MEDAREX INC Form 10-K February 27, 2008

<u>OuickLinks</u> -- Click here to rapidly navigate through this document

## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## **FORM 10-K**

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

#### ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ý **ACT OF 1934**

For the fiscal year ended December 31, 2007

#### TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES 0 **EXCHANGE ACT OF 1934**

For the transition period from to Commission File No. 0-19312

## **MEDAREX, INC.**

(Exact name of registrant as specified in its charter)

New Jersey

(State or other jurisdiction of incorporation or organization)

707 State Road, Princeton, New Jersey (Address of principal executive offices)

Registrant's telephone number, including area code: (609) 430-2880

Securities registered pursuant to Section 12(b) of the Act:

Title of Class

Common Stock (\$0.01 par value)

The NASDAQ Global Market under symbol MEDX

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Act. Yes ý No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

Indicate by check mark whether the 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

(I.R.S. Employer Identification No.)

22-2822175

08540

Name of Each Exchange on Which Registered

(Zip Code)

for the past 90 days. Yes  $\acute{y}$  No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.  $\circ$ 

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

 Large accelerated filer ý
 Accelerated filer o

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

 Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ý

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$1,664,800,000 as of June 29, 2007, based upon the closing sale price on the NASDAQ Global Market reported for such date. The determination of affiliate status for the purposes of this calculation is not necessarily a conclusive determination for other purposes. The calculation excludes approximately 10,160,000 shares held by directors, officers and shareholders whose ownership exceeded 5% of the registrant's outstanding Common Stock as of June 29, 2007. Exclusion of these shares should not be construed to indicate that such person controls, is controlled by or is under common control with the registrant.

As of January 31, 2008, the registrant had outstanding 127,458,777 shares of Common Stock, \$0.01 par value ("Common Stock"), which is registrant's only class of Common Stock.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the Annual Meeting of Shareholders scheduled to be held on May 15, 2008 (the "Proxy Statement") are incorporated by reference in Parts II and III of this Report. Other documents incorporated by reference in this report are listed in the Exhibit Index.

## MEDAREX, INC.

## TABLE OF CONTENTS

### FORM 10-K

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	22
Item 1B.	Unresolved Staff Comments	47
Item 2.	Properties	47
Item 3.	Legal Proceedings	47
Item 4.	Submission of Matters to a Vote of Security Holders	48
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	49
Item 6.	Selected Consolidated Financial Data	51
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	52
Item 7A.	Quantitative and Qualitative Disclosures about Market Risks	71
Item 8.	Consolidated Financial Statements and Supplementary Data	F-1
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosures	73
Item 9A.	Controls and Procedures	73
Item 9B.	Other Information	75
PART III		
Item 10.	Directors, Executive Officers, and Corporate Governance of the Registrant	75
Item 11.	Executive Compensation	75
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	75
Item 13.	Certain Relationships and Related Transactions, and Director Independence	75
Item 14.	Principal Accountant Fees and Services	75
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	76
	Signatures	82

Page

Certifications

#### PART I

In this Annual Report, "Medarex" or the "company," "we," "us" and "our" refer to Medarex, Inc., and our wholly-owned subsidiaries. This Annual Report contains forward-looking statements that involve risk and uncertainties. Actual events or results may differ materially from those discussed in this Annual Report. Factors that might cause such a difference include, but are not limited to, those discussed in the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as those discussed elsewhere in this Annual Report.

Medarex®, HuMAb-Mouse®, GenPharm®, KM-Mouse®, UltiMAb® and UltiMAb Human Antibody Development System® are registered trademarks of Medarex, Inc. All other company names, registered trademarks, trademarks and service marks included in this Annual Report are trademarks, registered trademarks, service marks or trade names of their respective owners.

#### Item 1. Business

#### Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of fully human antibody-based therapeutic product candidates. We believe that our UltiMAb® technology platform enables us to rapidly create and develop such products for a wide range of diseases, including cancer, inflammation, autoimmune disorders and other life-threatening and debilitating diseases.

Medarex is committed to building value by developing a diverse pipeline of antibody products to address major unmet healthcare needs in the world. Currently, over 40 antibody product candidates generated from our UltiMAb® technology are in human clinical trials, or have had regulatory applications submitted for such trials(1). 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 are in Phase 3 clinical trials or the subject of regulatory applications for marketing authorization. Seven of these late-stage product candidates were generated through the use of our UltiMAb® technology. In addition to the antibody candidates currently in Phase 3 trials, multiple product candidates in Phase 2, Phase 1 and preclinical testing are being developed by Medarex alone, by Medarex jointly with our partners, or separately by our partners. These partners include Amgen, Inc., Bristol-Myers Squibb Company, Centocor, Inc., Eli Lilly and Company, Genmab A/S, ImClone Systems Incorporated, MedImmune, Inc. and Novartis Pharma AG. We believe that through the broad use of our UltiMAb® technology, we are leveraging our efforts and our partners' efforts to create, develop and potentially commercialize innovative treatments for a wide range of diseases.

(1)

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

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

Our operations constitute one business segment. For additional financial information regarding the reportable segment, see "Results of Operations" in Item 7 and the Consolidated Financial Statements and Supplementary Data in Item 8 of this Annual Report on Form 10-K.

#### **Products in Development**

The following tables summarize potential therapeutic indications and development stages for selected antibody products in which Medarex has an economic interest, including our own product candidates and those of our partners (based on publicly available information), and is followed by brief descriptions of certain programs.

#### Selected Proprietary and Partnered Product Candidates in Clinical Development

PRODUCT	INDICATION	CLINICAL STATUS	PARTNER/LICENSEE
ipilimumab (anti-CTLA-4)	Melanoma and other Cancers	Phase 3 and earlier	Co-developing with BMS*
MDX-060 (anti-CD30)	Lymphoma	Phase 2	Wholly-owned
MDX-1100 (anti-IP10)	Ulcerative Colitis, Rheumatoid Arthritis	Phase 2 and earlier	Wholly-owned
MDX-066 and MDX-1388 (anti-Toxin A and B)	C. difficile Disease	Phase 2	Co-developing with Massachusetts Biologic Laboratories∆
MEDI-545 (anti-interferon α)	Lupus	Phase 1	MedImmune/AZN*
MDX-1106 (anti-PD-1)	Cancer, Hepatitis C	Phase 1	Co-developing with Ono Pharmaceutical Co. Ltd.§§
MDX-1401 (anti-CD30)	Lymphoma	Phase 1	Wholly-owned
MDX-1342 (anti-CD19)	Leukemia, Rheumatoid Arthritis	Phase 1	Wholly-owned
MDX-1411 (anti-CD70)	Cancer	Phase 1	Wholly-owned
Valortim (MDX-1303) (anti-anthrax PA)	Anthrax Infection	Phase 1	Co-developing with PharmAthene, $Inc.\Delta\Delta$

\*

We have the option to co-promote and share profits in the U.S. We expect to receive milestone payments as these product candidates move toward product approval and milestones and royalties on certain product sales, should commercialization occur.

Δ

We expect to share certain research and development costs associated with these products, as well as profits or losses associated with their commercialization, on a 50/50 basis.

§§

We have the right to develop and commercialize in North America, and Ono has the right to develop and commercialize outside of North America, in each case subject to payment of a royalty to the other party on sales in such territories, should commercialization occur.

 $\Delta \Delta$ 

PharmAthene is fully responsible for funding of research and development activities for MDX-1303 that are not supported by government funds. We expect to share profits associated with this product according to a pre-agreed allocation percentage.

#### Selected Licensee Product Candidates in Clinical Development

PRODUCT	INDICATION	CLINICAL STATUS	PARTNER/LICENSEE
ustekinumab	Inflammatory Diseases	BLA Filed	Centocor ♦
(anti-IL-12/IL-23)			
golimumab (anti-TNF $\alpha$ )	Inflammatory Diseases	Phase 3	Centocor ♦
ofatumumab (anti-CD20)	Lymphoma, Leukemia, Rheumatoid	Phase 3 and earlier	Genmab (partnered with
	Arthritis		GlaxoSmithKline)
zanolimumab (anti-CD4)	T-cell Lymphomas	Phase 3 and earlier	Genmab
zalutumumab (anti-EGFr)	Head and Neck Cancer and Lung Cancer	Phase 3 and earlier	Genmab
tremelimumab	Metastatic Melanoma and other Cancers	Phase 3 and earlier	Pfizer♣
(anti-CTLA-4)			
ACZ885 (anti-IL-1ß)	Muckle Wells Syndrome and Others	Phase 3 and earlier	Novartis Pharma♦
Amgen Antibodies 1 and 2	Undisclosed Diseases	Phase 2	Amgen♦
CNTO 95 (anti-integrins)	Cancer	Phase 2	Centocor♦
HuMax-IL-8 (anti-IL-8)	Palmoplantar Pustulosis	Phase 1/2	Genmab
NI-0401 (anti-CD3)	Crohn's Disease, Renal Transplantation	Phase 1/2	NovImmune, Inc.♦
AMG 714 (anti-IL-15)	Psoriasis	Phase 1	Genmab (partnered with
			Amgen)
BMS-66513 (anti-CD137)	Cancer	Phase 1	BMS♦
IMC-18F1 (anti-VEGFR)	Cancer	Phase 1	ImClone Systems ♦
IMC-3G3 (anti-PDGFR $\alpha$ )	Cancer	Phase 1	ImClone Systems↓
Other Antibodies	Undisclosed Diseases	Phase 1	•
Other Antibodies	Ulluisciosed Diseases	rilase 1	Amgen♦,
			Novartis Pharma♦,
			Eli Lilly♦,
			Genmab/Roche,
			Fibrogen♦,
			Others

We expect to receive milestone payments as these product candidates move through the regulatory process, and royalties on product sales, should commercialization occur.

We received an equity interest in Genmab in exchange for a license of our proprietary antibody technology. We are not entitled to license fees, milestone payments or royalties from the license of this particular product candidate.

We received an equity interest in Genmab in exchange for a license of our proprietary antibody technology. In addition, we expect to receive milestone payments for activities in Europe and Asia, as well as royalties on product sales in Europe and Asia that could reach double-digits, should commercialization of zanolimumab occur.

We expect to receive double-digit royalties on product sales, should commercialization occur.

+

#### Selected Proprietary and Partnered Product Candidates in Clinical Development

**Ipilimumab** (Anti-CTLA-4 Antibody) *Melanoma and other cancers.* Ipilimumab, previously known as MDX-010, is a fully human antibody targeting the cytotoxic T-lymphocyte antigen 4 immune receptor, known as CTLA-4, that we are developing jointly with Bristol-Myers Squibb Company, or BMS. CTLA-4 is a molecule found on the surface of T-cells that plays a critical role in regulating natural immune responses. The absence or presence of CTLA-4 can augment or suppress the immune response in fighting disease. Ipilimumab is designed to block the activity of CTLA-4, thereby sustaining an active immune response in its attack on cancer cells. We and BMS are pursuing a broad clinical development program with ipilimumab to evaluate its potential use as monotherapy or in combination with other cancer therapies in multiple registrational/Phase 3 trials that are ongoing or being planned for melanoma and prostate cancer; and in ongoing Phase 2 or earlier trials in lung, pancreatic, bladder, breast, lymphoma and leukemia cancers. A more detailed description of our collaboration with BMS is included herein under the section entitled "Our Antibody Partnerships BMS."

*Registrational/Phase 3 Programs in Melanoma:* We and BMS are pursuing a comprehensive registrational strategy for ipilimumab in metastatic melanoma, including clinical studies in second-line (previously treated), first-line (previously untreated) and adjuvant (surgically resected) treatment settings.

The ipilimumab registrational monotherapy program in second-line melanoma enrolled 487 patients diagnosed with advanced Stage III or Stage IV metastatic melanoma from three clinical trials conducted at multiple centers across North America, Europe, South America and Africa. The registrational trials included an open-label, single arm trial (008) evaluating efficacy in 155 patients who progressed on or following standard treatment; a randomized, double-blind trial (022) evaluating the efficacy of three dose levels (0.3, 3 or 10 mg/kg) of ipilimumab in 216 patients who were previously treated, relapsed or failed to respond to experimental treatment or were unable to tolerate currently approved therapies; and a randomized, double-blind, placebo-controlled trial (007) in 116 patients comparing the safety of ipilimumab, with or without prophylactic oral budesonide (primarily evaluating the rate of grade 2+ diarrhea). The U.S. Food and Drug Administration, or FDA, reviewed this program in November 2005 and, with respect to one study (008), entered into a Special Protocol Assessment Agreement, or SPA, in March 2006 concerning the suitability of the trial design, together with the totality of data from the program, to support regulatory approval.

In December 2007, we announced top-line data from these three registrational monotherapy trials (008, 022, 007). The results from study 008 did not achieve a target rate on its primary endpoint of best objective response, which was to rule out a best objective response rate of less than 10 percent, the conventional standard recommended by the Oncology Division Advisory Committee of the FDA as a guideline applied to uncontrolled studies. However, the totality of the data across the program as a whole included clear dose response data between the highest and lowest doses (study 022) and objective response data across the three studies that were consistent with observations from earlier clinical trials, including complete and partial responses and stable disease. In addition, patterns of response were observed that were potentially unique to this form of therapy that were noted to evolve over time. Overall, the safety results from the three registrational studies were generally consistent with data from previously reported clinical trials of ipilimumab. In 2008, we expect to present to the FDA the totality of the data from the three registrational trials with a goal of filing a Biologics License Application, or BLA. We also expect to present the data from these registrational trials at a medical conference in the second quarter of 2008.

In early 2008, we expect to complete enrollment of approximately 500 patients in a randomized, double-blind, two-arm Phase 3 trial (study 024) of ipilimumab in combination with dacarbazine (chemotherapy) or placebo in patients with previously untreated, unresectable Stage III or Stage IV metastatic melanoma (first-line). This trial was reviewed by the FDA under a SPA concerning the



suitability of the trial design to support regulatory approval. Data from this trial is expected in late 2008 or early 2009. In addition, in 2008, a Phase 3 trial of ipilimumab in the adjuvant setting (study 029) is expected to begin enrollment of up to 950 patients with surgically resected high-risk Stage III metastatic melanoma through the European Organization for Research and Treatment of Cancer.

We and BMS continue to evaluate the relative priorities of these studies and other ongoing studies in light of regulatory feedback, new clinical data, enrollment rates and other factors relevant to the timing of potential BLA filings.

*Fast Track and Orphan Drug Status:* In December 2006, the FDA granted Fast Track status for ipilimumab used as a monotherapy in previously treated metastatic melanoma patients and for ipilimumab used in combination with chemotherapy (dacarbazine) in previously untreated metastatic melanoma patients. In October 2004, the FDA granted Fast Track status for ipilimumab in combination with MDX-1379 for the treatment of second-line patients with unresectable Stage III or Stage IV melanoma. Fast Track status provides for expedited regulatory review for potential new drugs that demonstrate the potential to address unmet medical needs for the treatment of serious or life-threatening conditions. In June 2004, the FDA granted orphan drug designation to ipilimumab for the treatment of high risk Stage II, Stage III and Stage IV melanoma.

*Other Ongoing and Planned Studies:* As part of our joint ipilimumab clinical development collaboration with BMS, we are collaborating with BMS on the design and initiation of a Phase 3 trial in patients with prostate cancer. There are also multiple Phase 2 and early clinical trials underway or expected to commence in multiple tumor types. Some of these studies are designed to support our registrational/Phase 3 programs in melanoma and prostate cancers, and other studies are designed to explore the activity of ipilimumab in additional disease indications as monotherapy and in combination with other cancer therapies.

**MDX-060 and MDX-1401 (Anti-CD30 Antibodies)** *Lymphoma.* We are developing two fully human antibodies, MDX-060 and MDX-1401, that target CD30, a marker for activated lymphocytes that is present on the malignant cells of Hodgkin's disease, or HD, as well as other CD30-expressing cancers. MDX-1401 is a non-fucosylated version of the MDX-060 parental antibody and is enhanced for greater antibody-dependent cellular cytotoxicity, or ADCC, activity, an important mechanism in tumor lysis by antibodies. A Phase 2 proof-of-concept trial of MDX-060 in combination with genetiabine is ongoing in up to 72 patients with HD. A multi-dose, dose-escalation Phase 1 trial of MDX-1401 is underway and expected to enroll up to 36 patients with relapsed or refractory HD.

The FDA has granted orphan drug designation for MDX-060 for the treatment of CD30-positive T-cell lymphoma and for the treatment of HD.

**MDX-1100** (Anti-IP10 Antibody) Ulcerative Colitis, Rheumatoid Arthritis. We are developing MDX-1100, a fully human antibody that targets IP10 (also known as CXCL10), a chemokine expressed in association with multiple inflammatory disease indications such as rheumatoid arthritis, inflammatory bowel disease and multiple sclerosis. Data from a completed single-dose Phase 1 safety trial in 52 healthy volunteers showed that MDX-1100 was well-tolerated up to 10 mg/kg, in addition to demonstrating pharmacokinetics and biomarker activity. A multi-center, single-dose, dose-escalation Phase 1 trial is ongoing in up to 32 patients with ulcerative colitis. Phase 2 proof-of-concept clinical trials in ulcerative colitis and rheumatoid arthritis are planned to initiate in 2008.

