

MEDAREX INC  
Form 10-K  
March 15, 2006

# 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 ACT OF 1934

For the fiscal year ended December 31, 2005

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

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

Commission File No. 0-19312

## MEDAREX, INC.

(Exact name of registrant as specified in its charter)

**New Jersey**  
(State or other jurisdiction of incorporation or  
organization)  
**707 State Road, Princeton, New Jersey**  
(Address of principal executive offices)

**22-2822175**  
(I.R.S. Employer Identification No.)  
**08540**  
(Zip Code)

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

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

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

**Title of Class**  
Common Stock (\$.01 par value)

**Name of Each Exchange on Which Registered**  
The NASDAQ Stock Market, Inc. under  
symbol MEDX

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

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  No

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 for the past 90 days. Yes  No

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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.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$831.5 million as of June 30, 2005, based upon the closing sale price on the NASDAQ National 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 10,808,686 shares held by directors, officers and shareholders whose ownership exceeded 5% of the Registrant's outstanding Common Stock as of June 30, 2005. 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 February 28, 2006, the registrant had outstanding 111,964,174 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 to be held on May 18, 2006 (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.

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## 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. Ultra-Potent Toxin is a trademark 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 potential commercialization of fully human antibody-based therapeutic products. We believe that our UltiMAB Human Antibody Development System® enables us to rapidly create and develop such products for a wide range of diseases, including cancer, inflammation, autoimmune disorders and other life-threatening and debilitating diseases.

Currently, 31 antibody product candidates generated from our UltiMAB Human Antibody Development System are in human clinical trials, or have had regulatory applications submitted for such trials<sup>(1)</sup>. In 2006, we expect at least 11 Phase III clinical trials to be underway relating to five of the most advanced product candidates in which Medarex has an economic interest through co-promotion/profit sharing rights, royalties and/or equity ownership. In addition, our partner Genmab A/S has announced that it expects to initiate multiple Phase III trials for two additional product candidates in 2006. Four of the five product candidates currently in Phase III trials were generated through the use of our UltiMAB® technology and include:

- ipilimumab (also known as MDX-010), which we are developing jointly with Bristol-Myers Squibb Company, or BMS, for the treatment of metastatic melanoma and other cancers;
- golimumab (also known as CNTO 148) under development by Centocor, Inc. (a subsidiary of Johnson & Johnson) for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis;
- CNTO 1275 for the treatment of psoriasis, also under development by Centocor; and
- zanolimumab (also known as HuMax-CD4 ), being developed by Genmab A/S for the treatment of T-cell lymphoma.

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

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

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Medarex is committed to building value by developing a diverse pipeline of antibody products to address the world's unmet healthcare needs. In addition to the antibody candidates currently in Phase III trials, multiple product candidates in Phase II, Phase I and preclinical testing are being developed by Medarex either alone or jointly with or separately by our partners, including Amgen, Inc., BMS, Centocor, Eli Lilly and Company, Genmab, ImClone Systems Incorporated, MedImmune, Inc., Novartis Pharma AG, Novo Nordisk A/S and Schering 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.

In addition to our UltiMAB Human Antibody Development System, we have considerable experience in preclinical and clinical development as well as in manufacturing antibodies for clinical trials. Our existing manufacturing facility in Annandale, New Jersey currently has the capacity to undertake multiple antibody projects concurrently for clinical development purposes, meeting our near-term production demands. We have assembled a team of experienced scientific, production, clinical and regulatory personnel to facilitate the discovery and development of antibody-based products for us and for certain of our partners. We intend to add sales and marketing and additional manufacturing capabilities as needed.

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 in Item 8 of this Annual Report on Form 10-K.

