic melanoma, as well as in a second-line clinical trial of CP-675,206 as a monotherapy for metastatic melanoma.

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, Abbott Laboratories 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.

Other technologies can also be applied to the treatment of the diseases that we or our partners are pursuing. For example, immunoconjugates monoclonal antibodies linked to toxins 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 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 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 each of ipilimumab and MDX-1379 for specified metastatic melanoma patient populations, 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 the ipilimumab and MDX-1379 combination therapy, 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, MDX-1379 or our other products based on orphan drug exclusivity.

In addition, Pfizer has obtained orphan drug designation in the United States for CP-675,206 for specific patient populations, including metastatic melanoma. In April 2007, Pfizer, Medarex and BMS each agreed that it would not assert any orphan drug exclusivity to, and would take commercially reasonable steps to assure that such exclusivity does not, block one another from obtaining approval for their respective anti-CTLA4 antibody products anywhere in the world.

Prior to the agreement in April 2007, if Pfizer had been first to receive approval by the FDA for such patient populations, and CP-675,206 and ipilimumab were to be considered to be the same drug for orphan exclusivity purposes, Pfizer could have obtained exclusivity that would potentially have blocked us and our partner BMS from obtaining approval in the United States to sell ipilimumab, whether as a monotherapy or combination therapy, for such patient populations, including metastatic melanoma.

**We are subject to extensive and costly government regulation.**





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

delays in the approval of applications or supplements to approved applications;

refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;

warning letters;

fines;

import and/or export restrictions;

product recalls or seizures;

injunctions;

total or partial suspension of production;

civil penalties;

withdrawals of previously approved marketing applications or licenses;

recommendations by the FDA or other regulatory authorities against governmental contracts; and

criminal prosecutions.

In certain cases, we expect to rely on our partners to file 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.**



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Following completion of clinical trials, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of a BLA or NDA, to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to a BLA or NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study or reporting requirements or other restrictions on product distribution, or may deny the application. The FDA has established performance goals for review of NDAs and BLAs – six months for priority applications and 10-12 months or longer for standard application. However, the FDA is not required to complete its review within these time periods. The timing of final FDA review and action varies greatly, but can take years in some cases and often involves the input of an FDA advisory committee of outside experts. Product sales in the U.S. may commence only when a BLA or NDA is approved.

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our product candidates in the U.S. or in any foreign jurisdiction. None of our product candidates has been determined to be safe and effective. We have only limited experience in filing and pursuing applications necessary to obtain regulatory approval. It is possible that none of our product candidates will be approved for marketing.

Product candidates that appear promising in the early phases of development, such as in preclinical development or in early human clinical trials, may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results;

- the product candidate was not effective in treating the specified disease or condition;

- the product candidate had harmful side effects on humans or presented unacceptable safety risks;

- the governing regulatory authorities (such as the FDA) denied approval to the product candidate altogether or denied a commercially important indicated use;

- the product candidate was not economical for us to manufacture; and/or

- the product candidate was not cost effective in light of alternative therapies.

We cannot guarantee that we will ever be able to produce commercially successful products.

**If we or our manufacturing partners do not comply with current good manufacturing practices requirements, we will not be able to commercialize our product candidates.**





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We will depend on our own manufacturing facilities and/or on those of our partners and other third parties to manufacture products generated through the use of our human antibody technology if we are able to commercialize any of our product candidates. Before commercializing a new drug, manufacturers must demonstrate compliance with the applicable cGMP requirements which include quality control and quality assurance requirements as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of our technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. We, our partners or third party contract

manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, costly required corrective and preventative actions, the shutdown of manufacturing facilities, injunctions, monetary fines and/or civil or criminal sanctions.

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



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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.

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.**

New federal legislation was recently enacted known as the FDA Amendments Act of 2007, which grants FDA extensive new 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 new legislation, 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.**



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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 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 patent position of biotechnology intellectual property involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide sufficient protection against competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed 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 seek protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide protection or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information, or breach of these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

**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> technology 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 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 completed its merger with Amgen in April 2006. As a result, Amgen has 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>. Effective September 2002, we entered into a collaboration and license agreement with Kirin, which provides for us to exchange certain cross-licenses for each other's technology for the development and commercialization of human antibody products made using the HuMAb-Mouse<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 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 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.**



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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, in a final office action, rejected the patentability of such claims. Genentech has announced its intent to respond to such action 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 reexamination 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 the licensee.