**MDX-066 and MDX-1388 (Anti-Toxin A and Anti-Toxin B Antibodies)** *Clostridium difficile Associated Diarrhea.* MDX-066 (also known as CDA-1) and MDX-1388 (also known as CDA-2) are fully human antibodies that we are co-developing with the Massachusetts Biologic Laboratories of the University of Massachusetts Medical School, or MBL. MDX-066 and MDX-1388 are designed to target Toxin A and Toxin B, respectively, the toxins produced by the bacterium *Clostridium difficile*, which are associated with a serious and sometimes deadly form of diarrhea called *Clostridium difficile* associated diarrhea, or CDAD. A randomized, double-blind, single-dose, placebo-controlled Phase 2 clinical trial

of MDX-066 in combination with MDX-1388 is ongoing in up to 200 patients with CDAD and is designed to assess the efficacy of the combination of the two antibodies against placebo as an addition to standard of care antibiotics to resolve CDAD more quickly and to prevent subsequent relapse of disease. We expect to share certain research and development costs associated with this product, as well as profits or losses associated with its commercialization, on a 50/50 basis.

**MEDI-545 and MEDI-546 (Anti-Type 1 IFN Antibodies)** *Systemic Lupus Erythematosus.* Pursuant to a collaboration with us, MedImmune, Inc. (wholly owned by AstraZeneca plc), or MedImmune, is developing MEDI-545 (previously known as MDX-1103) and MEDI-546 (previously known as MDX-1333), fully human antibodies that target two different components of the Type 1 IFN pathway, which is believed to be involved with systemic lupus erythematosus, or SLE, disease activity. MEDI-545 is an antibody designed to block multiple Type 1 IFNα subtypes, and MEDI-546 is an antibody in preclinical development that is designed to block the receptor of Type 1 IFNα.

MedImmune is evaluating MEDI-545 in a multi-dose Phase 1b trial and a single-dose Phase 1 trial in SLE, and a dose-escalation Phase 1 trial in psoriasis. In December 2007, MedImmune highlighted data from a Phase 1 study assessing the safety and efficacy of MEDI-545 treatment, which showed consistent evidence of clinical activity across multiple measures of disease in patients with mild-to-moderate SLE. Under the collaboration, MedImmune is responsible for the continued development of these antibodies. Prior to the initiation of a pivotal trial, we may elect to co-develop and co-promote in return for a profit-share in the U.S.

**MDX-1106** (Anti-PD-1 Antibody) *Cancer, HCV.* MDX-1106 (also known as ONO-4538) is a fully human anti-PD-1 antibody that we are co-developing with Ono Pharmaceutical and hold 100% commercial rights in North America. MDX-1106 is designed to target PD-1, a receptor expressed on the surface of activated lymphocytes and is potentially involved in tumor evasion of immune system responses. A dose-escalation Phase 1 safety trial is ongoing in up to 48 patients with recurrent or treatment-refractory solid tumors (including melanoma, renal, ovarian and prostate cancers). A single-dose, dose-escalation Phase 1 safety trial will enroll up to 34 patients with active hepatitis C genotype 1 infection (HCV). We have the right to develop and commercialize MDX-1106 in North America, and Ono has the right to develop MDX-1106 outside of North America, in each case subject to payment of a royalty to the other party on sales in such territories, should commercialization occur.

**MDX-1342** (Anti-CD19 Antibody) Chronic Lymphocytic Leukemia, Rheumatoid Arthritis. We are developing MDX-1342, a fully human antibody that selectively binds to CD19 expressed on B-cells (without targeting stem cells or fully differentiated plasma cells, which lack CD19 expression) and induces the depletion and elimination of CD19-positive B-cells. CD19 is a B-cell specific membrane protein that is broadly expressed during B-cell development and implicated in B-cell cancers, inflammatory diseases and autoimmune disorders. Two separate Phase 1 trials will establish and evaluate the safety and tolerability profile, as well as other factors, for the treatment of chronic lymphocytic leukemia, or CLL, and for rheumatoid arthritis, or RA. One is an open-label, multi-dose, dose-escalation Phase 1 trial that is expected to enroll up to 52 patients with relapsed or refractory CLL. The other is a randomized, single-dose, dose-escalation, placebo-controlled Phase 1 trial that is expected to enroll up to 90 patients with RA.

**MDX-1411 (Anti-CD70 Antibody)** *Cancer.* We are developing MDX-1411, a fully human antibody that targets the CD70 receptor, which is a member of the tumor necrosis factor family and expressed in a number of cancers. Our initial clinical trial is focused on the treatment of clear cell renal carcinoma, or ccRC. The open-label, multi-center, dose-escalation, multi-dose Phase 1 trial is expected to enroll up to 40 patients with advanced ccRC and designed to determine the safety, tolerability and maximum tolerated dose of MDX-1411, as well as to characterize preliminary efficacy and pharmacokinetics. Additional clinical trials are planned in other cancers, including lymphoma.

**Other Proprietary Product Candidates.** In addition to product candidates in clinical development, we are currently actively engaged in preclinical and research activities with respect to a number of additional product candidates that may move forward into clinical development in the future, including antibodies targeting PD-L1 or used as antibody-drug conjugates.

#### Selected Licensee Product Candidates in Clinical Development

**Ustekinumab** (Anti-IL-12/IL-23 Antibody) *Inflammatory Diseases.* Centocor, Inc., or Centocor, and Janssen-Cilag International NV (both members of the Johnson & Johnson family of companies) are developing ustekinumab (CNTO 1275), a human antibody generated from our UltiMAb® technology that targets IL-12/IL-23 for the treatment of inflammatory diseases and is being investigated as an infrequently administered subcutaneous injection. In February 2008, Centocor announced that the BLA for ustekinumab has been accepted for review by the FDA for the treatment of adult patients with chronic moderate to severe plaque psoriasis. Centocor also reported that the Marketing Authorization Application for ustekinumab was submitted in Europe in December 2007 and is currently under review by the European Medicines Agency, or EMEA. We expect to receive milestone payments as this product candidate moves through the regulatory process, and royalties on product sales, should commercialization occur.

**Golimumab** (Anti-TNF $\alpha$  Antibody) Inflammatory Diseases. Centocor and its partner, Schering-Plough Corporation, are developing golimumab (CNTO 148), a next-generation human anti-TNF $\alpha$  antibody generated from our UltiMAb® technology for the treatment of inflammatory diseases. With ongoing Phase 3 studies for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, golimumab is being studied as a monthly subcutaneous injection and an every twelve-week intravenous infusion therapy. In November 2007, Centocor announced Phase 3 data showing that golimumab significantly improved arthritis, skin and nail manifestations in patients with psoriatic arthritis, and significantly reduced signs and symptoms of disease in patients with ankylosing spondylitis. Additionally, Centocor has stated that a BLA for golimumab is expected to be filed in the first half of 2008. We expect to receive milestone payments as this product candidate moves through the regulatory process, and royalties on product sales, should commercialization occur.

**Ofatumumab** (Anti-CD20 Antibody) *Lymphoma, Leukemia, Rheumatoid Arthritis*. Genmab A/S, or Genmab, and its partner, GlaxoSmithKline, are developing ofatumumab (HuMax-CD20), a fully human antibody generated from our UltiMAb® technology that targets CD20, a molecule found on B cells. According to Genmab, ofatumumab is in multiple Phase 3 studies for CLL, non-Hodgkin's lymphoma, or NHL, and rheumatoid arthritis. In addition, Phase 2 studies are ongoing for diffuse large B-cell lymphoma and for first-line treatment in CLL and NHL. We have an equity interest in Genmab, but are not entitled to license fees, milestone payments or royalties from the license of this particular product candidate.

**Zanolimumab** (Anti-CD4 Antibody) *T-cell Lymphomas.* Genmab is developing zanolimumab (HuMax-CD4), a fully human antibody generated from our UltiMAb® technology that targets the CD4 receptor on T-cells. According to Genmab, zanolimumab is in a Phase 3 trial for cutaneous T-cell lymphoma and in two Phase 2 trials for non-cutaneous T-cell lymphoma. We have an equity interest in Genmab. In addition, we expect to receive milestone payments for activities in Europe and Asia, as well as royalties on product sales in Europe and Asia that could reach double-digits, should commercialization of zanolimumab occur.

**Zalutumumab** (Anti-EGFr Antibody) *Cancer.* Genmab is developing zalutumumab (HuMax-EGFr), a fully human antibody generated from our UltiMAb® technology that targets EGFr, a receptor molecule that has been found in excess on many types of tumor cells. According to Genmab, zalutumumab is in two Phase 3 trials and one Phase 1/2 trial for head and neck cancer, and a Phase 2 trial in non small cell lung cancer. We have an equity interest in Genmab, but are not entitled to license fees, milestone payments or royalties from the license of this particular product candidate.

**Tremelimumab** (Anti-CTLA-4 Antibody) *Metastatic Melanoma, Cancer*. Pfizer, Inc., or Pfizer, is developing tremelimumab (CP-675,206), a fully human anti-CTLA-4 antibody generated by using transgenic mouse technology substantially similar to our UltiMAb® technology. According to Pfizer, tremelimumab is in Phase 3 development for melanoma, and in Phase 2 trials for lung, genitourinary and gastrointestinal cancers. We expect to receive double-digit royalties on product sales, should commercialization occur.

**ACZ885** (Anti-IL-1β Antibody) *Muckle Wells Syndrome, Others.* Novartis Pharma AG, or Novartis, is developing ACZ885, a fully human antibody generated from our UltiMAb® technology that targets IL-1β. According to Novartis, ACZ885 is in Phase 3 development for Muckle Wells Syndrome, an inherited inflammatory disease caused by a rare genetic mutation, with a submission for regulatory approval planned for 2009. ACZ885 is also in Phase 2 trials for systemic juvenile arthritis, rheumatoid arthritis, chronic obstructive pulmonary disease, Type 2 diabetes and other inflammatory diseases. We expect to receive milestone payments as this product candidate moves through clinical trials, and royalties on product sales, should commercialization occur.

**Other Product Candidates.** Our licensing partners have active early clinical and preclinical development programs that we anticipate may lead to the identification of new antibody product candidates and novel combinations with antibodies currently in development. We expect these development efforts to lead to additional clinical candidates in both the near and long term. We are aware of a number of other antibody product candidates derived from our UltiMAb® technology for which our licensing partners have commenced Phase 2 or Phase 1 clinical trials, including antibodies for disclosed and undisclosed disease indications by Amgen, Novartis, Eli Lilly and Genmab/Roche. In general, we expect to receive milestones as these product candidates move through the regulatory process and royalties on product sales, should commercialization occur.

#### **Our Antibody Technology Platforms**

Antibodies are natural proteins produced in the human body by B cells and serve as an important defense against disease. Human B cells produce millions of different types of antibodies, all with varying shapes that allow them to attach to and, as a result, neutralize different disease targets. For example, certain antibodies seek out and attach to viruses, bacteria and diseased cells, making them susceptible for destruction by the human immune system. Others attach to specific disease targets and block their interaction with other molecules or can be used to deliver a cytotoxic agent to directly kill cancer cells.

#### The UltiMAb® Technology Platform

Our solution to making antibodies with fully human protein sequences is to use transgenic strains of mice in which mouse antibody gene expression is suppressed and replaced with human antibody gene expression. Because our mice contain genes encoding human antibodies, we believe the antibodies we generate are more likely to have favorable safety profiles and be eliminated less rapidly from the human body, potentially reducing the frequency and amount of dosing required to affect disease targets. Additionally, our fully human antibodies with lowered binding affinities for their respective targets. Our human antibody technology includes (i) our HuMAb-Mouse® technology, (ii) Kirin's TC Mouse technology, and (iii) the KM-Mouse® technology, a crossbred mouse that combines the characteristics of our HuMAb-Mouse® with those of the TC Mouse . In total these technologies constitute our UltiMAb Human Antibody Development System®.

Our HuMAb-Mouse® technology refers to transgenic mice in which the mouse genes for creating antibodies have been disrupted and functionally replaced by human antibody genes. Our HuMAb-Mouse® transgenic strains contain key gene sequences from unrearranged human antibody genes that

code for both the heavy and light chains of human antibodies. Because genes determine what proteins are made, our transgenic mice make human antibody proteins. We have thus created mice that have the ability to make fully human monoclonal antibodies. This result avoids the need to humanize murine monoclonal antibodies, and because the human genes in our HuMAb-Mouse® are stable, they are passed on to the mice offspring and, therefore, bred indefinitely at relatively low cost and without additional genetic engineering. Our HuMAb-Mouse® can generate fully human antibodies with affinities in the picomolar range, or as high as  $10^{12}$  (molar<sup>[nc\_cad,220]1</sup>).

Through our collaboration with Kirin, we have access to the Kirin TC Mouse , which contains complete sets of the variable and constant genes found in the corresponding natural human immunoglobulin loci, including all heavy chain classes that encode all isotypes (IgG1-4, IgA1-2, IgD, IgM and IgE). The TC Mouse also has the ability to make fully human monoclonal antibodies. Together with Kirin, we have developed the KM-Mouse®, a crossbred mouse that combines the characteristics of our HuMAb-Mouse® with those of Kirin's TC Mouse , retaining the capability to produce all human antibody isotypes with an immune response that we believe is previously unseen in any human antibody producing mouse system.

Our unique technology platform constitutes what we believe to be the most complete technology solution available in the marketplace for generating fully human antibodies and enables us to produce antibodies that we believe set the industry standard in that they (i) are fully human, (ii) are of a very high affinity, and (iii) can be produced and manufactured relatively quickly and efficiently. We are not aware of any licenses required to create fully human antibodies using our UltiMAb® technology platform to a target owned by the user except under patents currently owned or licensed by us.

#### Antibody-Drug Conjugates

In addition to our human antibody technology, we are developing our proprietary Antibody-Drug Conjugate, or ADC, technology platform to complement our UltiMAb® platform and to generate and develop potentially significant antibody cytotoxic therapeutics for a variety of oncology indications. Our ADC platform includes a class of DNA alkylating agents, which have been designed to overcome multi-drug resistance. We expect to file an IND for our first ADC program in 2008.

#### Our Research, Development and Manufacturing

Our product development efforts are supported by our experience in both generating and developing numerous human antibodies and in manufacturing clinical supply materials. We believe this experience, together with access to novel therapeutic targets, will allow us to rapidly generate and develop a large, diverse pipeline of fully human antibody products. We intend to develop some of these product candidates for our own account and some in collaboration with other companies, leveraging their respective research and development resources.

Our antibody generation resources include highly trained teams of scientists in our research facilities located in Milpitas and Sunnyvale, California, as well as scientists in Annandale and Bloomsbury, New Jersey, who work with our UltiMAb Human Antibody Development System® to generate antibodies for our own development and for our partners. These scientists are experienced in molecular biology, protein chemistry, animal biology, pharmacology, toxicology, process science and formulation development. Other development resources include in-house medical professionals with product development expertise in oncology, infectious diseases, rheumatology, immunology and pulmonology, and consulting arrangements with leading academic researchers.

In addition to our experience in generating antibodies, we have considerable experience in clinical development and clinical supply antibody manufacturing. To facilitate the development and commercialization of antibody-based products for us and for our partners, we have assembled a team of

experienced scientific, production and regulatory personnel. This team operates in Bloomsbury, New Jersey, and in our clinical trial material manufacturing production facility in Annandale, New Jersey.

Our Bloomsbury, New Jersey, research and development facility is situated on approximately 135 acres of land and currently contains space for approximately 165,000 square feet of laboratory and office space. We completed a renovation of these facilities in 2004 and currently use approximately 100,000 square feet in these facilities, accommodating approximately 200 employees engaged in antibody research, development and manufacturing.

We lease approximately 45,000 square feet of laboratory, clinical trial production and office space in Annandale, New Jersey, where we manufacture antibody products for use in clinical development and clinical trials conducted by us and by certain of our partners. Our Annandale facility currently has the capacity to develop up to 15 antibody projects per year and operates in accordance with current good manufacturing practices, or cGMP, regulatory requirements for the manufacture of clinical trial materials. We believe that our existing facility in Annandale is adequate for the production of materials for clinical trials of our products and for providing the support we offer to certain of our partners in connection with our human antibody technology in the near-term. In September 2003, we entered into a clinical supply agreement with Lonza Group Ltd. with respect to ipilimumab and MDX-060. Our partner BMS is responsible for securing commercial supply arrangements for ipilimumab and is currently in negotiations with respect to 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.

#### **Our Antibody Partnerships**

As of February 1, 2008, we have more than 35 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to enable other companies to use our UltiMAb® technology in their development and commercialization of new therapeutic products.

#### BMS

In 2005, we entered into a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. Under the terms of the collaboration, we and BMS have each granted the other certain intellectual property licenses and product rights on a worldwide basis to enable us to collaborate in the 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® technology, that is antagonistic to CTLA-4. Ipilimumab is currently under investigation for the treatment of a broad range of cancers. A more detailed description of our ipilimumab development program is included herein under the section entitled "Products in Development."

As part of the collaboration, BMS is responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the U.S. and Europe, with the remaining 35% to be paid by us. We and BMS will share equally the costs of any clinical trials of products intended solely for regulatory approval in the U.S., and BMS will be fully responsible for all development costs that relate solely to regulatory approval in Europe and other parts of the world.

Under the terms of the collaboration, we have the option to co-promote any product in the U.S. If we exercise a co-promotion option with respect to a product for use in the first cancer indication for which an initial regulatory approval filing is accepted by the FDA, we will have the right and obligation to co-promote such product for use in all cancer indications, even if such indications are the subject of additional filings or approvals, and even if we opted-out of the development of any such indication.