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**Products in Development**

The following table summarizes potential therapeutic indications and development stages for antibody products in which Medarex has an economic interest, including our product candidates and those of our partners (based on publicly available information), and is followed by brief descriptions of each specific program:

***Phase III Product Candidates in Clinical Development***

| <b>PRODUCT</b>             | <b>INDICATION</b>   | <b>CLINICAL STATUS</b> | <b>PARTNER</b>                            |
|----------------------------|---|------------------------|---|
| ipilimumab (MDX-010)       | Metastatic Melanoma   | Phase III              | Co-developing with BMS(1)                 |
| golimumab (CNTO 148)       | Rheumatoid Arthritis,<br>Psoriatic Arthritis,<br>Ankylosing Spondylitis | Phase III              | Centocor(2)                               |
| CNTO 1275                  | Psoriasis   | Phase III              | Centocor(2)                               |
| zanolimumab<br>(HuMax-CD4) | T-cell Lymphoma   | Phase III              | Genmab (partnered with Serono<br>S.A.)(3) |
| ticilimumab (CP-675,206)   | Metastatic Melanoma   | Phase III              | Pfizer(4)                                 |

- (1) We have the option to co-promote and share profits in the U.S. We expect to receive milestone payments as this product candidate moves toward product approval, and royalties on product sales outside the U.S., should commercialization occur.
- (2) We expect to receive milestone payments as this product candidate moves through clinical trials, and royalties on product sales, should commercialization occur.
- (3) 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.
- (4) We expect to receive double-digit royalties on product sales, should commercialization occur.

**Phase II Product Candidates in Clinical Development**

| <b>PRODUCT</b>       | <b>INDICATION</b>   | <b>CLINICAL STATUS</b> | <b>PARTNER</b>  |
|----------------------|---|------------------------|---|
| ipilimumab (MDX-010) | Metastatic Melanoma, Prostate, Breast, Renal Cell and Other Cancers | Phase II and earlier   | Co-developing with BMS(1)                                       |
| MDX-066              | <i>C. difficile</i> Disease   | Phase II               | Co-developing with Massachusetts Biologic Laboratories (MBL)(2) |
| MDX-060              | Lymphoma  | Phase II               | Wholly-owned by Medarex   |
| MDX-070              | Prostate Cancer   | Phase II               | Wholly-owned by Medarex   |
| HuMax®-CD20          | Rheumatoid Arthritis, Lymphoma                                      | Phase II               | Genmab(3)   |
| AMG 714              | Rheumatoid Arthritis  | Phase II               | Genmab (partnered with Amgen)(3)                                |
| Amgen Antibody-1     | Undisclosed Disease   | Phase II               | Amgen(4)  |

- (1) We have the option to co-promote and share profits in the U.S. We expect to receive milestone payments as this product candidate moves toward product approval, and royalties on product sales outside the U.S., should commercialization occur
- (2) 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.
- (3) 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 these product candidates.
- (4) We expect to receive milestone payments as this product candidate moves through clinical trials, and royalties on product sales, should commercialization occur.



*Phase I/II and Phase I Product Candidates in Clinical Development*

| PRODUCT             | INDICATION   | CLINICAL STATUS | PARTNER   |
|---------------------|--|-----------------|---|
| MDX-214             | Cancer   | Phase I/II      | Wholly-owned by Medarex   |
| MDX-018             | Inflammatory Disease   | Phase I/II      | Co-developing with Genmab(1)                                      |
| HuMax-EGFr          | Head and Neck Cancer   | Phase I/II      | Genmab(2)   |
| CNTO 95             | Cancer   | Phase I/II      | Centocor(3)   |
| MDX-1307            | Colorectal, Pancreatic and/or Bladder Cancer                           | Phase I         | Celldex Therapeutics, Inc.(4)                                     |
| Novartis Antibody-1 | Autoimmune Disease   | Phase I         | Novartis Pharma(3)  |
| Novartis Antibody-2 | Autoimmune Disease   | Phase I         | Novartis Pharma(3)  |
| Amgen Antibody-2    | Undisclosed Disease  | Phase I         | Amgen(3)  |
| Amgen Antibody-3    | Undisclosed Disease  | Phase I         | Amgen(3)  |
| FG-3019             | Idiopathic Pulmonary Fibrosis; Diabetic Nephropathy; Pancreatic Cancer | Phase I         | FibroGen, Inc.(3)   |
| HGS-TR2J            | Cancer   | Phase I         | Kirin Brewery Co., Ltd. (partnered with Human Genome Sciences)(5) |
| Lilly Antibody      | Undisclosed Disease  | Phase I         | Eli Lilly(3)  |
| MDX-1100            | Ulcerative Colitis   | Phase I         | Wholly-owned by Medarex   |
| MEDI-545            | Lupus  | Phase I         | MedImmune(6)  |
| MDX-1303            | Anthrax Infection  | Phase I         | Co-developing with PharmAthene, Inc.(7)                           |
| MDX-1388            | <i>C. difficile</i> Disease  | Phase I         | Co-developing with MBL(8)   |
| BMS-66513           | Cancer   | Phase I         | BMS(3)  |
| Roche Antibody      | Undisclosed  | Phase I         | Genmab (partnered with Roche)(2)                                  |
| Undisclosed         | Undisclosed  | Phase I         | Undisclosed   |
| NI-0401             | Autoimmune Disease   | Phase I         | NovImmune, Inc.(3)  |
| Undisclosed         | Cancer   | Phase I         | ImClone(3)  |