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.**



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Historically, there has been significant volatility in the market prices of biotechnology companies' securities. During the two-year period ended September 30, 2007, the sale prices of our common stock ranged between \$7.45 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:

fluctuations in our operating results;

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

published reports by securities analysts;

progress with clinical trials;

governmental regulation;

developments in patent or other proprietary rights;

developments in our relationship with collaborative partners;

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

changes in our management;

matters relating to the investigation of our past stock option grant practices; and

general market conditions.

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

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



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As of October 31, 2007, we had 17,136,069 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 \$10.66 per share and we had reserved 5,125,212 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 with the exception of the 5,500,000 shares discussed in the following paragraph. 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.

At our annual meeting of shareholders held on May 18, 2006, our shareholders approved an amendment to our 2005 Equity Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under the plan by 5,500,000 shares. We intend to file a registration statement on Form S-8 under the

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Securities Act covering these additional shares, and such registration statement will become effective upon filing. Shares issued upon the exercise of options related to such additional shares, other than shares issued to affiliates, will be freely tradeable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

As of October 31, 2007, we had reserved 619,372 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 October 31, 2007, 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.

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





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As of October 31, 2007, we had 127,271,314 shares of common stock outstanding, of which approximately 8,500,000 are restricted securities as that term is defined in Rule 144 under the Securities Act. Under certain circumstances, these restricted securities may be sold without registration pursuant to such rule. We are unable to predict the effect that sales made under Rule 144 or pursuant to any registration may have on the market price of our common stock. The sale of a significant number of additional securities, or even the possibility thereof, may lower the market price of our common stock.

**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.**



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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 October 31, 2007, \$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.**



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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, 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.**



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**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.**

We intend to retain any future earnings to finance the growth and development of our business, and we do not plan



We intend to retain any future earnings to finance the growth and development of our business, and we do not plan

**Item 6. Exhibits**

(a) Exhibits:

Exhibit 3.1 Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003.

Exhibit 3.2 Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed October 31, 2007.

Exhibit 4.1 Reference is made to Exhibits 3.1 and 3.2.

Exhibit 4.2 Form of Specimen Common Stock Certificate, incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 33-39956) filed April 12, 1991.

Exhibit 4.3 Form of Rights Agreement (including Form of Rights Certificate), incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed May 25, 2001.

Exhibit 4.4 Indenture dated May 3, 2004 between the Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K filed May 4, 2004.

Exhibit 4.5 Registration Rights Agreement, dated May 3, 2004, by and among the Registrant, Goldman Sachs & Co. and J.P. Morgan Securities, Inc., incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed May 4, 2004.

Exhibit 4.6 First Supplemental Indenture dated October 4, 2006 among Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed October 5, 2006.

Exhibit 10.1 Restricted Stock Agreement dated August 31, 2007 between the Registrant and Christian S. Schade.

Exhibit 10.2 Employment Agreement entered into on October 5, 2007 between Christian S. Schade, Senior Vice President and Chief Financial Officer and Medarex, Inc., incorporated herein by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K, filed October 12, 2007.

Exhibit 10.3 Employment Agreement entered into on October 5, 2007 between Dr. Nils Lonberg, Senior Vice President and Scientific Director and Medarex, Inc., incorporated herein by reference to Exhibit 99.2 to Registrant's Current Report on Form 8-K, filed October 12, 2007.

Exhibit 10.4 Employment Agreement entered into on October 5, 2007 between Dr. Geoffrey M. Nichol, Senior Vice President, Product Development and Medarex, Inc., incorporated herein by reference to Exhibit 99.3 to Registrant's Current Report on Form 8-K, filed October 12, 2007.

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Exhibit 10.5 Medarex, Inc. 2005 Equity Incentive Plan, as amended, incorporated herein by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K/A, filed November 2, 2007.

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

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

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

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

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Indicates management contract or compensatory plan.

**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: November 2, 2007

By: /s/ HOWARD H. PIEN  
**Howard H. Pien**  
**President and Chief**  
**Executive Officer**  
**(Principal Executive Officer)**

Date: November 2, 2007

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