Even if we elect to co-promote a product for cancer indications, however, we would need to exercise a separate option to co-promote that product with respect to any indication other than cancer. If we do not exercise our co-promotion option with respect to a product for use in the first cancer indication for which an initial regulatory approval filing is accepted by the FDA, then we will not have the right or obligation to co-promote such product for any cancer indications, unless the filing for that first cancer indication is not approved by FDA.

Under the terms of the collaboration, we could receive up to \$205.0 million from BMS if all regulatory milestones are met, plus up to an additional \$275.0 million in sales-related milestones. In addition, if we exercise our co-promotion option with respect to ipilimumab for the metastatic melanoma indication, and regulatory approval is obtained, we would receive 45% of any profits from commercial sales of such product in the U.S. In the event we choose not to exercise our co-promotion rights with respect to a product, BMS will have exclusive commercial rights in the U.S. and will pay us royalties on commercial sales. Regardless of whether or not we exercise our co-promotion option, outside the U.S., BMS will have exclusive commercial rights for products and will pay us royalties on commercial sales.

Pursuant to these agreements, BMS made an initial cash payment to us of \$25.0 million and also purchased 2,879,223 shares of our common stock at \$8.6829 per share, for \$25.0 million in cash.

A description of the termination provisions of the BMS collaboration is included herein under Note 9 ("Collaboration Agreements") to the Consolidated Financial Statements.

#### Pfizer

In 2004, we entered into a series of agreements with Pfizer. The first agreement, or the Pfizer Amendment, amended our existing collaborative research and license and royalty agreements with Pfizer to provide for the discovery and development of up to 50 antibody products over ten years. The second and third agreements were a sublicense by us to Pfizer and a cross-license of certain patents and patent applications solely relating to our respective anti-CTLA-4 antibody programs, together, the Pfizer Licenses. The fourth agreement was a stock purchase agreement also related to the anti-CTLA-4 programs. Pursuant to certain of these agreements, Pfizer made an initial cash payment to us of \$80.0 million and purchased, through its wholly-owned subsidiary Pfizer Overseas Pharmaceuticals, 4,827,808 shares of our common stock at \$6.21 per share, for \$30.0 million in cash.

Under the Pfizer Amendment, we expect to use our UltiMAb® technology to generate product candidates to disease-associated targets identified by Pfizer. We will receive standard market rates for performing these antibody-making services. The product candidates generated by the collaboration will then be transferred to Pfizer, which will be fully responsible for the worldwide development and commercialization of such product candidates, including the payment of all costs and expenses related thereto. We have no future payment obligations relating to the development and commercialization of these product candidates. We have the potential to receive research funding, license fees and milestone payments, if certain development milestones are met, as well as royalties on any commercial sales of the products.

We and Pfizer have retained all rights to our respective separate anti-CTLA-4 products. Pursuant to the Pfizer Licenses, which are non-exclusive, we have the potential to receive milestones and double-digit royalty payments based upon commercial sales of any Pfizer anti-CTLA-4 antibody product whether or not such product was generated using our UltiMAb® technology. In contrast, we have no future payment obligations to Pfizer in connection with any anti-CTLA-4 product we may develop. Both we and Pfizer are independently developing antibodies to CTLA-4, including our ipilimumab and Pfizer's tremelimumab product candidates.



A description of the termination provisions of our agreements with Pfizer is included herein under Note 9 ("Collaboration Agreements") to the Consolidated Financial Statements.

#### Our 50/50 Collaborative Partnerships

We have continued to increase our access to novel therapeutic targets by establishing collaborations with other companies and institutions that have identified potential therapeutic targets or have created platforms for the identification of such targets. We actively seek opportunities to in-license and/or acquire such targets and intend to develop novel therapeutic products by producing fully human antibodies that interact with such targets. Typically, a collaborator will provide one or more target antigen(s), and we will generate and develop antibodies against the antigen(s) using our UltiMAb® technology. We and our collaborators typically agree to share equally the costs of clinical development and manufacturing, as well as revenues, expenses and profits associated with any products arising under the collaboration. We believe this allows us to participate in the research and development of substantially more potential candidates than we could develop on our own if we bore the entire cost of development. Our partnered product candidates are listed under "Products in Development" above.

#### **Our Out-Licensing Partnerships**

Our licensing partners typically obtain licenses to one or more of our antibody generating technologies which allow these partners to develop and commercialize antibody-based products using our technology. We could receive license fees, milestone payments and royalties on product sales in connection with each of these products. Under these licenses, there is usually an initial period during which our licensing partner may elect to enter into a research license for antibodies to a particular designated target. Subsequently, our partner may elect to obtain a commercial license for one or more specific monoclonal antibodies. In some cases, once a partner has obtained a commercial license for monoclonal antibodies to a given target, we can no longer license our human antibody technology to a different company for that particular target.

The financial terms of our licensing partnerships typically include license fees and a series of milestone payments commencing upon initiation of clinical trials and continuing through to commercialization. These fees and milestones may total up to \$7.0 to \$10.0 million per antibody if the antibody receives approval from the FDA or equivalent foreign agencies. A licensing partnership may involve multiple antibodies. Under these partnerships, we expect to also receive royalties on any product sales. In some cases, our partners reimburse us for research and development activities we conduct on their behalf. Generally, under the terms of these agreements, our partners are responsible for all costs of product development, manufacturing and commercialization of any products. Certain product candidates under development by our Licensees of which we are aware are listed under "Products in Development" above.

#### Our Cross-Licensing and In-Licensing Partnerships

#### Kirin

In 2002, we entered into a collaboration and license agreement with Kirin, which contains cross-licenses for certain of each other's technologies for the development and commercialization of human antibody products. Under the collaboration and license agreement, we and Kirin developed the KM-Mouse®, a unique crossbred mouse that combines the traits of our HuMAb-Mouse® with Kirin's TC Mouse and exchanged cross-licenses 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 December 31, 2007, we have not made any milestone payments to Kirin, although approximately \$2.8 million has been paid to Kirin as of December 31, 2007 representing a payment due

Kirin as a result of our collaboration with Pfizer. Based on products we are developing which use or we believe may use Kirin technology and that (i) are currently in clinical trials, or (ii) we anticipate may enter clinical trials through the end of 2009, we may be required to make milestone payments to Kirin aggregating up to approximately \$8.5 million with respect to such products. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

whether or not a decision is made to request a license from Kirin;

the type of license requested (research or commercial);

the success and timing of development efforts and clinical trials of product candidates covered by any such licenses;

the type of product developed (payment obligations differ depending on whether a product is an *ex vivo* therapeutic, *in vivo* therapeutic, research reagent or diagnostic product); 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 we may be obligated to make payments to Kirin in the future is subject to the success of our efforts with respect to products we are developing that utilize the Kirin technology and, accordingly, is inherently uncertain.

Unless terminated earlier, the collaboration and license agreement with Kirin 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 Cross-Licensing and In-Licensing Partnerships**

In addition to our collaboration with Kirin, we have entered into a number of other agreements that contain in-licenses of third-party technology which may be used together with our own platform technologies for the generation, development and/or manufacture of our antibody products. We have also entered into other third-party agreements that contain licenses associated with antibody products that target specific antigens. Many of these agreements contain milestone payments, which we will be required to pay, that become due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of our products currently under development trigger such milestone payments. Through December 31, 2007, we had made milestone payments of approximately \$1.7 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of 11 products we are developing for which milestones are potentially due and that (i) are now in clinical trials, or (ii) which we anticipate may enter clinical trials before the end of 2009, we may be obligated to make future milestone payments aggregating up to approximately \$63.9 million with respect to such products. In general, potential milestone payments for our antibody products may or may not be triggered under these licenses, and may vary in size, depending on a number of variables, almost all of which are currently uncertain. Typically, the events that trigger these payments per product include:

submission of IND(s) or foreign equivalents;

commencement of Phase 1, Phase 2 and/or Phase 3 clinical trials or foreign equivalents;

submission of BLA(s) or foreign equivalents; and

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

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

#### Strategic Investments

#### Genmab

We originally owned approximately 44% of Genmab A/S, a Danish biotechnology company listed on the Copenhagen Stock Exchange. We have various licensing and co-partnering arrangements with Genmab. See "Products in Development". As a result of a series of transactions, including a sale of 2,500,000 shares of Genmab in February 2008 resulting in net proceeds to us of approximately \$151.8 million, and a sale of 2,578,500 shares of Genmab in February 2007 resulting in net proceeds to us of approximately \$152.1 million, our interest in Genmab has been reduced to approximately 5.1%.

#### Celldex

In 2004, we assigned and licensed to Celldex, our then wholly-owned subsidiary, certain intellectual property related to our vaccine technology, including the rights to CDX-1307 (previously known as MDX-1307), one of our product candidates for the treatment of cancer, as well as the IND associated with this product candidate.

In 2005, Celldex acquired Lorantis Limited and Alteris Therapeutics, Inc., privately held biotechnology companies. As a result of these transactions, our ownership percentage of Celldex was reduced to approximately 60%. In October 2007, Celldex executed a merger agreement with AVANT Immunotherapeutics, Inc., a publicly traded biotechnology company (NASDAQ: AVAN), which develops vaccines and other immunotherapies and has three commercialized products, including Rotarix® for the treatment of rotavirus. 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 on March 6, 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, which will be publicly traded, upon successful completion of the merger.

#### **Intellectual Property**

Proprietary protection for our products, processes and know-how is important to our business. Our practice is to file patent applications to protect technology, inventions, and improvements that we consider important to the development of our business. We also rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We plan to aggressively prosecute and defend our patents and proprietary technology.

We have filed applications for a number of patents, have been granted patents or have obtained rights relating to our technology platforms, and various product candidates.

As of December 31, 2007, we hold an ownership interest in a total of approximately 66 issued patents in the U.S. and 323 issued patents in foreign countries with respect to technologies and products. In addition, we hold an ownership interest in a total of 99 U.S. patent applications and 645

applications in foreign countries. We also hold exclusive and non-exclusive rights in numerous in-licensed patents and patent applications relevant to our business.

Our patent portfolio includes granted patents and applications directed to our UltiMAb® technology, including our HuMAb-Mouse® technology. This includes patents and applications that are wholly owned, jointly owned and in-licensed rights. These patents, most of which are in the same patent family, claim the transgene, the transgenic mouse and methods of obtaining high affinity antibodies, among others. Although our earliest patents in this portfolio will expire starting in 2008, the majority of the HuMAb-Mouse® technology patents expire between 2011 and 2015. In addition, we continue to file patent applications directed to improvements in our HuMAb-Mouse® technology. Still further, our patent portfolio directed to improvements in the mouse technology that is jointly owned with Kirin will expire in 2022.

Our patent portfolio includes granted patents and applications directed to our UltiMAb® products, including patent filings claiming human antibodies against dozens of targets. These include patent applications describing several of our particular human antibody product candidates, such as our anti-CTLA-4 (ipilimumab), anti-CD30 (MDX-060, MDX-1401), anti-PD-1 (MDX-1106), anti-PD-L1 (MDX-1105), anti-IP10 (MDX-1100), anti-CD19 (MDX-1342) and CD70 (MDX-1411) product candidates.

Our patent portfolio also includes granted patents and applications directed to our ADC technology, including patent filings relating to toxins and linkers, as well as antibody-drug conjugates *per se*. These patent filings are wholly owned, and we continue to file patent applications directed to improvements and new embodiments of our inventions. The earliest of these patents will expire in 2022.

We have been assigned patent rights relating to MEDI-545 and MEDI-546 by Nufarm, B.V., Medisup International N.V., Pharma Pacific Pty. Ltd and Laboratorie European de Biotechnologie. We have acquired patent rights relating to MDX-1100 through our acquisition of Ability Biomedical. In addition, we have acquired patent rights from Corixa Corporation relevant to our ADC technology.

In 2007, 18 U.S. provisional or utility patent applications and 10 Patent Cooperation Treaty, or PCT, applications were filed by or on behalf of Medarex.

From time to time, we may decide to selectively divest some of our patents or pending patent applications as our business evolves. Multiple provisional U.S. applications may be combined in a single U.S. and/or PCT filing; provisional U.S. filings expire in favor of a PCT filing which will eventually become national stage filings in the U.S. and other countries; and applications containing multiple inventions may be filed separately in multiple divisional applications. Thus, these patent and patent application counts will not always correspond from year to year.

In addition to the patents and patent applications in which we hold an ownership interest, we hold exclusive and non-exclusive licenses to many other patents and applications, including the license to the Abgenix, Inc., or Abgenix, (and now Amgen) intellectual property mentioned below. For example, these technologies include microinjection of transgene DNA, homologous recombination, chromosome transfer, yeast artificial chromosome transgene technology and other relevant technologies. We also hold an exclusive sub-license to intellectual property created at the University of California relating to aspects of ipilimumab and also have licenses from BMS and Pfizer concerning other intellectual property related to ipilimumab. We have a license from the U.S. Public Health Service with respect to MDX-1379.

We own registrations for the following trademarks in the listed jurisdictions: Medarex® in the U.S., the European Union, Canada, Australia and Switzerland; HuMAb-Mouse®, UltiMAb Human Antibody Development System® in the U.S., Canada and European Union; KM-Mouse® and Putting the Immune System to Work in the European Union; GenPharm® in the U.S.; and UltiMAb® in the European Union.



#### **Regulatory Issues**

#### General

The production, distribution and marketing of products employing our technology, and our research and development activities, are subject to extensive governmental regulation in the U.S. and in other countries. In the U.S., our products are regulated both as drugs and as biological products and are subject to the Federal Food, Drug, and Cosmetic Act, as amended, the Public Health Service Act, as amended, and the regulations promulgated under these statutes, as well as to other federal, state, and local statutes and regulations. These laws, and similar laws outside the U.S., govern the clinical and non-clinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record keeping, reporting, advertising and promotion of our products. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA's and other health authorities' delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions, including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions and/or civil or criminal penalties.

The following paragraphs provide further information on certain legal and regulatory issues with a particular potential to affect our operations or the future marketing of products employing our technology.

*Research, Development, and Product Approval Process.* The research, development, and approval process in the U.S. and elsewhere is intensive and rigorous, and generally takes many years. The typical process required by the FDA before a therapeutic drug or biological product may be marketed in the U.S. includes:

submission to the FDA of an application for an IND, which must become effective before human clinical trials may commence;

preliminary human clinical studies to evaluate the drug or biologic and its manner of use; adequate and well-controlled human clinical trials to establish (i) for a drug or a biological product (such as an antibody), whether it is safe and effective for its intended uses, and (ii) for a biological product, whether it is also pure and potent;

FDA review of whether the facility in which the drug or biologic is manufactured, processed, packed or held meets standards designed to assure the product's continued quality; and

submission of an appropriate product application to the FDA, and approval of the application by the FDA.

During preclinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations, and are subject to good laboratory practices requirements. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. An IND must be submitted to the FDA and become effective before studies in humans may commence.

Clinical trial programs in humans generally follow a three-phase process. Typically, Phase 1 studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease, to determine the metabolic and pharmacological action of the product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase 2, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the



safety profile of the product candidate. In Phase 3, large-scale clinical trials are generally conducted in hundreds of patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate as required by U.S. and foreign regulatory agencies.

In the case of products for cancer and certain other life-threatening diseases, the initial human testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will also provide results traditionally obtained in Phase 2 studies. These studies are often referred to as "Phase 1/2" studies. Notwithstanding the foregoing, even if patients participate in initial human testing and a Phase 1/2 study carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

Before proceeding with a study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment, or SPA. Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product's efficacy. Where the FDA agrees to an SPA, the agreement may not be changed by either the sponsor or the FDA except if the sponsor and the FDA agree to a change, or a senior FDA official determines that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the testing began. SPAs thus help establish up-front agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

U.S. law requires that studies conducted to support approval for product marketing be "adequate and well controlled." In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice, or GCP, requirements, and informed consent must be obtained from all study subjects.

The clinical trial process for a new compound can take 10 years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, who must review and approve all research involving human subjects, or by data safety monitoring committees, who also monitor certain studies to protect the welfare of study subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market.

Following the completion of clinical trials, the data are analyzed to determine whether the trials successfully demonstrated safety and effectiveness, and whether a product approval application may be submitted. In the U.S., if the product is regulated as a drug, a New Drug Application, or NDA, must be submitted and approved before commercial marketing may begin. If the product, such as an antibody, is regulated as a biologic, a BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness (and, in the case of a biologic, purity and potency) of the compound from laboratory, animal and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

Each domestic and foreign biopharmaceutical manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA or BLA and must be registered with the FDA. The application will not be approved until the FDA conducts a manufacturing inspection,

approves the applicable manufacturing process for the drug or biological product, and determines that the facility is in compliance with cGMP requirements.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing a BLA or NDA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For fiscal year 2007, the NDA or BLA review fee alone was \$896,200, and for fiscal year 2008 this fee is \$1,178,000, although certain limited deferrals, waivers and reductions may be available.

Each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will "file" the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable. The FDA has established performance goals for the review of NDAs and BLAs six months for priority applications and 10 months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. The FDA's review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval.

Significant legal and regulatory requirements also apply after FDA approval to market under an NDA or BLA. These include, among other things, requirements related to adverse event and other reporting, product advertising and promotion, and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

The regulatory framework applicable to the production, distribution, marketing, sale and/or reimbursement of our products may change significantly from the current descriptions provided herein in the time that it may take for any of our products to reach a point at which an NDA or BLA is approved.