(1) Under our collaboration with Genmab on MDX-018, we have the right to 100% of all revenues and profits in Asia. Outside of Asia, we and Genmab share in the revenues and profits on a 50/50 basis, subject to certain payments that Genmab owes us with respect to milestones and royalties on MDX-018.

(2) 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 these product candidates.

(3) We expect to receive milestone payments as this product candidate moves through clinical trials, and royalties on product sales, should commercialization occur.

(4) In April 2004, we assigned our rights to this product candidate to Celldex, in which we currently have an equity interest of approximately 60%. We will not be entitled to license fees or milestone payments with respect to this product. We expect to receive royalties on product sales, should commercialization occur.

(5) We expect to receive royalties on product sales, should commercialization occur.

(6) We have the option to co-promote and share profits in the U.S. We expect to receive milestone payments as this product candidate moves toward product approval, and royalties on product sales outside the U.S., should commercialization occur.

(7) 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 preagreed allocation percentage.

(8) 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.

**Selected Preclinical Product Candidates**

| PRODUCT  | INDICATION | CLINICAL STATUS | PARTNER  |
|----------|------------|-----------------|--|
| MDX-1333 | Lupus      | Preclinical     | MedImmune(1)                                       |
| MDX-1106 | Cancer     | Preclinical     | Co-developing with Ono Pharmaceuticals Co. Ltd.(2) |

(1) We have the option to co-promote and share profits in the U.S. We expect to receive milestone payments as this product candidate moves toward product approval, and royalties on product sales outside the U.S., should commercialization occur.

(2) We have the right to develop and commercialize MDX-1106 in North America, and Ono has the right to develop and commercialize 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.

**Phase III Product Candidates in Clinical Development**

**Ipilimumab (Anti-CTLA-4 Antibody) *Metastatic Melanoma.*** Ipilimumab (also known as MDX-010) is a fully human antibody that targets the cytotoxic T-lymphocyte antigen 4 immune receptor, known as CTLA-4. This receptor, which is a molecule found on the surface of T-cells, has been shown to diminish or down-regulate the immune response to tumors or infectious agents. By using a fully human antibody to block the activity of CTLA-4, we believe that patients immune systems may be able to mount a stronger immune response against foreign pathogens and cancers. We initially focused on the use of this antibody for the treatment of metastatic melanoma and prostate cancer and have expanded clinical studies into other indications such as breast, renal cell, prostate, ovarian and other cancers. We have also expanded the ipilimumab clinical program to include combination studies with chemotherapy, immunotherapy and vaccines. Effective January 2005, we entered into a collaboration with BMS to develop and potentially commercialize ipilimumab for melanoma and any additional disease indications. A more detailed description of our collaboration with BMS is included herein under the section entitled **Our Human Antibody Partnering Business BMS.**

**Metastatic Melanoma Registrational Program:** We and BMS are pursuing a registrational program of clinical studies investigating ipilimumab for the treatment of metastatic melanoma. In addition to an ongoing pivotal vaccine combination study in second-line patients (i.e., patients who have failed to respond to previous treatment with melanoma therapies other than ipilimumab) who are HLA-A2 positive, the components of this program also include monotherapy studies in second-line patients and a dacarbazine, or DTIC, combination study in previously untreated patients, each of which is expected to begin enrollment in the first half of 2006.