*"Fast Track" Approval.* The Federal Food, Drug and Cosmetic Act, as amended, and FDA regulations provide certain mechanisms for the accelerated "Fast Track" approval of products intended to treat serious or life-threatening illnesses which have been studied for safety and effectiveness and which demonstrate the potential to address unmet medical needs. The procedures permit early consultation and commitment from the FDA regarding the preclinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, NDAs or BLAs to be approved on the basis of valid surrogate markers of product effectiveness, thus accelerating the normal approval process. Where the FDA approves a product on the basis of a surrogate marker, it requires the sponsor to perform post-approval, or Phase 4, studies as a condition of approval. In addition, the FDA may impose restrictions on distribution or promotion or both activities in connection with any accelerated approval, and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the product. Special rules would also apply to the submission to FDA of advertising and promotional materials prior to use.

*Orphan Drugs.* Under the Orphan Drug Act, special incentives exist for companies to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that

affect fewer than 200,000 people in the U.S. Companies may request that the FDA grant a drug orphan designation prior to approval. Products designated as orphan drugs are eligible for special grant funding for research and development, the FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications, and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity prevents the FDA approval of applications by others for the same drug and the designated orphan disease or condition. The FDA may approve a subsequent application from another entity if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another entity or a similar drug from receiving approval for the same or other uses.

#### Other U.S. Regulatory Requirements

In the U.S., the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, 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, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, 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, unfair competition, and other laws.

Moreover, we are now, and may become subject to, additional federal, state and local laws, regulations and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation and disposal of human tissue, waste and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

#### Foreign Regulatory Requirements

We and our collaborative partners are subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, we must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current U.S. law, there are significant restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

#### **Reimbursement and Pricing Controls**

In many of the markets where we or our collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls

by law and to drug reimbursement programs with varying price control mechanisms. Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence, such as published medical literature, and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

#### Competition

We face competition in several different forms. Our human antibody generation activities currently face competition from several companies and from other technologies. In addition, the actual products being developed by us or by our partners also face actual and potential competition.

The development of biotechnology and pharmaceutical products is a highly competitive business subject to rapid technological change. We know of many pharmaceutical and biotechnology companies conducting research or development of therapeutic monoclonal antibody products. Many of these companies have commenced clinical trials with, and several have successfully commercialized, antibody products. Some of these companies are also pursuing product development efforts for the same disease areas or against the same biological targets as we or our partners are pursuing.

We face competition from many companies that provide the services of generating monoclonal antibodies for antibody-based therapeutics. One competitor with respect to our human antibody technology has been Abgenix, which was acquired by Amgen, in April 2006. As a result of the cross-license agreement with GenPharm, our wholly owned subsidiary, Abgenix had offered to potential partners the use of its transgenic mouse known as XenoMouse® to generate fully human monoclonal antibodies.

In addition, we have entered into agreements with each of Kirin and Genmab, respectively, which 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. Certain of our other partners who have licensed our transgenic mouse technology also could compete with us with respect to the development and commercialization of certain antibodies.

In 2007, Regeneron Pharmaceuticals, Inc., or Regeneron, licensed its VelocImmune® monoclonal antibody generation technology to AstraZeneca, Astellas Pharma and Sanofi-aventis. Regeneron claims that its VelocImmune® mice have humanized immune systems that can be used to generate human antibodies, potentially enabling Regeneron, AstraZeneca and any other Regeneron licensees to compete with us in the generation of therapeutic antibodies. AstraZeneca also has access to antibody generation technologies through its ownership of Cambridge Antibody Technology Group plc (part of the AstraZeneca group of companies), or CAT.

Other companies are also developing, or have developed technologies for generating human or partially human antibodies. For example, Xenerex Biosciences (a subsidiary of Avanir Pharmaceuticals), or Xenerex, and XTL Biopharmaceuticals Ltd., or XTL, each have developed technology that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies in functionally modified mice.

Numerous other companies are developing therapeutic products comprising human antibody components. Furthermore, several companies are developing, or have developed, technologies not



involving animal immunization that result in libraries composed of numerous human antibody sequences. For example, phage display technology is being used by companies such as Dyax Corp., CAT, and MorphoSys AG to develop potentially therapeutic products comprising human antibody sequences. XOMA Ltd. and PDL BioPharma, Inc., or PDL BioPharma, both offer technologies to convert mouse antibodies into antibodies closely resembling human antibodies. Companies such as Johnson & Johnson, MedImmune (a subsidiary of AstraZeneca), Amgen, Biogen Idec, Inc., Novartis, Genentech, Inc., PDL BioPharma, Wyeth, BMS, Abbott Laboratories, Alexion Pharmaceutical, Inc. and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market and that are derived from recombinant DNA that comprise human antibody sequences. Numerous additional companies are developing therapeutic products comprising human antibody components.

We are aware of several pharmaceutical and biotechnology companies actively engaged in research and development of antibody-based products that have commenced clinical trials with or have successfully commercialized antibody products. Some of these companies, such as Pfizer, ImClone Systems, Johnson & Johnson, Wyeth, Amgen, Abbott, UCB Pharma, Biogen Idec, CAT (acquired by AstraZeneca), MorphoSys AG, Genentech, Inc., Human Genome Sciences, Millennium and PDL BioPharma are addressing diseases and disease indications that are being targeted by us and certain of our partners. For example, Pfizer is developing tremelimumab, an anti-CTLA-4 antibody in Phase 3 development, in potential competition with our product candidate, ipilimumab. Several of the foregoing companies are also licensees of our transgenic mouse technology. As we focus more on our activities in developing our own antibodies for cancer, infectious diseases and inflammatory diseases, the list of our competitors may extend to an even larger number of pharmaceutical and biotechnology companies. Many of these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development divisions than we have. In addition, many of these competitors, either alone or together with their partners, undertaking preclinical testing and human clinical trials, obtaining FDA and other regulatory approvals of such products and the manufacturing and commercialization of such products. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or other non-U.S. equivalent marketing approval and commercializing products more rapidly than us.

Other technologies can also be applied to the treatment of the diseases that we or our partners are pursuing. For example, antibody-drug conjugates monoclonal antibodies linked to toxins are being developed by others, such as ImmunoGen, Inc., Seattle Genetics, Inc. and Genentech, 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, or cytokines) 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, erythropoeitin, DNAse, tPA, glucocerebrosidase, PDGF, and a number of other biological response modifiers. Continuing development of new chemical entities and other drugs by pharmaceutical and other biotechnology companies also carries with it the potential discovery of agents for treating disease indications targeted by drugs that we or our partners are developing.

#### Marketing

Our potential products may be marketed and sold in several possible ways, depending on the product, including: solely by us, jointly by us and our collaborative partners, or solely by or on behalf of our collaborative or our licensing partners. Marketing and sales rights with respect to ipilimumab are subject to the terms of our collaboration with BMS. We believe that a small sales force could

successfully introduce and detail certain of our potential products that have concentrated marketplaces. Other products, however, may require a larger sales force. Currently, we have no sales force. We may develop our own internal sales force for these products if they proceed to commercialization.

We acknowledge that the successful marketing of some of our potential products may be beyond the capabilities of all but the largest pharmaceutical organizations. For this reason, we, along with our collaborative partners, may license to major pharmaceutical companies individual products serving large markets or those that will be widely distributed and/or detailed geographically, if the products are approved by the FDA. Our collaboration with BMS is an example of this kind of relationship.

#### Employees

As of December 31, 2007, we employed 500 full-time employees, of whom approximately 428 were engaged in research and development activities. As of that date, there were 72 employees involved in business development, legal, finance and other administrative functions. None of our employees is covered by a collective bargaining agreement. We have entered into employment contracts with certain of our executive officers. Our success will depend in large part upon our ability to attract and retain employees. We face competition for employees from other companies, research and academic institutions, government agencies and other organizations. We believe we maintain good relations with our employees.

#### **Available Information**

We were incorporated in the State of New Jersey on July 8, 1987. Our principal executive offices are located at 707 State Road, Princeton, New Jersey 08540. Our telephone number is (609) 430-2880.

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy our reports, proxy statements and other information at the SEC's public reference room at 100 F Street N.W., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. Our SEC filings are also available at the SEC's web site at *www.sec.gov*. In addition, you can read and copy our SEC filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street N.W., Washington, D.C. 20006.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC, on our website at *www.medarex.com*, by contacting the Investor Relations Department at our corporate offices by calling (609) 430-2880, or by sending an e-mail message to *information@medarex.com*. You can direct requests for literature to the information request section on our website.

#### Item 1A. Risk Factors

#### **Forward Looking Information**

This Annual Report contains forward-looking statements within the meaning of Sections 27A and 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations, beliefs, intentions, or strategies regarding the future. 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. Forward-looking statements include, without limitation, statements in this section, and in the sections entitled "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report regarding, among other things, uncertainties relating

to our technology; history of operating losses and anticipation of future losses; uncertainty of product development; uncertainty relating to competitive products, need for additional capital and uncertainty of change; uncertainty of patent and proprietary rights; management of growth, and risks of acquiring new technologies; uncertainties related to clinical trials; government regulation and uncertainty of obtaining regulatory approval; dependence on research collaborators and scientific advisors; uncertainty of health care reform measures and third-party reimbursement and risk of product liability. All forward-looking statements included in this Annual Report are based on information available to us as of the date hereof, and we do not assume any obligation to update any such forward-looking statements. Our actual results may differ materially from the results discussed in the forward-looking statements. Among the factors that could cause actual results to differ materially are the factors detailed below. Accordingly, in addition to the other information in this Annual Report, the following factors should be considered carefully. References to our products, business, financial results or financial condition should be considered to refer to us and our subsidiaries unless the context otherwise requires.

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.

Neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA or comparable foreign authorities or been commercialized. Product candidates employing our human antibody technology may not advance beyond clinical development and may not demonstrate clinical safety and effectiveness sufficient to obtain marketing authorization.

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

delays in product development, clinical testing or manufacturing;

slower than expected patient enrollment;

unplanned expenditures in product development, clinical testing or manufacturing;

failure in clinical trials;

failure to receive or delay in receipt of regulatory approvals;

emergence of superior or equivalent products;

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

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

election by our partners not to pursue product development;

failure by our partners to develop products successfully;

failure to receive adequate coverage and reimbursement for our products from health care payors;

changes in legal and regulatory requirements; and

failure to achieve market acceptance.

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

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

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

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

We have incurred large operating losses, and we anticipate that these losses will continue for the foreseeable future. In particular, as of December 31, 2007, we had an accumulated deficit of approximately \$990.7 million. Our net loss was \$27.1 million for the year ended December 31, 2007. Our net loss for the year ended December 31, 2007 includes a realized gain of approximately \$152.1 from the sale of a portion of our Genmab stock. Excluding this realized gain, our net loss for the year ended December 31, 2007 would have been \$179.2 million. 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.

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

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

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

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

changes in regulatory requirements for clinical trials;

delays in manufacturing;

costs and expenses associated with preclinical testing and clinical trials;

the timing of regulatory approvals, if any;

sales and marketing expenses; and

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

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

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

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

The SEC is conducting an informal inquiry into our historical stock option granting practices and related accounting and disclosures. In addition, the United States Attorney's Office for the District of New Jersey is conducting a grand jury investigation relating to the same matters. We understand that the governmental inquiry and investigation relate to the same subject matter underlying the investigation (the "Investigation") conducted by a special investigation committee of our independent directors relating to our stock option grant practices from 1996 through June 30, 2006. Based upon the information obtained in the Investigation, through July 2002, we had a practice, in many instances, of selecting dates for our stock option grants and restricted stock grants as of the date when the stock price was the lowest during the month of grant, without disclosing this practice in our public filings and without properly measuring the compensation expense on a date that the terms of the equity awards were finalized. Subsequent to July 2002, while this practice of selecting dates ceased by us in response to new legal and regulatory reporting requirements, there were two annual equity grants for rank and file employees for which the measurement dates differed from the grant dates recorded in our books and records, which the Investigation revealed were primarily a result of administrative delays, with no apparent intent to achieve favorable exercise prices. Based on the results of the Investigation, we restated our financial statements for the quarter ended March 31, 2006 and the years ended December 31, 2005, 2004 and 2003, respectively.

Criminal or civil charges could be filed against us and we could be required to pay significant fines or penalties in connection with either or both of the governmental inquiry and investigation or other governmental investigations. We have incurred, and continue to incur, substantial costs related to the governmental inquiry and investigation and they continue to cause a diversion of our management's

time and attention which could have a material adverse effect on our financial condition and results of operations. Any criminal or civil charges by the SEC or the U.S. Attorney's Office or any fines or penalties imposed by either the SEC or the U.S. Attorney's Office or other governmental agency could materially harm our business, results of operations, financial position and cash flows.

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

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

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

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

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

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

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

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

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

We will continue to expend substantial resources for research and development, including costs associated with developing our 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.

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 to do so, which may not be available to us on satisfactory terms or at all. In addition, if new indebtedness is incurred, the risks relating to our ability to service our indebtedness that we face could intensify.

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

limiting our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;

limiting our flexibility in planning for, or reacting to, changes in our business;

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

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

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

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

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

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

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

To obtain FDA approval to market a new drug product, we or our partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our partners will have to conduct extensive preclinical testing and "adequate and well-controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Delays associated with product candidates for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. Moreover, we will continue to be affected by delays associated with the preclinical testing and clinical trials of certain product candidates conducted by our partners over which we have no control. We rely on third parties, including our partners, academic institutions and clinical research organizations to conduct, supervise or monitor many of our clinical trials. We have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

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

the inability to manufacture sufficient quantities of qualified materials in accordance with current good manufacturing practices, or cGMPs, for use in clinical trials;

the need or desire to modify our manufacturing processes;

slower than expected rates of patient recruitment;

modification of clinical trial protocols;

the inability to adequately observe patients after treatment;

changes in regulatory requirements for clinical trials;

the lack of effectiveness during the clinical trials;

unforeseen safety issues;

delays, suspension or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site, or for some studies due to the data safety monitoring committee charged with overseeing the study as a whole; and

government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for our product candidates. In a number of instances, we have terminated the development of certain product candidates in the early stages of human clinical testing due to a lack of effectiveness.

Generally, our clinical trials, including our melanoma trials for ipilimumab, are conducted in patients with serious or life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product candidate is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our product candidates. In trials of ipilimumab, the most commonly reported drug-specific adverse events are primarily immune-related, ranging from mild in most cases to severe in a very few number of instances, and are consistent with the mechanism of action of CTLA-4 blockade. These events are organ-specific, principally involving the gastrointestinal tract (diarrhea or colitis), the skin (severe rash or pruritis), the endocrine glands (reduced pituitary function) and the liver (increased liver enzymes). Other than a very small number of fatalities not directly related to disease progression or complications of the disease being treated, representing approximately 1% of over 2,000 patients treated in all previous trials of ipilimumab, which may or may not be attributable to our product candidates, the majority of adverse events with ipilimumab, treatment and without further significant complications. From our collective experience in treating over 2,000 patients with ipilimumab, treatment guidelines have been established to ensure proper management and most of these adverse events are manageable and resolve following withdrawal of ipilimumab or appropriate medical therapy, such as corticosteroids. In addition, we and BMS are exploring potential biomarkers that may be predictive of clinical responses. We cannot assure you that additional safety issues will not arise with respect to our products in the future.

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

Clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for any of our product candidates. We expect to commence new clinical trials from time to time in the course of our business as our product development work continues. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of that product candidate as well

as other product candidates. Any change in, or termination of, our clinical trials could materially harm our business, financial condition and results of operations.

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

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

In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

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

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

establishment and demonstration of clinical efficacy and safety, especially as compared to conventional treatments;

cost-effectiveness;

alternative treatment methods;

reimbursement policies of government and third-party payors; and

marketing and distribution support for our product candidates.

In addition, many of our activities involve genetic engineering in animals and animal testing, controversial subjects which have generally received adverse publicity from animal rights activists and various other interest groups. Such adverse publicity could decrease market acceptance of products employing our technology.

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

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

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the government or third-party payors, the market for products employing our human antibody technology will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct post-marketing studies to demonstrate the cost-effectiveness of our products. Such studies may require

us to dedicate a significant amount of resources. Our product candidates may not be considered cost-effective. Third-party payors may not reimburse sales of products employing our human antibody technology, or enable us or our partners to sell them at profitable prices.

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

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

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

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

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

We may also encounter problems with the following:

production yields;

quality control and assurance;

shortages of qualified personnel;

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

changes in FDA requirements;

production costs; and/or

development of advanced manufacturing techniques and process controls.

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations,

a requirement for all pharmaceutical products. We are currently pursuing late-stage clinical and commercial supply agreements with cGMP-compliant third-party manufacturers with available capacity to meet our internal production timetables. We have entered into clinical supply agreements with Lonza with respect to ipilimumab and MDX-060. As part of our collaboration with BMS, we assigned to BMS the clinical supply agreement with respect to ipilimumab. Our partner BMS is responsible for securing commercial supply agreements for ipilimumab and is currently in negotiations with respect to such arrangements. BMS may not be able to successfully consummate such arrangements. We do not currently have the capability to manufacture our product candidates under development in large commercial quantities and have no experience in commercial-scale manufacturing. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin producing antibodies under cGMP regulations.

We cannot make assurances that we will be able to contract with such companies for clinical and/or commercial supply on acceptable terms or in a timely manner, if at all. Moreover, even if we are able to enter into clinical and/or commercial supply manufacturing arrangements with cGMP-compliant third-party manufacturers, we cannot assure you that such manufacturers will be able to produce products that are substantially equivalent to the product candidates that we have produced in our own facilities and used in our clinical trials. Such manufacturers may encounter difficulties in production scale-up, including problems involving production yields, quality control and quality assurance and shortage of qualified personnel. Moreover, they may not perform as agreed or may not continue to manufacture our products for the time required by us to successfully market our products. These third parties may fail to deliver the require quantities of our products or product candidates on a timely basis and at commercially reasonable prices. If such companies are not able to produce products that are substantially equivalent to our product candidates, the progress of our clinical trials and/or commercialization of our products may be delayed and our business, financial condition and results of operations may be materially harmed.

In addition, we and any third-party manufacturer will be required to register manufacturing facilities with the FDA and other regulatory authorities, and provide periodic product listing information on the products manufactured at each registered facility. The facilities will be subject to inspections confirming compliance with cGMP or other regulations. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other regulatory authorities can impose regulatory sanctions including, among other things, imposition of a shut down of manufacturing operations, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval.

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

We depend, in part, on our partners to support our business, including the development of product candidates generated through the use of our antibody technology. In particular, under the terms of our collaboration and co-promotion agreement with BMS, we have granted a license to commercialize our lead product candidate, ipilimumab, to BMS for the treatment of all diseases. We have also granted to BMS a sub-license to MDX-1379 for use in combination with ipilimumab for the treatment of metastatic melanoma. The successful development and commercialization of ipilimumab is dependent, in large part, on the actions of BMS, which are outside of our control. The failure of BMS to act in accordance with its obligations under the collaboration and co-promotion agreement or to prioritize or devote sufficient resources to ipilimumab development and commercialization, or a change of control of BMS, may cause us to incur substantial additional costs in order to develop and commercialize ipilimumab, which could materially harm our business.

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

We currently, or in the future may, rely on our partners to:

access proprietary antigens for the development of product candidates;

access skills and information that we do not possess;

fund our research and development activities;

manufacture products;

fund and conduct preclinical testing and clinical trials;

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

commercialize and market future products.

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

our partners have significant discretion whether to pursue planned activities;

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

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

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

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

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

Our licensing partners generally have the right to terminate our partnerships at any time. Our ability to continue our current partnerships and to enter into additional partnerships is dependent in large part on our ability to successfully demonstrate that our UltiMAb® 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® technology, engage in direct competition with us in the area of generating fully human monoclonal antibodies for antibody-based therapeutics. In addition, a company that has a strategy of purchasing companies rather than entering into partnership arrangements might have less incentive to enter into a collaboration agreement with us. Moreover, disputes may arise with respect to the ownership of rights to any technology or products developed with any current or future partner. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays or termination in the research, development or commercialization of product candidates. If we are not able to establish additional partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and

we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely:

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

significantly increase our need for capital; and/or

place additional strain on management's time.

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

# Due to the size of our equity interest in Celldex Therapeutics, Inc., we must consolidate the results of its operations in our financial statements, which may include significant losses.

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, 2007, our share, net of minority interest, of Celldex's net loss included in our financial statements was approximately \$10.5 million. In October 2007, Celldex and AVANT Immunotherapeutics, Inc. announced the signing of a definitive merger agreement. Closing of the merger is contingent upon a vote of approval by AVANT's current shareholders expected to take place at a special meeting of shareholders on March 6, 2008. It is expected that Medarex will own approximately 35% of the combined entity, which will be publicly traded, upon successful completion of the merger. A more detailed description of our relationship with Celldex is included herein under the section entitled "Strategic Investments Celldex."

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

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

We are exposed to equity price risk on our strategic investments in our publicly-traded partners, and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. Under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, these investments are designated as available-for-sale and are reported at fair value on our consolidated balance sheet. Unrealized holding gains and losses on available-for-sale securities are generally excluded from earnings and reported within other comprehensive income which is a separate component of shareholders' equity. Under our accounting policy, marketable equity securities are generally considered to be impaired if their fair value is less than our cost basis in such securities for more than six months, or some other period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of available-for-sale securities is considered to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. For the year ended December 31, 2006, we recorded an impairment charge of \$5.2 million on investments in partners whose securities are publicly traded. During the years ended December 31, 2007 and 2005, no impairment charges were recorded related to the value of our investments in publicly traded companies. If we deem these investments to be further impaired at the end of any future reporting period, we may incur additional impairment charges on these investments.

In addition, we have investments in several of our partners whose securities are not publicly traded. The value of our investments in these companies are inherently more difficult to estimate than our investments in publicly traded companies. We estimate the value of these investments by using information acquired from industry trends, management of these companies, financial statements and

other external sources. Specifically, our determination of any potential impairment of the value of privately held securities includes an analysis of the following for each company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financing and potential strategic alternatives. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is considered to be other than temporary. For the years ended December 31, 2007, 2006 and 2005, we recorded impairment charges of approximately \$2.1 million, \$0 and \$33.3 million, respectively, on our investments in privately-held companies. Approximately \$29.3 million of the 2005 impairment charge related to IDM Pharma prior to the share exchange with Epimmune, Inc., at which time IDM Pharma became a publicly-traded company. Future adverse changes in market conditions or adverse changes in operating results of these companies may also require an impairment charge in the future.

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

For us to pursue product development and commercialization plans, we will need to hire additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, sales and marketing, relevant law and finance. We may not be able to attract and retain personnel on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. If we are not able to attract and retain qualified personnel, our business, financial condition and results of operations may be materially harmed.

#### We have had and may continue to face product liability claims related to the use or misuse of products developed by us or our partners.

The administration of drugs to humans, in clinical trials or after approval and during commercialization, may expose us to product liability claims. Consumers, healthcare producers or persons selling products based on our technology may be able to bring claims against us based on the use of our product candidates in clinical trials and the sale of products based on our technology. Product liability claims may be expensive to defend and may result in large judgments against us. We have obtained limited product liability coverage for our clinical trials, under which coverage limits are \$20.0 million per occurrence and \$20.0 million in the aggregate. Although we believe these coverage limits are adequate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. We intend to increase our coverage limits as we progress into additional late-stage clinical trials and to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

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

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

We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapeutics. Some of these companies have commenced clinical trials of antibody product candidates or have successfully commercialized antibody products. Many of these companies are addressing the same disease indications as are we and our partners. Also, we compete with companies that offer antibody generation services to other companies that have disease related target antigens. These competitors have specific expertise or technology related to monoclonal antibody development. In the past, we competed directly with Abgenix, which merged with Amgen in April 2006, with respect to the generation of fully human antibodies from transgenic mice. Abgenix had offered potential partners the use of its XenoMouse® technology to generate fully human monoclonal antibodies. Regeneron has licensed its VelocImmune® monoclonal antibody generation technology to AstraZeneca, Astellas Pharma Inc. and Sanofi-aventis, potentially enabling such licensees to compete with us in the generation of therapeutic antibodies. Regeneron may also compete with us directly in the generation technologies through its ownership of Cambridge Antibody Technology. In addition, we have entered into agreements with each of Kirin and Genmab, respectively, that grant these companies licenses to our proprietary transgenic mouse technology platform, enabling them to compete with us in offering antibody generation and development services in certain markets.

Xenerex and XTL have developed technologies that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies in functionally modified mice. Numerous additional companies are developing therapeutic product candidates comprising human antibody components. Furthermore, several companies are developing, or have developed, technologies that do not involve immunization of animals for creating antibodies comprising human antibody sequences. XOMA and PDL BioPharma both offer technologies to convert mouse antibodies into antibodies closely resembling human antibodies. In addition, phage display technology is being used by companies, such as CAT, Dyax and MorphoSys to generate potentially therapeutic products comprising human antibody sequences. Companies such as Johnson, MedImmune (a subsidiary of AstraZeneca), Amgen, Biogen Idec, Novartis, Genentech, PDL BioPharma, Wyeth, BMS, Abbott Laboratories, Alexion Pharmaceuticals, Inc. and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market and that are derived from recombinant DNA that comprise human antibody components.

We have entered into license agreements with Pfizer, designed to give each party freedom to operate with respect to the development and commercialization of antibodies to CTLA-4. Among other things, these license agreements allow Pfizer to compete with us in such development and commercialization efforts, but Pfizer is obligated to make certain milestone and royalty payments to us based upon future sales of any Pfizer anti-CTLA-4 antibody product. Pfizer is developing tremelimumab, a fully human antibody generated by using transgenic mouse technology substantially similar to our HuMAb-Mouse® technology that targets the T-cell receptor CTLA-4. According to publicly available information, Pfizer is developing tremelimumab in a Phase 3 clinical trial for metastatic melanoma and in earlier Phase 2 or Phase 1 trials for other cancers.

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

agents. Continuing development of new chemical entities and other drugs by pharmaceutical and other biotechnology companies carries with it the potential discovery of agents for treating disease indications also targeted by drugs that we or our partners are developing.

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

developing products;

undertaking preclinical testing and clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing and commercializing products.

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

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

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

Our competitive strategy includes seeking orphan drug designation for eligible products (i.e., certain products for diseases with small patient populations). In the United States, the first drug with an orphan drug designation for a given disease to receive regulatory approval for such disease generally receives marketing exclusivity for the use of the drug for such disease for a period of seven years from approval. The orphan drug exclusivity bars others from obtaining approval for the same drug for the designated indication during the seven years, unless the subsequent applicant can demonstrate that its product is clinically superior to the drug with exclusivity or the prior applicant is unable to provide adequate supply to meet medical need. Orphan drug exclusivity is also available in markets outside the United States on similar terms.

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

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

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

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

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

impose additional costs on us or our partners;

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

adversely affect our receipt of revenues or royalties.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, restrictions may be placed on our ability to market or distribute the product, or post-approval study or other requirements might be imposed, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. If we, our partners or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things:

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

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

warning letters;

fines;

import and/or export restrictions;

product recalls or seizures;

injunctions;

total or partial suspension of production;

civil penalties;

withdrawals of previously approved marketing applications or licenses;

limitations on previously approved marketing applications or licenses, or new post-approval requirements;

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

criminal prosecutions.

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

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

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our product candidates in the U.S. or in any foreign jurisdiction. We have only limited experience in filing and pursuing applications necessary to obtain regulatory approval. It is possible that none of our product candidates, including ipilimumab, will be approved for marketing. We cannot guarantee that we will ever be able to produce commercially successful products.

# We intend to file a BLA in 2008 for ipilimumab in metastatic melanoma which may not be accepted for filing by the FDA, or if accepted, may never be approved by the FDA.

We recently announced the top line results for three registrational monotherapy trials for ipilimumab in metastatic melanoma (008, 022, 007) and that we intended to file a BLA in 2008 based on the totality of the data from those trials. The FDA may decide not to accept our BLA for filing and, while the FDA has established performance goals for the review of BLAs six months for priority applications and 10 months for regular applications the FDA may take longer than that in its review of our BLA and the FDA may never give its approval.

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

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved BLA or NDA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the BLA or NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. New legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to FDA's cGMP requirements. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran's Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

#### If we are able to obtain approvals for our products, we could face competition from "generic" or "follow-on" versions of our products.

Under current U.S. law and FDA policy, generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, may be approved through an abbreviated approval process. In general terms, the generic applicant references an approved innovator

product for which full clinical data demonstrating safety and effectiveness exist for the approved conditions of use. The generic applicant in turn need only demonstrate that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as the referenced innovator drug, and that the generic product is absorbed in the body at the same rate and to the same extent as the referenced innovator drug (this is known as bioequivalence). In addition, the generic application must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the referenced innovator drug.

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

If the law is changed or if FDA somehow extends its existing authority in new ways, and third parties are permitted to obtain approvals of versions of our antibody products through an abbreviated approval mechanism, and without conducting full clinical studies of their own, it could materially harm our business. Such products would be significantly less costly than ours to bring to market, and could lead to the existence of multiple lower priced competitive products. This would substantially limit our ability to obtain a return on the investments we have made in those products.

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

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

the Occupational Safety and Health Act;

the Environmental Protection Act;

the Toxic Substances Control Act;

the Federal Food, Drug and Cosmetic Act;

the Resource Conservation and Recovery Act; and

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

In particular, with respect to environmental laws, our product development activities involve the use of hazardous materials, and we may incur significant costs as a result of the need to comply with these laws. Our research, development and manufacturing activities involve the controlled use of hazardous materials, chemicals, viruses and radioactive compounds. We are subject to federal, foreign, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts of terrorism, from these materials. In the event of an accident, we could be held liable for any damages that result, and any resulting liability could exceed our resources. We may also be required to incur significant costs to comply with environmental laws and regulations in the future.

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

#### We depend on patents and proprietary rights.

Our success depends in part on our ability to:

apply for, obtain, protect and enforce patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

in-license or acquire certain technologies.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued or, if issued, may not be held enforceable. The products and product candidates currently being developed or considered for development are in the area of biotechnology, an area in which there are extensive patent filings. We rely on patent protection against use of our proprietary products and technologies by competitors. The patent position of biotechnology intellectual property generally is highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict with certainty the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents.

Patents, if issued, may be challenged, invalidated or circumvented. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire, or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. Thus, any patents that we own or license from third parties may not provide sufficient protection against competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed which is not covered by an issued patent. The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. In addition to patents, we rely on trade secrets and proprietary know-how. We protect these secrets and know-how, in part, through confidentiality and proprietary information agreements.

We generally require our staff members, material consultants, scientific advisors and parties to collaboration and licensing agreement to execute confidentiality agreements upon the commencement of employment, the consulting relationship or the collaboration or licensing arrangement with us. These agreements may not provide protection or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information, or breach of these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

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

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

Our patents and applications covering the HuMAb-Mouse® and the KM-Mouse® technologies include patents and applications that cover particular human antibodies. These patents do not cover all human antibodies. Our patents may not protect against the importation of products, such as antibodies, made using the HuMAb-Mouse® or KM-Mouse® technology.

We do not have exclusive access to the patents underlying the HuMAb-Mouse®. In March 1997, prior to our acquisition of GenPharm, GenPharm entered into a cross-license and settlement agreement with Abgenix, Cell Genesys, Inc., Xenotech, L.P. and Japan Tobacco, Inc., pursuant to which Abgenix and these entities paid 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® technology. Abgenix merged with Amgen in 2006. As a result, Amgen may have access to such patents, patent applications, third party licenses and inventions. Our business may suffer from the competition of these entities and their licensees.

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

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

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

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

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

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

We currently produce our product candidates and our partners' product candidates using recombinant antibodies from host cells and may choose to produce additional product candidates in this manner. If any of our antibody product candidates are produced in the manner ultimately claimed in the Genentech patent, which claims survive the re-examination and any appeal processes, then we may need to obtain a license, should one be available. We have a license to this patent from Genentech for our anti-CTLA-4 product candidate (ipilimumab) but currently do not have licenses for any of our other antibody product candidates. If we desire a license for any of our other antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

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

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

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

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

#### Our stock price may be volatile.

Historically, there has been significant volatility in the market prices of biotechnology companies' securities. During the two-year period ended December 31, 2007, the sale prices of our common stock ranged between \$8.51 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;

interim or final results of, or speculation about, clinical trials from our lead product candidate, ipilimumab;

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.

As of January 31, 2008, we had 17,587,695 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 \$10.43 per share and we had reserved 5,149,281 shares of common stock for issuance pursuant to future grants of options under our equity incentive plans. We have filed registration statements on Form S-8 under the Securities Act covering all of these shares. Shares issued pursuant to the requirements of Rule 144.

As of January 31, 2008, we had reserved 516,688 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 under the Securities Act covering all of those shares. All shares issued under this plan,

other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

The exercise of all or a portion of the outstanding options may result in a significant increase in the number of shares of our common stock that will be subject to trading on the NASDAQ Global

Market and the issuance and sale of the shares of our common stock upon the exercise thereof may have an adverse effect on the price of our common stock.

As of January 31, 2008, we had 10,936,935 shares of common stock reserved for issuance pursuant to the conversion of the \$150.0 million aggregate principal amount of our outstanding 2.25% Convertible Senior Notes due May 15, 2011. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or redemption by us at a conversion rate of 72.9129 shares per each \$1,000 principal amount of the notes (\$13.72 per share), subject to adjustment.

# Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our debt, which may adversely affect our business and the price of our common stock.

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our outstanding 2.25% Convertible Senior Notes due May 15, 2011. As of January 31, 2008, \$150.0 million aggregate principal amount of these notes was outstanding. In each instance, we may pay the repurchase price in cash or, at our option, in common stock. These change of control events include, without limitation, (i) the acquisition by any third party of at least 50% of our common stock; or (ii) our merger or consolidation with or into any other person, any merger or consolidation of another person into us or our sale or other disposal of all or substantially all of our assets, except in certain limited circumstances provided in the indentures relating to the notes. Such repurchase rights may be triggered at a time at which we do not have sufficient funds available to pay the repurchase price in cash or determine that payment in cash is otherwise inadvisable. In such event, the issuance of a significant number of additional shares of common stock in payment of the repurchase price may lower the market price of our common stock.