Under a Special Protocol Assessment agreement, or SPA, with the FDA, a Phase III pivotal trial of ipilimumab in combination with MDX-1379 (a melanoma peptide vaccine based on gp100) commenced enrollment in September 2004. We expect to enroll approximately 750 second-line HLA-A2 positive patients with unresectable Stage III or Stage IV melanoma in centers worldwide. The patients are randomized to receive one of three regimens on a 3:1:1 basis, with approximately 450 patients receiving ipilimumab/MDX-1379 combination, approximately 150 patients receiving MDX-1379 alone and



approximately 150 patients receiving ipilimumab alone. All patients receiving ipilimumab will receive a dose of three mg/kg every three weeks for up to four doses. Best objective response rate (complete and partial responses) will be used as the basis for an initial Biological License Application, or BLA, submission. Secondary endpoints of disease progression and overall survival data will continue to be collected from patients being followed in this Phase III trial. Treatment assignment is blinded, with oversight by an independent Data Monitoring Committee, or DMC.

A single-arm monotherapy registrational study to enroll up to 150 patients with metastatic melanoma previously-treated with DTIC is expected to begin enrollment in the first half of 2006. We are seeking an SPA for this study. We are currently working out the final SPA details with the FDA, and we and BMS are considering how best to allocate the second-line patients between this study and the ongoing Phase III trial to ensure that we complete enrollment for at least one second-line trial this year. Other supportive Phase II studies using monotherapy in second-line patients with metastatic melanoma started in November 2005, and January 2006, respectively.

A DTIC combination registrational study to enroll up to 500 patients with previously untreated metastatic melanoma is also expected to begin enrollment in the first half of 2006.

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

Our Phase III pivotal trial of ipilimumab in combination with the MDX-1379 vaccine was initiated based on data from a Phase II clinical trial in which 56 patients with metastatic melanoma were treated with one of two dose regimens of ipilimumab in combination with MDX-1379. As of November 2005, of the 29 patients treated in the high-dose treatment cohort, four patients experienced anti-tumor responses, with two patients experiencing complete responses ongoing for over 40 months, and one patient experiencing a partial response ongoing for over 43 months. Of the 27 patients treated in the low-dose treatment cohort, three patients experienced partial responses, two of which have had ongoing responses nearing three years. Historically, median survival after diagnosis of metastatic melanoma is six to nine months. Our ipilimumab monotherapy registrational trial is based upon data from completed and ongoing Phase II studies in previously-treated metastatic melanoma and renal cell cancer indicating efficacy as monotherapy and adequate tolerability of ipilimumab at doses up to 10 mg/kg. Our registrational trial of ipilimumab in combination with DTIC is based upon Phase II data in which the combination of ipilimumab and DTIC produced an overall response rate of 17% with an acceptable safety profile.

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, and in March 2005, orphan drug designation was granted to MDX-1379 for the treatment of HLA-A2-positive patients with Stage IIB, Stage IIC, Stage III and Stage IV melanoma. In October 2004, Fast Track status was granted to the development program for ipilimumab in combination with MDX-1379 for the treatment of second-line patients with unresectable Stage III or Stage IV melanoma.

Additional human clinical trials of ipilimumab are described in the section entitled "Phase II Product Candidates in Clinical Development" below.

*Adverse Events:* Our ipilimumab clinical trials are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is used in combination with approved therapies that themselves have significant adverse event profiles. In trials of ipilimumab, the most common drug-specific adverse events include diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. These events were anticipated and are consistent with an immune-based mechanism of action due to ipilimumab-mediated CTLA-4 blockade. Other than a very small number of fatalities not directly related to disease progression, representing less than 1% of over 600 patients treated in all previous trials, which may or may not be attributable to our product

candidates, the majority of adverse events resolved or improved with treatment and without further significant complications. Through our experience in over 600 patients who have received ipilimumab, collectively, treatment algorithms have evolved and are in place to diagnose and manage the adverse events, which are statistically correlated with clinical response. In addition, Phase II clinical trials are underway to explore the prophylactic use of oral non-absorbable steroids to minimize the gastrointestinal events sometimes associated with ipilimumab activity, as well as to explore potential biomarkers that may be predictive of clinical responses.