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

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

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

a classified board of directors;

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

advance notice requirements for shareholder proposals and nominations;

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

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

We are also afforded the protections of the New Jersey Shareholders Protection Act. This New Jersey statute contains provisions that impose restrictions on shareholder action to acquire control of our company. The effect of the provisions of our shareholder rights plan, restated certificate of incorporation and amended and restated by-laws and New Jersey law may discourage third parties from acquiring control of our company. In addition, these measures may result in the entrenchment of our management and may prevent or frustrate any attempt by shareholders to replace or remove our current management.

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

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

#### Item 1B. Unresolved Staff Comments

As of the date of filing of this Annual Report on Form 10-K, there are no comments from the SEC's staff in connection with its review of our periodic or current reports under the Exchange Act that remain unresolved.

#### Item 2. Properties

The following is a description of our owned and leased properties:

Location	Leased/ Owned	Square Feet	Use	Lease Expiration Date
Annandale, New Jersey	Leased	45,000	Production, Office	2011
Bloomsbury, New Jersey	Owned	165,000	Laboratory, Office	N/A
Milpitas, California	Owned	65,000	Laboratory, Office	N/A
Sunnyvale, California	Leased	37,000	Laboratory, Office	2009
Princeton, New Jersey	Leased	20,000	Corporate Headquarters, Office	2013

We believe that our existing owned and leased facilities are adequate for the production of materials for clinical trials of our current products and for providing the services we currently offer to our partners in connection with our human antibody technology.

#### Item 3. Legal Proceedings

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. At the conclusion of the SEC's informal inquiry and the U.S. Attorney's Office investigation, the Company could be subject to regulatory or other fines or penalties or other contingent liabilities, however, no outcome is determinable at this time.

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.

#### Item 4. Submission of Matters to a Vote of Security Holders

None.

#### PART II

#### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on The NASDAQ Global Market under the symbol "MEDX." The following table sets forth, during the periods indicated, the high and low sales prices per share of our common stock, as reported on The NASDAQ Global Market:

	(	Common Stock Price		
	_	High		Low
Year ended December 31, 2006				
First Quarter	\$	16.07	\$	12.23
Second Quarter	\$	13.01	\$	8.51
Third Quarter	\$	11.41	\$	8.72
Fourth Quarter	\$	16.23	\$	10.42
Year ended December 31, 2007				
First Quarter	\$	15.03	\$	11.30
Second Quarter	\$	16.59	\$	12.69
Third Quarter	\$	18.23	\$	13.79
Fourth Quarter	\$	15.10	\$	10.05

The number of shares of our common stock outstanding as of January 31, 2008 was 127,458,777. As of January 31, 2008, there were approximately 689 record holders of our common stock.

No dividends have been paid on our common stock. We currently expect to retain our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item is contained in Part III of this Annual Report on Form 10-K under "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

#### Stock Price Performance Graph

The following Stock Price Performance Graph does not constitute soliciting material and should not be deemed filed or incorporated by reference into any of our other filings under the Securities Act of 1933, as amended, or under the Exchange Act, except to the extent specifically incorporated therein. The stock price performance shown on the graph is not necessarily indicative of future price performance.

The graph and table below compare the cumulative total shareholder return (stock price appreciation plus reinvested dividends, if any) on an annual basis for our common stock against the cumulative total returns on the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index.

#### **COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among Medarex, Inc., The NASDAQ Composite Index And The NASDAQ Biotechnology Index

\* \$100 invested on 12/31/02 in stock or index-including reinvestment of dividends. Fiscal year ending December 31.

#### **Cumulative Total Return**

	 12/02	12/03	12/04	12/05	12/06	_	12/07
Medarex, Inc.	\$ 100.00	\$ 157.72	\$ 272.91	\$ 350.63	\$ 374.43	\$	263.80
NASDAQ Composite NASDAQ Biotechnology	100.00 100.00	149.75 146.95	164.64 164.05	168.60 185.29	187.83 183.09		205.22 186.22

The above graph and table assume \$100 invested on December 31, 2002, with all dividends reinvested, in each of our common stock, the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index.

#### Item 6. Selected Consolidated Financial Data

The information set forth below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and Supplementary Data and related notes thereto included in Item 8 of this Form 10-K to fully understand the factors that may affect the comparability of the information presented below.

	For the Year Ended December 31,					
		2007	2006	2005	2004	2003
			(In thousands,	except per sha		
Statement of Operations Data:						
Revenues:	<i>.</i>	<b>.</b>		<b>.</b>		
Sales Contract and license revenues	\$	\$	\$ 26,736	\$ 30,226	\$	25
Sales, contract and license revenues from Genmab		33,823 2,083	1,553	4,067	9,119 3,355	5,833 5,316
Reimbursement of development costs		20,352	20,357	17,162	5,555	5,510
Total revenues		56,258	48,646	51,455	12,474	11,174
Costs and expenses:						
Cost of sales						3
Research and development		198,317	194,512	136,940	123,012	97,803
General and administrative		46,925	51,928	28,969	25,259	23,840
Acquisition of in-process technology		6,900		8,447	5,455	6,500
Total costs and expenses		252,142	246,440	174,356	153,726	128,146
Operating loss		(195,884)	(197,794)	(122,901)	(141,252)	(116,972)
Equity in net loss of affiliate		(1)0,001)	(1,037)	(6,323)	(19,791)	(14,997)
Interest and dividend income		20,290	17,352	14,740	9,228	11,301
Gain on sale of Genmab stock		152,143				
Impairment loss on investments in partners		(2,141)	(5,170)	(33,347)	(7,309)	(1,400)
Interest expense		(6,162)	(4,709)	(4,233)	(12,845)	(11,777)
Minority interest Celldex		4,699	6,891	4,410		
Debt conversion expense					(10,151)	
Net loss on extinguishment of debt					(4,241)	
Non-cash gain on loss of significant influence in Genmab			3,202			
Loss before provision for income taxes		(27,055)	(181,265)	(147,654)	(186,361)	(133,845)
Provision for income taxes		12	436	358	31	69
Loss before cumulative effect of change in accounting principle Cumulative effect of change in accounting principle	_	(27,067)	(181,701)	(148,012)	(186,392)	(133,914)
Net loss		(27,067) \$	(181,701) \$	(148,012) \$	(186,392) \$	(134,744)
		(,,) +	() +	(1.10,012) +	() +	(,
Basic and diluted net loss per share(1):						
Loss before cumulative effect of change in accounting principle	\$	(0.21) \$	(1.50) \$	(1.34) \$	(2.29) \$	(1.71)
Cumulative effect of change in accounting principle						(0.01)
Net loss	\$	(0.21) \$	(1.50) \$	(1.34) \$	(2.29) \$	(1.72)
Weighted average common shares outstanding(1)						
basic and diluted		126,665	121,126	110,309	81,494	78,314
		120,005	,	,	01,494	76,514
			De	cember 31,		
		2007	2006	2005	2004	2003

December 31,

	 	(In	thousands)		
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 639,937 \$	883,876 \$	351,307 \$	374,507 \$	358,458
Working capital	448,140	441,329	327,733	339,956	349,389
Total assets	759,860	954,693	486,876	549,345	557,726
Long term convertible debt	143,505	141,581	150,000	296,986	300,000
Cash dividends declared per common share					
Accumulated deficit	(990,721)	(963,654)	(781,953)	(633,941)	(447,549)
Total shareholders' equity	445,256	640,173	159,245	106,235	232,963

<sup>(1)</sup> 

Computed on the basis described in Note 2 to the Consolidated Financial Statements.

#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

#### Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of fully human antibody-based therapeutic products. We believe that our UltiMAb® technology platform enables us to rapidly create and develop such product candidates for a wide range of diseases, including cancer, inflammation, autoimmune disorders and other life-threatening and debilitating diseases.

Medarex is committed to building value by developing a diverse pipeline of antibody products to address major unmet healthcare needs in the world. Currently, over 40 antibody product candidates generated from our UltiMAb® technology are in human clinical trials, or have had regulatory applications submitted for such trials(1). 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 are in Phase 3 clinical trials or the subject of regulatory applications for marketing authorization. Seven of these late-stage product candidates were generated through the use of our UltiMAb® technology. In addition to the antibody candidates currently in Phase 3 trials, multiple product candidates in Phase 2, Phase 1 and preclinical testing are being developed by Medarex alone, by Medarex jointly with our partners, or separately by our partners. These partners include Amgen, Inc., Bristol-Myers Squibb Company, Centocor, Inc., Eli Lilly and Company, Genmab A/S, ImClone Systems Incorporated, MedImmune, Inc. and Novartis Pharma AG. We believe that through the broad use of our UltiMAb® technology, we are leveraging our efforts and our partners' efforts to create, develop and potentially commercialize innovative treatments for a wide range of diseases.

(1)

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

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

A portion of our revenue is derived from licensing our fully human antibody technology to pharmaceutical and biotechnology companies. The terms of these license agreements typically include potential license fees and a series of potential milestone payments commencing upon the initiation of clinical trials and continuing through commercialization. These payments may total \$7.0 million to \$10.0 million per product if the antibody receives approval from the U.S. Food and Drug Administration, or FDA, and equivalent foreign agencies. In general, we are also entitled to receive



royalties on product sales. Additional revenue may be earned from the sales to, and in some cases, the manufacturing of antibodies for, our partners, as well as from government grants.

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 December 31, 2007, we had an accumulated deficit of approximately \$990.7 million. Over the next several years, we expect to incur substantial expenses as we continue to identify, develop and manufacture our potential products, invest in research, move forward with our product development and prepare to commercialize our product(s). Our commitment of resources to research and the continued development and potential commercialization of our product candidates will require substantial additional funds. Our operating expenses may also increase as we invest in research or acquire additional technologies, as additional potential product candidates are selected for clinical development and as some of our earlier stage product candidates move into later stage clinical development. In addition, we may incur significant milestone payment obligations as our products progress towards commercialization. In the absence of substantial revenues from new corporate collaborations or other sources, we will incur substantial operating losses and may be required to raise additional funds through debt or equity financings or sales of stock of partners in which we have an equity ownership or delay, reduce or eliminate certain of our research and development programs.

#### **Critical Accounting Policies**

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

#### **Revenue Recognition**

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

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

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

Revenue from milestone payments is recognized when each milestone is achieved, when collectibility of such milestone payment is assured and we have no future performance obligations relating to that event. Milestone payments are triggered either by the results of our research efforts or by the efforts of our partners and include such events as submission of an Investigational New Drug Application, or IND, commencement of Phase 1, 2 or 3 clinical trials, submission of a Biologic License Application, or BLA, and regulatory approval of a product. Milestone payments are substantially at risk at the inception of an agreement.

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

Revenues derived from reimbursements of costs associated with the development of product candidates are recorded in compliance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, or 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 credit risk and perform part of the services required in the transaction, we believe we have met the criteria to record revenue for the gross amount of the reimbursements.

We sell antibodies primarily to partners in the United States and overseas. Revenue from these sales is recognized when the antibodies are shipped and we have no further obligations related to the development of the antibodies.

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

#### Investments

Our investment policy calls for investments in fixed income high grade securities such as U.S. corporate debt securities, U.S. treasury obligations and money market funds for which we believe there is not a significant risk of loss. Our primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return consistent with these two objectives. However, in the course of our business, we have made and may continue to make investments in companies (both public and private) as part of our strategic collaborations. Investments in companies whose securities are publicly traded (other than Genmab) are classified as marketable securities on our consolidated balance sheets. The fair market value of investments in our partners whose securities are publicly traded (other than Genmab) represented approximately 0.8% of total marketable securities as of December 31, 2007 and approximately 2.2% of total marketable securities as of December 31, 2006.

Under SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, our marketable securities are classified as available-for-sale securities and are carried at fair value. Marketable securities will include those securities of debt and publicly traded equity securities accounted for under the fair value method. These securities trade on listed exchanges; therefore, fair value is readily available. These securities are also subject to an impairment charge when we believe an investment has experienced a decline in value that is other than temporary. Under our accounting



policy, a decline in the value of our investments is deemed to be other than temporary and such investments are generally considered to be impaired if their value is less than our cost basis for more than six (6) months, or some other applicable period in light of the facts and circumstances surrounding the investments.

In addition, in connection with our collaborative partnering business, we sometimes make strategic investments in the securities of companies that are privately held. Investments in our partners whose equity is not publicly traded are classified in a separate line item in our consolidated balance sheet entitled "Investments in, and advances to, other partners" and were \$6.0 million as of December 31, 2007. These securities are carried at original investment cost and adjusted for other than temporary impairment charges, if any. Because these securities are not listed on a financial exchange, the value of these investments is inherently more difficult to estimate than investments in public companies. We value these investments by using information acquired from industry trends, management of these companies, financial statements, and other external sources. Specifically, our determination of any potential impairment of the value of privately held securities includes an analysis of the following for each company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financings and potential strategic alternatives. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is other than temporary.

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

#### Stock Based Compensation

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

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

The fair value of each option grant is estimated using the Black-Scholes option pricing method. The fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period (generally 4 years). Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. In order to estimate the grant date fair value, option pricing models require the use of estimates and assumptions as to



(i) the expected term of the option, (ii) the expected volatility of the price of the underlying stock, (iii) the risk free interest rate for the expected term of the option and (iv) pre-vesting forfeiture rates. The expected term of the option is based upon the contractual term, taking into account expected employee exercise and expected post-vesting termination behavior. The expected volatility of the price of the underlying stock is based on the historical volatility of our common stock. The risk free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected life assumed on the date of grant. Pre-vesting forfeiture rates are estimated based on past voluntary termination behavior, as well as an analysis of actual option forfeitures. The following table sets forth the assumptions used to calculate the fair value of options granted for the years ended December 31, 2007, 2006 and 2005:

	2007	2006	2005
Expected dividend yield	0%	0%	0%
Expected volatility	81% - 83%	82% - 84%	98% - 99%
Weighted average expected volatility	81.7%	82.8%	99.1%
Risk free interest rates	3.55% - 4.88%	4.59% - 5.11%	4.16% - 4.50%
Expected life of options (years)	5.00	6.25	6.25

Our results of operations for the year ended December 31, 2007 include incremental share based compensation expense of approximately \$20.0 million. As of December 31, 2007, the total unrecognized compensation cost related to non-vested stock options was approximately \$38.2 million. This cost is expected to be recognized over a weighted average period of 2.8 years.

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

#### Valuation of Long-Lived and Intangible Assets

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

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

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

a significant negative industry or economic trend.

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

#### Acquired In-Process Technology

In-process technology expense for significant technology acquisitions is determined based on an analysis using risk-adjusted cash flows expected to be generated by products that may result from in-process technologies which have been acquired. This analysis includes forecasting future cash flows that are expected to result from the progress made on each in-process project prior to the acquisition date. Cash flows are estimated by first forecasting, on a product-by-product basis, net revenues expected from the sales of the first generation of each in-process project and risk adjusting these revenues to reflect the probability of advancing to the next stage of the FDA approval process. The forecast data in the analysis is based on internal product level forecast information maintained by us in

the ordinary course of business. The inputs used in analyzing in-process technology are based on assumptions, which we believe to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Appropriate operating expenses are deducted from forecasted net revenues on a product-by-product basis to establish a forecast of net returns on the completed portion of the in-process technology. Finally, net returns are discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and us as well as product specific risks associated with the acquired in-process research and development products. The product specific risk factors include the product's phase of development, type of product candidate under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, a discount rate is used for the valuation, which represents a considerable risk premium to our weighted average cost of capital. The valuations used to estimate in-process technology require us to use significant estimates and assumptions that if changed, may result in a different valuation for in-process technology.

#### 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**

#### Years Ended December 31, 2007, 2006 and 2005

#### **Contract and License Revenues**

Contract and license revenues totaled \$33.8 million, \$26.7 million and \$30.2 million for the years ended December 31, 2007, 2006 and 2005, respectively. Contract and license revenues for 2007 increased by \$7.1 million or 27% as compared to 2006. This increase relates principally to \$8.0 million in milestone payments received from our contract and licensing business. Contract and license revenues for 2006 decreased by \$3.5 million or 12% as compared to 2005. This decrease relates principally to \$4.0 million in milestone payments received from our contract and licensing business in 2005 for which no comparable payments were received in 2006. Because contract and license revenues depend to a large extent on the product development efforts of our partners and licensees, our year-to-year contract and license revenues can fluctuate significantly and are inherently difficult to predict.

#### Contract and License Revenues from Genmab

Contract and license revenues from Genmab were \$2.1 million, \$1.6 million and \$4.1 million for the years ended December 31, 2007, 2006 and 2005, respectively. Contract and license revenues from Genmab for 2007 increased by \$0.5 million or 34% as compared to 2006. This increase is primarily the result of an increase in research license extensions granted to Genmab in 2007 as compared to 2006. Contract and license revenues from Genmab for 2006 decreased by \$2.5 million or 62% as compared to 2005. This decrease is primarily the result of a decrease in antibody exclusive licenses granted to Genmab in 2006 as compared to 2005.

#### **Reimbursement of Development Costs**

Revenues derived from the reimbursement of costs associated with the development of our product candidates are recorded in compliance with EITF Issue 99-19. Reimbursement of development costs totaled \$20.4 million, \$20.4 million and \$17.2 million for the years ended December 31, 2007, 2006 and 2005, respectively, and related primarily to the development of ipilimumab with Bristol-Myers Squibb Company, or BMS.

#### **Research and Development Expenses**

Research and development expenses for our products in development were \$198.3 million, \$194.5 million and \$136.9 million for the years ended December 31, 2007, 2006 and 2005, respectively. Research and development expenses in 2007 increased by \$3.8 million, or 2% as compared to 2006, and research and development expenses in 2006 increased by \$57.6 million, or 42% as compared to 2005. Historically, we have not accounted for our research and development expenses on a project-by-project basis and therefore, we do not provide a breakdown of such historical information in that format. We track our costs in the categories discussed below, namely, "research" and "product development" and by the types of costs as outlined below.