**Golimumab (Anti-TNF  $\alpha$  Antibody) *Inflammatory Diseases.*** In May 2005, Centocor reported that it was developing golimumab (also known as CNTO 148), a high affinity, fully human antibody that targets TNF $\alpha$  for inflammatory diseases. According to publicly available information, golimumab is in five separate Phase III clinical trials for active rheumatoid arthritis (three trials), active psoriatic arthritis (one trial) and ankylosing spondylitis (one trial). In addition, golimumab is in a Phase II clinical trial for severe persistent asthma.

**CNTO 1275 (Anti-IL-12/IL-23 Antibody) *Inflammatory Diseases.*** In May 2005, Centocor reported that it was developing CNTO 1275, a high affinity, fully human antibody that targets IL-12/IL-23 for the treatment of inflammatory diseases. According to publicly available information, CNTO 1275 is in a Phase III clinical trial for severe plaque-type psoriasis. In addition, CNTO 1275 is in Phase II clinical trials for psoriatic arthritis, multiple sclerosis and Crohn's disease.

**Zanolimumab (Anti-CD4 Antibody) *T-cell Lymphomas.*** Genmab and Serono are developing zanolimumab (also known as HuMax-CD4), a fully human antibody that targets the CD4 receptor on cells known as T-cells, which are believed to be involved in promoting autoimmune disease. In April 2005, Genmab reached an agreement with the FDA for a SPA agreement for a pivotal Phase III trial for the treatment of cutaneous T-cell lymphomas, or CTCL, which is currently underway.

In March 2004, Genmab announced that zanolimumab had been granted Fast Track status by the FDA for patients with CTCL. Genmab has also disclosed that zanolimumab has received orphan drug designation for the treatment of CTCL by the European Agency for the Evaluation of Medicinal Products in April 2004 and by the FDA in August 2004.

In August 2005, Genmab announced that it had entered into a global development and commercialization agreement with Serono for zanolimumab under which Genmab will continue to conduct, at Serono's expense, the ongoing pivotal study in CTCL and the Phase II study in non-cutaneous T-cell lymphoma.

**Ticilimumab (Anti-CTLA 4 Antibody) *Metastatic Melanoma.*** Pfizer is developing ticilimumab (also known as CP-675,206), a fully human antibody generated by using transgenic mouse technology substantially similar to our HuMAb-Mouse® technology. Pfizer's antibody targets the immune receptor CTLA-4. According to publicly available information, a first-line Phase III clinical trial comparing ticilimumab alone to chemotherapy alone for metastatic melanoma was initiated by Pfizer in December 2005. This two-arm, randomized Phase III clinical trial is expected to enroll up to 630 patients, with a primary endpoint being overall survival. Secondary endpoints are said to include durable responses, progression-free survival at six months, objective tumor responses and duration of such responses and human anti-human antibody, or HAHA, responses.

#### ***Phase II Product Candidates in Clinical Development***

**Ipilimumab (Anti-CTLA-4 Antibody) *Metastatic Melanoma; Prostate, Breast, Renal Cell and Other Cancers.*** As part of our joint ipilimumab clinical development program with BMS, there are multiple Phase II and early clinical trials underway or expected to commence in multiple tumor types, including melanoma, prostate, breast, renal, pancreatic, colorectal, ovarian, lymphoma and others. Some of these studies are designed to support our registrational program in melanoma, 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-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 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.

In October 2005, we initiated a randomized, placebo-controlled MDX-066 Phase II clinical trial for CDAD. The single-dose Phase II clinical trial is expected to enroll up to 150 hospitalized patients with CDAD and is designed to assess the safety and tolerability of MDX-066 when added to standard of care. MBL filed an IND for the combination of both the anti-Toxin A and B antibodies in 2005. A Phase I trial of this combination is underway.

**MDX-060 (Anti-CD30 Antibody) *Lymphoma.*** MDX-060 is a fully human antibody that targets CD30, which is a marker for activated lymphocytes and is present on the malignant cells of Hodgkin's disease, or HD, and anaplastic large cell lymphoma, or ALCL, as well as other CD30-expressing cancers. Through its ability to target CD30-expressing tumor cells, we believe that MDX-060 may facilitate the elimination of such cells by the immune system. We have observed responses in HD and ALCL in early Phase I and Phase II clinical trials and have expanded the development program to include three additional Phase II clinical trials to further explore the activity profile of MDX-060 as monotherapy for refractory HD, as a combination therapy with gemcitabine for HD, and as monotherapy in ALCL. In October 2004, the FDA granted orphan drug designation to MDX-060 for the treatment of HD. In January 2006, orphan drug designation was received for the treatment of CD30-positive T-cell lymphoma.