Our research costs consist of costs associated with the breeding, care and continued development of the HuMAb-Mouse® 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 (including manufacturing). Such product development costs also include personnel costs, facilities (including depreciation), supply expense related to antibody manufacturing and clinical trial expenses.

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

	Year Ended December 31,					
	2007		2006		2005	
Research Product Development	\$ 64,143 134,174	\$	64,882 129,630	\$	44,926 92,014	
Total	\$ 198,317	\$	194,512	\$	136,940	
	,		- )-		;;	

#### **Research** Costs

Research costs in 2007 decreased by \$0.7 million, or 1% as compared to 2006. Research costs in 2006 increased by \$20.0 million, or 44% as compared to 2005. The changes in research costs primarily relate to the following.

Personnel costs in 2007 were \$23.3 million, an increase of \$1.8 million or 8% as compared to 2006. Personnel costs in 2006 were \$21.5 million, an increase of \$6.6 million or 44% as compared to 2005. Approximately \$3.3 million of the 2006 increase is the result of the adoption of Statement No. 123(R), effective January 1, 2006. In addition, the increased personnel costs are attributable to staff needed to support higher levels of new product development opportunities, the continued development of our UltiMAb® system, and the performance of contract services for our collaborative partners. Personnel costs include primarily salary, benefits,

payroll taxes, stock option compensation and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our research activities.

License and technology access fees in 2007 were \$9.0 million, a decrease of \$3.7 million or 29% as compared to 2006. License and technology access fees in 2006 were \$12.7 million, an increase of \$7.3 million or 134% as compared to 2005. Increases and decreases in license and technology access fees are primarily the result of the timing of 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 costs for 2007, 2006 and 2005 are payments to certain companies and research and academic institutions and other entities for licenses to certain technologies for which there are no comparable payments. We expect license fees, including funds paid to certain partners, to increase in the future.

Supply costs in 2007 were \$7.9 million, a decrease of \$0.3 million or 3% as compared to 2006. Supply costs in 2006 were \$8.2 million, an increase of \$2.0 million or 32% as compared to 2005. The increased supply costs in 2006 are primarily attributable to the continued development of our UltiMAb® system, and the performance of contract services for our collaborative partners. Included in these costs are materials, chemicals and disposables. We expect these costs to increase as we continue to expand our research efforts.

Facility costs in 2007 were \$13.0 million, an increase of \$1.5 million or 13% as compared to 2006. Facility costs in 2006 were \$11.5 million, an increase of \$2.8 million or 32% as compared to 2005. The increase in facility costs primarily relates to the substantial investments made in our research facilities in recent years. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for 2007, as compared to 2006, and for 2006, as compared to 2005. We expect to incur increased facility costs as a result of continued capital expansion, renovations and replacements.
 Product Development Costs

Product development costs in 2007 increased by \$4.5 million, or 4% as compared to 2006. Product development costs in 2006 increased by \$37.6 million, or 41% as compared to 2005. The increases in product development costs primarily relate to the following:

Contract manufacturing costs in 2007 were \$7.5 million, a decrease of \$0.4 million or 5% as compared to 2006. Contract manufacturing costs in 2006 were \$7.9 million, a decrease of \$2.4 million or 24% as compared to 2005. The decrease in third party contract manufacturing costs in 2007 and 2006 primarily represents a decrease in production and packaging expenses for a Phase 3 pivotal trial of ipilimumab in combination with MDX-1379, which began in the third quarter of 2004 and was transferred to BMS in the second half of 2005. We expect costs to third party manufacturers will increase in the future in order to support the advancement of our clinical pipeline.

Personnel costs in 2007 were \$38.0 million, an increase of \$1.2 million or 3% as compared to 2006. Personnel costs in 2006 were \$36.8 million, an increase of \$10.5 million or 40% as compared to 2005. Approximately \$5.8 million of the 2006 increase is the result of the adoption of Statement No. 123(R), effective January 1, 2006. The increased personnel costs are a result of the increased staff needed to support more extensive clinical trial activities primarily for ipilimumab. Personnel costs primarily include salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our product development activities and progress our product candidates through clinical trials.

Clinical research fees in 2007 were \$18.6 million, an increase of \$3.4 million or 22% as compared to 2006. Clinical research fees in 2006 were \$15.2 million, an increase of \$3.7 million

or 32% as compared to 2005. The 2007 increase resulted primarily from the continuing ipilimumab Phase 3 trial. The 2006 increase resulted primarily from the continuing MDX-060 Phase 2 trial. 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.

Reimbursement of our share (35%) of the BMS costs for the development of ipilimumab in 2007 were \$24.9 million, an increase of \$1.6 million or 7% as compared to 2006. Reimbursement of our share (35%) of the BMS costs for the development of ipilimumab were \$23.3 million, an increase of \$17.0 million or 270% as compared to 2005. 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.

We expect product development costs to increase in the future as more of our product candidates enter clinical trials. In addition, we may be obligated to make milestone payments on certain of our product candidates as they progress through the clinical trial process. Completion of clinical trials may take several years or more. The length of time varies according to the type, complexity and intended use of the product candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following periods:

Clinical Phase	Estimated Completion Period
Phase 1	1-2 Years
Phase 2	1-2 Years
Phase 3	2-4 Years

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

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

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

the number of clinical sites required for trials; and

the number of patients that ultimately participate.

We continue to explore new collaborative arrangements that may affect future spending for research and development. As part of our partnering strategy, a significant portion of the research and development expenses incurred in connection with products using our technology is expected to be borne by our partners. We believe this allows us to participate in the research and development of substantially more potential product candidates than we could develop on our own if we bore the entire cost of development. Products using our technology are currently in various stages of development from preclinical to Phase 3. The successful development of these product candidates is dependent on many factors, including among other things, the efforts of our partners, unforeseen delays in, or expenditures relating to, preclinical development, clinical testing, manufacturing or regulatory approval, failure to receive regulatory approval, failure to receive market acceptance, the emergence of competitive products and the inability to produce or market our products due to third-party proprietary rights.

#### General and Administrative Expenses

General and administrative expenses include compensation, professional services, consulting, travel and facilities (including depreciation) and other expenses related to legal, business development, finance, information systems and investor relations. General and administrative expenses totaled \$46.9 million, \$51.9 million and \$29.0 million for the years ended December 31, 2007, 2006 and 2005, respectively. General and administrative expenses decreased by \$5.0 million in 2007, or 10% as

compared to 2006. The 2007 decrease was primarily attributable to lower legal fees associated with the Company's investigation of its prior stock option grant practices. General and administrative expenses increased by \$22.9 million in 2006, or 79% as compared to 2005. The 2006 increase is primarily attributable to the following; (i) approximately \$9.4 million in legal fees associated with the Company's investigation of its prior stock option grant practices, (ii) approximately \$5.6 million attributable to the operations of Celldex Therapeutics, Inc., or Celldex, (iii) approximately \$6.5 million is the result of the adoption of Statement No. 123(R), effective January 1, 2006 and (iv) approximately \$3.7 million in non-cash stock based compensation expense associated with one of our officers stepping down in November 2006. 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 year ended December 31, 2007 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 to be technologically feasible and had no alternative future use, and, as a result was charged to operations as acquisition of in-process technology during 2007.

Acquisition of in-process technology for the year ended December 31, 2005 related to acquisition of all of the outstanding capital stock of Lorantis Limited, or Lorantis, a privately held biotechnology company based in Cambridge, U.K. and the acquisition of substantially all assets of Alteris Therapeutics, Inc., or Alteris, a privately held biotechnology company based in Philadelphia, PA, in each case by Celldex. These acquisitions were completed in October 2005. The total cost of these acquisitions (including transaction costs) was \$42.8 million, of which approximately \$8.4 million (based upon independent third-party valuations) of in-process research and development was determined not to be technologically feasible and had no alternative future uses at the time of the respective acquisitions, and, as a result, was charged to operations as acquisition of in-process technology during 2005.

#### Equity in Net Loss of Affiliate

Equity in net loss of affiliate represents our share of Genmab's net loss for the years ended December 31, 2006 and 2005. Genmab is an affiliated company and during these periods was accounted for using the equity method of accounting (see Note 10 to the consolidated financial statements). The recognition of our share of Genmab's net losses reduces the carrying value, or basis, of our investment in Genmab.

Equity in net loss of affiliate was \$0, \$1.0 million and \$6.3 million for the years ended December 31, 2007, 2006 and 2005, respectively.

Equity in net loss of affiliate in 2006 decreased by \$5.3 million, or 84% as compared to 2005. The 2006 decrease was primarily 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%. Beginning February 1, 2006 we 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 February 2007, we sold 2,578,500 shares of Genmab thereby reducing our ownership percentage to approximately 10.8%. In February 2008, we sold an additional 2,500,000 shares of Genmab further reducing our ownership percentage to approximately 5.1%. See further discussion under "Other Liquidity Matters."

In August 2005, Genmab sold approximately 2.5 million shares of its stock to a corporate partner in connection with a global development and commercialization agreement. As a result of this sale of stock, our ownership percentage in Genmab was reduced from approximately 24.7% to approximately 22.2%. The difference between our proportionate share of the equity and our carrying value after completion of Genmab's sale of stock to the corporate partner was approximately \$8.0 million and was accounted for in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investment in Common Stock* and Staff Accounting Bulletin No. 51, *Accounting for Sales of Stock by a Subsidiary* increasing our investment in Genmab and capital in excess of par value.

#### Interest, Dividend Income and Realized Gains

Interest, dividend income and realized gains consists primarily of interest earned from our cash, cash equivalents and marketable securities. Interest, dividend income and realized gains was \$20.3 million, \$17.4 million and \$14.7 million for the years ended December 31, 2007, 2006 and 2005, respectively. Interest, dividend income and realized gains in 2007 increased by \$2.9 million, or 17% as compared to 2006. The increase reflects a combination of higher interest rates earned on our investment portfolio as well as higher average cash balances reflecting the proceeds received (approximately \$152.1 million) from our February 2007 sale of approximately 2.5 million shares of Genmab stock. Interest, dividend income and realized gains in 2006 increased by \$2.6 million, or 18% as compared to 2005. The increase primarily reflects higher interest rates earned on our investment portfolio. In addition, we have higher interest and dividend income in 2006 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 (see further discussion under Liquidity and Capital Resources).

#### Gain on Sale of Genmab Stock

In February 2007, we received approximately \$152.1 million in net proceeds from the sale of approximately 2.6 million shares of Genmab stock resulting in a realized gain of approximately \$152.1 million as our cost basis for these shares was zero. See Note 10 to the consolidated financial statements for further explanation. The sale of the approximately 2.6 million shares of Genmab shares reduced our equity ownership in Genmab to approximately 10.8%.

#### Impairment Loss on Investments in Partners

We recorded impairment charges of \$0, \$5.2 million and \$0 for the years ended December 31, 2007, 2006 and 2005, respectively, related to investments in certain of our partners (other than Genmab) whose securities are publicly traded. The 2006 impairment charge was the result of losses on one of our investments which were considered to be other than temporary. If we deem these investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

In addition, we have investments in several partners whose securities are not publicly traded. Because these securities are not publicly traded, the value of these investments is more difficult to estimate than investments in publicly traded companies. We recorded impairment charges of \$2.1 million, \$0 and \$33.3 million for the years ended December 31, 2007, 2006 and 2005, respectively, related to investments in certain of our partners whose securities are not publicly traded. Approximately \$29.3 million of the 2005 impairment charge related to our investment in IDM prior to its business combination with Epimmune, Inc. The amount of the IDM impairment charge was calculated as the difference between (i) the estimated per share value expected to be received by IDM shareholders upon completion of its merger with Epimmune, publicly announced on March 16, 2005, and (ii) our carrying value. This transaction closed in the third quarter of 2005 and our investment in

IDM was reclassified to marketable securities. If we deem these investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

#### Interest Expense

Interest expense was primarily related to interest and amortization of issuance costs on our 2.25% Convertible Senior Notes issued in May 2004, or the 2.25% notes. Interest expense was \$6.2 million, \$4.7 million and \$4.2 million for the years ended December 31, 2007, 2006 and 2005, respectively. The 2007 increase of \$1.5 million or 31%, as compared to 2006 reflects the amortization of additional debt discount 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. Interest expense in 2006 increased by \$0.5 million, or 12%, as compared to 2005. Interest expense in 2007, 2006 and 2005 relates to interest and amortization of issuance costs on our 2.25% notes. The 2.25% notes are due in May 2011 and interest is payable semi-annually on May 15 and November 15 of each year.

#### Minority Interest Celldex

Minority interest in loss of Celldex was \$4.7 million, \$6.9 million and \$4.4 million for the years ended December 31, 2007, 2006 and 2005, respectively. Minority interest in loss of Celldex represents 40% of Celldex's net loss for approximately nine months of 2007, 2006 and for the period from October 12, 2005 through December 31, 2005. For the final three months of 2007, minority interest represents 100% of Celldex's net loss. During October 2007, the minority interest in the equity of Celldex was reduced to zero and accordingly, we (as the majority shareholder) are required to record 100% of Celldex's losses. Prior to October 12, 2005 we owned 100% of the outstanding capital stock of Celldex. As a result of certain acquisitions by Celldex (see Note 13 to the consolidated financial statements) our ownership percentage was reduced from 100% to approximately 60%. Celldex's results of operations for 2007, 2006 and 2005 have been consolidated for reporting purposes and the \$4.7 million, \$6.9 million and \$4.4 million (the portion of Celldex's net loss for 2006 and the period from October 12, 2005 through December 31, 2005 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 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 2006.

#### **Provision for Income Taxes**

Our provision for income taxes of \$12 thousand, \$0.4 million and \$0.4 million for the years ended December 31, 2007, 2006 and 2005, respectively, relates primarily to the New Jersey alternative minimum tax assessment.

#### Liquidity and Capital Resources

We require cash to fund our operations, to make capital expenditures and strategic investments, and to pay debt service on our convertible notes. Since inception, we have financed our operations through the sale of our securities in public and private placements, sales of our products for research purposes, development and manufacturing services, technology transfer and license fees and milestone payments. We expect to continue to fund our cash requirements from these sources in the future. In 2007, 2006, and 2005, we received combined net proceeds of \$182.3 million from sales of our equity and debt securities.

At December 31, 2007 and 2006, we had \$348.8 million and \$339.5 million, respectively, in cash, cash equivalents and marketable securities (other than Genmab). Approximately \$4.9 million and \$14.0 million of cash and cash equivalents included in the December 31, 2007 and 2006 balance sheets relates to Celldex and is consolidated for accounting purposes. We primarily invest our cash equivalents and marketable securities in highly liquid, interest-bearing, investment grade and government securities to preserve principal. In addition, as of December 31, 2007, the fair value of our investment in Genmab, which is classified as marketable securities was approximately \$291.2 million.

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

#### Cash Used in Operating Activities

Cash used in operating activities was \$148.6 million, \$138.3 million and \$88.9 million for the years ended December 31, 2007, 2006 and 2005, respectively. This reflects an increase of \$10.3 million in 2007 as compared to 2006 and an increase of \$49.4 million in 2006 as compared to 2005.

Cash used in operating activities was comparable in 2007 and 2006. The 2006 increase was primarily due to increased research and development expenses (\$57.6 million) and increased general and administrative expenses (\$22.9 million) as a result of the factors discussed above.

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

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

Net cash provided by investing activities was \$134.5 million in 2007 and \$84.1 million in 2005. Net cash used in investing activities was \$55.1 million in 2006. Cash was provided by and used in investing activities primarily as follows:

Capital expenditures of \$9.7 million, \$13.5 million and \$9.3 million in 2007, 2006 and 2005, respectively. The capital expenditures for these periods reflect an investment in laboratory automation as well as the addition of machinery and equipment.

Net sales of marketable securities were \$65.9 million in 2005. The net sales of marketable securities in 2005 were primarily to fund operations and capital expenditures offset in part, by the proceeds received from the BMS collaboration (\$50.0 million).

Net purchases of marketable securities were \$7.9 million and \$41.6 million in 2007 and 2006, respectively. The 2007 net purchases were the result of the proceeds received from the February 2007 sale of 2.5 million shares of our Genmab stock (see further discussion below). The 2006 net purchases were the result of proceeds received from our April 2006 public offering (see further discussion below).

Net cash of approximately \$29.7 million in 2005 provided through the acquisition of Lorantis by Celldex (see further explanation in the section entitled "*Other Liquidity Matters*").

We expect 2008 capital expenditures to be approximately \$14.0 million representing the purchase of machinery and scientific equipment and continued investment in lab automation.

#### Cash Provided by Financing Activities

Cash provided by financing activities was \$16.3 million, \$134.9 million and \$31.1 million in 2007, 2006 and 2005, respectively. In 2007, cash provided by financing activities consisted primarily of proceeds received from the exercise of stock options. In 2006, cash provided by financing activities consisted primarily of approximately \$128.0 million in net proceeds received from our April 2006 public offering (see further discussion below). In 2005, cash provided by financing activities consisted primarily of proceeds received primarily of proceeds received (\$25.0 million) from the sale of common stock to BMS in connection with our collaboration.

In April 2006, we completed a public offering of 10 million shares of common stock at a public offering price of \$11.75 per share. In May 2006, the underwriters exercised in full their option to purchase an additional 1.5 million shares of common stock at the public offering price of \$11.75 per share. The exercise of the option to purchase the additional 1.5 million shares increased the size of the public offering to a total of 11.5 million shares of common stock resulting in net proceeds to us of approximately \$128.0 million.

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

#### **Other Liquidity Matters**

As of December 31, 2007, we had federal net operating loss (NOL) carryforwards of approximately \$588.6 million. These NOL carryforwards will expire in the years 2008-2027 (as more fully described in Note 5 to the consolidated financial statements), if not utilized. We determined that an ownership change under Section 382 of the Internal Revenue Code of 1986, as amended, occurred during 1998. The effect of this ownership change was the imposition of a \$3.2 million annual limitation on the use of NOL carryforwards attributable to periods before the change. This annual limitation will result in the expiration of some NOL carryforwards before they become available for utilization. At December 31, 2007 the amount of NOL subject to the limitation was \$38.3 million and the amount not subject to limitation was \$550.3 million. We have not performed a detailed analysis since 2000 to determine whether an additional ownership change under Section 382 has occurred. The effect of an additional ownership change if any would be the imposition of an additional annual limitation on the use of NOL carryforwards attributable to periods before the change.

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

Under the terms of the share purchase agreement with Ability Biomedical, we made cash payments totaling approximately \$606 thousand and issued a total of 731,823 shares of our common stock valued at approximately \$4.3 million in exchange for all of Ability Biomedical's issued and outstanding stock not already owned by us.

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 was made on November 30, 2007.

In September 2004, we entered into a series of agreements with Pfizer. The first agreement amended our existing collaborative research and license and royalty agreements with Pfizer to provide for the discovery and development of up to 50 antibody products over ten years. The second and third agreements were a sublicense from us to Pfizer and a cross-license of certain patents and patent applications, in each case solely relating to our respective anti-CTLA-4 antibody programs. The fourth agreement was a stock purchase agreement also related to the anti-CTLA-4 programs. Pursuant to certain of these agreements, Pfizer made a cash payment to us of \$80.0 million and purchased 4,827,808 shares of our common stock at a purchase price equal to \$6.21 per share for an aggregate purchase price of \$30.0 million.

In January 2005, we entered into a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. Under the terms of the collaboration, we and BMS each granted the other certain intellectual property licenses and product rights on a worldwide basis in order to enable us to collaborate in research and development of certain therapeutic antibody-based products for the treatment of cancer and other diseases, and, in the event that further development work is successful, to commercialize any resulting products. In particular, the collaboration includes a grant by us to BMS of a license to commercialize ipilimumab, a fully human antibody product candidate developed using our UltiMAb® technology. Ipilimumab is currently under investigation for the treatment of a broad range of cancers. We and BMS are pursuing a broad clinical development program with ipilimumab to evaluate its potential use as monotherapy or in combination with other cancer therapies in multiple registrational/Phase 3 trials that are ongoing or being planned for melanoma and prostate cancer; and in ongoing Phase 2 or earlier trials in lung, pancreatic, bladder, breast, lymphoma and leukemia cancers.

As part of the collaboration, BMS is responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the U.S. and Europe, with the remaining 35% to be paid by us. We and BMS will share equally the costs of any clinical trials of products intended solely for regulatory approval in the U.S., and BMS will be fully responsible for all development costs that relate solely to regulatory approval in Europe and other parts of the world.

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

which an initial regulatory approval filing is accepted by the FDA, then we will not have the right or obligation to co-promote such product for any cancer indications, unless the filing for that first cancer indication is not approved by FDA.

Under the terms of the collaboration, we could receive up to \$205.0 million from BMS if all regulatory milestones are met, plus up to an additional \$275.0 million in sales-related milestones. In addition, if we exercise our co-promotion option with respect to ipilimumab for the metastatic melanoma indication, and regulatory approval is obtained, we would receive 45% of any profits from commercial sales of such product in the U.S. In the event we choose not to exercise our co-promotion rights with respect to a product, BMS will have exclusive commercial rights in the U.S. and will pay us royalties on commercial sales. Regardless of whether or not we exercise our co-promotion option outside the U.S., BMS will have exclusive commercial rights for products and will pay us royalties on commercial sales.

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

In October 2005, Celldex completed the acquisition of all of the issued and outstanding shares of capital stock of Lorantis and substantially all of the assets of Alteris. 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.

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

The 2.25% notes mature on May 15, 2011 and are redeemable at our option on or after May 15, 2010. Holders of the 2.25% notes may require us to repurchase the notes if we undergo a "change in control" as defined in the indenture. We received net proceeds from the offering of the 2.25% notes of approximately \$145.2 million (after deducting the initial purchasers' discounts and offering expenses). The costs of issuance of the 2.25% notes of approximately \$4.8 million have been deferred and are being amortized over the term of the 2.25% notes. In May 2011, or earlier if we undergo a change in control, we may be required to use a significant portion of our cash to repay the remaining balance (\$150.0 million) of the 2.25% notes. If our cash is not sufficient to meet our obligations under the 2.25% notes, we would be required to seek additional financing.

#### **Contractual Obligations**

Our material contractual obligations under lease, debt and research funding agreements for the next five years, and thereafter, as of December 31, 2007, are as follows:

		Payments Due by Period								
	Less Than 1 Year			1-3 Years		4-5 Years		After 5 Years		Total
					(in t	housands)				
Contractual Obligations(1)										
Convertible notes(2)	\$	3,375	\$	6,750	\$	151,688	\$		\$	161,813
Research and development funding(3)		41,181		791		266		266		42,504
Operating leases and other		3,911		6,221		3,055		139		13,326
Total contractual cash obligations	\$	48,467	\$	13,762	\$	155,009	\$	405	\$	217,643

(1)

This table does not include (a) any milestone payments which may become payable to third parties under research collaborations or license agreements as the timing and likelihood of such payments are not known, (b) any royalty payments to third parties as the amounts of such payments, timing and/or the likelihood of such payments are not known, (c) amounts, if any, that may be committed in the future to construct additional facilities, and (d) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

(2)

Our convertible notes may be converted to common stock prior to the maturity date and, therefore, may not require the use of our capital resources.

(3)

Research and development funding for "Less than 1 year" includes up to \$38.3 million that we anticipate may be used under our collaboration agreement with BMS to fund our share of the expected costs of the development of ipilimumab during 2008. This amount represents our costs; net of reimbursement of 65% from our partner BMS, as well as our share (35%) of the BMS development costs during 2008. The amounts that we actually spend during 2008 for the development of ipilimumab may vary significantly depending on numerous factors, including the outcome of our meetings with regulatory authorities, results from current and future clinical trials, the continued analysis of the clinical trial data for ipilimumab, actions taken by our partner BMS under the collaboration agreement and technological developments.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

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

In 2002, we entered into a collaboration and license agreement with Kirin, which cross-licenses certain of each other's technologies for the development and commercialization of human antibody products. Under the collaboration and license agreement, we and Kirin developed the KM-Mouse®, a unique crossbred mouse that combines the traits of our HuMAb-Mouse® with Kirin's TC Mouse and exchanged cross-licenses 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 December 31, 2007, we have not made any milestone payments to Kirin although approximately \$2.8 million has been paid to Kirin as of December 31, 2007 representing a payment due Kirin as a result of our collaboration with Pfizer. Based on products we are developing which use or, we believe may use, Kirin technology that (i) are currently in clinical trials, or (ii) we anticipate may enter clinical trials through the end of 2009, we may be required to make milestone payments to Kirin

aggregating up to approximately \$8.5 million with respect to such products. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

whether or not a decision is made to request a license from Kirin;

the type of license requested (research or commercial);

the success and timing of development efforts and clinical trials of product candidates covered by any such licenses;

the type of product developed (payment obligations differ depending on whether a product is an *ex vivo* therapeutic, *in vivo* therapeutic, research reagent or diagnostic); and

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

We have also entered into a number of other agreements that contain licenses of third-party technology which may be used together with our own platform technologies for the generation, development and/or manufacture of our antibody products. In addition, we have entered into other third-party agreements that contain licenses associated with antibody products that target specific antigens. Many of these agreements contain milestone payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of our products currently under development trigger such milestone payments. Through December 31, 2007, we have made milestone payments of approximately \$1.7 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of 11 products we are developing for which milestones are potentially due and that (i) are now in clinical trials, or (ii) which we anticipate may enter clinical trials before the end of 2009, we may be obligated to make future milestone payments aggregating up to approximately \$63.9 million with respect to such products. In general, potential milestone payments for our antibody products may or may not be triggered under these licenses, and may vary in size, depending on a number of variables, almost all of which are currently uncertain. Typically, the events that trigger these payments per product include:

submission of IND(s) or foreign equivalents;

commencement of Phase 1, Phase 2 and/or Phase 3 clinical trials or foreign equivalents;

submission of BLA(s) or foreign equivalents; and

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

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

#### Future Liquidity Resources

Our current sources of liquidity are our cash, cash equivalents and marketable securities, interest and dividends earned on such cash, cash equivalents and marketable securities, contract and licensing revenue and sales of our products for research. We believe that such sources of liquidity will be sufficient to meet our operating, debt service, and capital requirements for at least the next 24 months. To the extent our 2.25% notes are converted into shares of our common stock on or before their

maturity date, we will have use of that portion of the principal amount of the notes to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, sales of stock of partners in which we have an equity ownership, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We cannot assure you that we will be able to raise such additional funds. We may be unable to raise sufficient funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

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

In December 2007, the EITF reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the requirements of EITF 07-1; however we do not believe that its adoption will have a significant impact on our consolidated financial statements.

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

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* (Statement No. 160), which amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to improve the relevance, comparability and transparency of the financial information that a reporting entity provides in its consolidated financial statements. Statement No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries not held by the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent's equity. Statement No. 160 also requires the amount of consolidated net income attributable to the parent and to the

non-controlling interest to be clearly identified and presented on the face of the consolidated statement of operations. Changes in a parent's ownership interest while the parent retains its controlling financial interest must be accounted for consistently, and when a subsidiary is deconsolidated, any retained non-controlling equity investment in the former subsidiary must be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any non-controlling equity investment. Statement No. 160 also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. Statement No. 160 applies prospectively to all entities that prepare consolidated financial statements and applies prospectively for all fiscal years, and interim periods within those fiscal years, beginning on for after December 15, 2008. We are currently evaluating the requirements of Statement No. 160; however we do not believe that its adoption will have a significant impact on our consolidated financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. We are currently evaluating the requirements of EITF 07-3; however we do not believe that its adoption will have a significant impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (Statement No. 159). Statement No. 159 permits entities to elect to measure certain assets and liabilities at fair value with changes in the fair values of those items (unrealized gains and losses) recognized in the statement of income for each reporting period. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under Statement No. 159, fair value elections can be made on an instrument by instrument basis, are irrevocable, and can only be made upon specified election date events. In addition, new disclosure requirements apply with respect to instruments for which fair value measurement is elected. Statement No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact, if any, that the adoption of Statement No 159 will have on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, (Statement No. 157), which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. Statement No. 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. We are currently evaluating the requirements of Statement No. 157; however, we do not believe that its adoption will have a material effect on our consolidated financial statements.

#### Item 7A. Quantitative and Qualitative Disclosures about Market Risks

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



experience reinvestment risk as fixed income securities mature and are reinvested in securities bearing lower interest rates.

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

As a result, this "credit crisis" may have a potential impact on the determination of the fair value of financial instruments or possibly require impairments in the future should the value of certain investments suffer a decline in value which is determined to be other than temporary. We currently do not believe that any change in the market value of fixed income investments in our portfolio to be material or warrant a determination that there was an other than temporary impairment.

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

## Item 8. Consolidated Financial Statements and Supplementary Data

#### Index to Consolidated Financial Statements

	Page
Medarex, Inc.	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2007 and 2006	F-3
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005	F-4
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2007, 2006 and 2005	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005	F-6
Notes to Consolidated Financial Statements F-1	F-7

#### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders Medarex, Inc.

We have audited the accompanying consolidated balance sheets of Medarex, Inc. and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion based on our audits, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Medarex, Inc. and subsidiaries at December 31, 2007 and 2006, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 in conformity with U.S. generally accepted accounting principles.

As discussed in Note 7 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payments" applying the modified prospective method.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Medarex, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 25, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey February 25, 2008

F-2

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

### (In thousands, except share data)

		December 31			
		2007		2006	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	37,335	\$	34,511	
Marketable securities		311,437		304,983	
Marketable securities Genmab		152,000		150,000	
Prepaid expenses and other current assets		29,013		22,271	
Total current assets		529,785		511,765	
Property, buildings and equipment:					
Land		6,780		6,780	
Buildings and leasehold improvements		87,217		85,123	
Machinery and equipment		68,729		61,076	
Furniture and fixtures		5,122		5,025	
		167,848		158,004	
Less accumulated depreciation and amortization		(87,923)		(73,663)	
		79,925		84,341	
Marketable securities Genmab		139,165		344,382	
Investments in, and advances to, other partners		6,040		8,141	
Segregated securities		1,530		1,477	
Other assets		3,415		4,587	
Total assets	\$	759,860	\$	954,693	
LIABILITIES AND SHAREHOLDERS' EQUITY					
Current liabilities:	¢	7.570	¢	7 1 5 4	
Trade accounts payable	\$	7,579	\$	7,154	
Accrued liabilities Deferred contract revenue current		47,194 26,872		42,250 21,032	
Deferred contract revenue current		20,872	_	21,032	
Total current liabilities		81,645		70,436	
Deferred contract revenue long-term		85,103		94,115	
Other long-term liabilities		4,351		3,689	
2.25% Convertible senior notes due May 15, 2011		143,505		141,581	
Minority interest		·		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; 127,453,308 shares issued					
and 127,419,468 shares outstanding at December 31, 2007 and 124,288,191 shares issued and 124,244,059 outstanding at December 31, 2006		1,275		1,243	
		,		, -	

	December 31		
Capital in excess of par value	1,145,453		1,107,487
Treasury stock, at cost 33,840 shares in 2007 and 44,132 shares in 2006	(85)		(111)
Accumulated other comprehensive income	289,334		495,208
Accumulated deficit	 (990,721)		(963,654)
Total shareholders' equity	445,256		640,173
Total liabilities and shareholders' equity	\$ 759,860	\$	954,693

See notes to these consolidated financial statements.

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

#### (In thousands, except per share data)

	For the Year Ended December 31					l
		2007		2006		2005
Contract and license revenues	\$	33,823	\$	26,736	\$	30,226
Contract and license revenues from Genmab		2,083		1,553		4,067
Reimbursement of development costs		20,352		20,357		17,162
Total revenues		56,258		48,646		51,455
Costs and expenses:						
Research and development		198,317		194,512		136,940
General and administrative		46,925		51,928		28,969
Acquisition of in-process technology	_	6,900				8,447
Total costs and expenses		252,142		246,440		174,356
Operating loss		(195,884)		(197,794)		(122,901)
Equity in net loss of affiliate				(1,037)		(6,323)
Interest, dividend income and realized gains		20,290		17,352		14,740
Gain on sale of Genmab stock		152,143				
Impairment loss on investments in partners		(2,141)		(5,170)		(33,347)
Interest expense		(6,162)		(4,709)		(4,233)
Minority interest Celldex		4,699		6,891		4,410
Non-cash gain on loss of significant influence in Genmab				3,202		
Pre tax loss		(27,055)		(181,265)		(147,654)
Provision for income taxes		12		436		358
Net loss	\$	(27,067)	\$	(181,701)	\$	(148,012)
Basic and diluted net loss per share	\$	(0.21)	\$	(1.50)	\$	(1.34)
Weighted average number of common shares outstanding basic and diluted		126,665		121,126		110,309

See notes to these consolidated financial statements.

F-4

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

## (Dollars in thousands)

	Common	Stock	Treasury Stock						
	Number of Shares	Amount	Capital in Excess of par Value	of	Amount (		Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
Balance at December 31, 2004	85,865,333	\$ 859	\$ 732,778	(191,640)	\$ (482)	\$ 372	\$ 6,649	\$ (633,941)	\$ 106,235
Issuance of common stock for exercise									
of options	904,067	9	4,481						4,490
Stock based compensation	15,000		2,739			(704)	)		2,035
Vesting of restricted stock units under									
deferred compensation plan			1,246						1,246
Withdrawal from executive deferred									
compensation plan				106,340	267	(267)	)		
Issuance of common stock in connection with collaboration									
agreements, net	2,879,223	29	24,971						25,000
Issuance of common stock in connection with the redemption of									
convertible note	21,875,353	219	143,564						143,783
Issuance of common stock under the									
employee stock purchase plan	234,254	2	1,427						1,429
Appreciation of equity method investee			8,039						8,039
Subsidiary stock issuance			24,000						24,000
Net loss								(148,012)	(148,012)
Other comprehensive income (loss)									
foreign currency translation									
adjustment							(610)		(610)
unrealized loss on securities							(8,390)		(8,390)
Comprehensive loss									(157,012)
Balance at December 31, 2005	111,773,230	1,118	943,245	(85,300)	(215)	(599)	(2,351)	(781,953)	159,245
Issuance of common stock for exercise									
of options	883,149	9	5,976						5,985
Stock based compensation	(15,000)		19,343			703			20,046
Vesting of restricted stock units under									
deferred compensation plan			1,194						