**MDX-070 (Anti-PSMA Antibody) *Prostate Cancer.*** MDX-070 is a fully human antibody that targets Prostate Specific Membrane Antigen, or PSMA. PSMA is a cell surface marker that is preferentially expressed on malignant prostate tissues and also on blood vessels in other tumors. Interim data from a multi-dose, dose-escalation Phase II clinical trial of MDX-070 in patients with hormone refractory prostate cancer indicated that the antibody was safe and well-tolerated at all doses tested. We expect to complete dosing and review the data for the disease marker prostate specific antigen, or PSA, response in the Phase II clinical trial in 2006 and potentially expand the MDX-070 development program to include a docetaxel combination study and a second-generation immunoconjugate of the anti-PSMA antibody.

**HuMax-CD20 (Anti-CD20 Antibody) *Rheumatoid Arthritis, Lymphoma.*** Genmab is developing HuMax-CD20, a fully human antibody targeting CD20, a molecule found on B cells. A Phase II clinical trial is underway for the treatment of rheumatoid arthritis. In March 2006, Genmab reported positive results from this trial. In addition, two Phase I/II clinical trials using HuMax-CD20 in patients with non-Hodgkin's lymphoma, or NHL, and chronic lymphocytic leukemia, or CLL, are ongoing. In December 2005, Genmab reported positive results from the Phase I/II clinical trial for CLL. In December 2004, Genmab announced that this product candidate was granted Fast Track designation by the FDA for the treatment of CLL. In February 2006, Genmab announced that it expects to initiate two Phase III trials in 2006 of HuMax-CD20, one in CLL and one in Rituxan® refractory follicular lymphoma.

**AMG 714 (Anti-IL-15 Antibody) *Rheumatoid Arthritis.*** AMG 714, formerly known as HuMax-IL15, is a fully human antibody that is being developed under an agreement between Genmab and Amgen and that targets Interleukin-15 (IL-15), an immune system signaling molecule that appears early in the cascade of events that ultimately leads to inflammatory disease. According to Genmab, Amgen has reformulated AMG 714 in a different cell line, and the antibody is undergoing preclinical testing. Amgen anticipates entering a Phase I study with the new formulation in 2006. In addition, a Phase II clinical trial for rheumatoid arthritis has been completed and data from this study is expected to be presented in 2006. Amgen has taken responsibility for further development of AMG 714.

**Amgen Antibody-1 *Undisclosed Disease.*** We are aware of one antibody product candidate derived from our technology

being developed by Amgen that is in Phase II clinical trials for an undisclosed indication.

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*Selected Phase I/II, Phase I and Preclinical Product Candidates*

We and our 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. Our programs and those of our partners include, among others, the following:

**MDX-214 (Anti-EGFr/CD89 Antibody) *Cancer.*** We are developing MDX-214, a fusion protein consisting of human epidermal growth factor, or EGF, genetically linked to a fully human antibody fragment that targets CD89, a trigger molecule expressed on immune effector cells. Through the use of EGF, the natural ligand to the epidermal growth factor receptor, or EGFr, MDX-214 is designed to direct CD89 positive effector cells to EGFr-overexpressing tumor cells, potentially facilitating the interaction of the immune system with the cancer. An experimental Phase I/II clinical trial in up to 48 patients is ongoing for the treatment of refractory or relapsed EGFr-expressing cancers, including cancers of the head and neck, breast, colon, prostate, lung and ovary. Preliminary clinical results to date in this proof-of-concept study suggest that we may not continue further development of this product candidate.

**MDX-018 (Anti-inflammation Antibody) *Inflammatory Disease.*** MDX-018, also known as HuMax-Inflam, is a fully human antibody that we are co-developing with Genmab. In December 2004, we and Genmab announced safety and efficacy results from an ongoing Phase I/II European clinical trial of MDX-018 in patients suffering from an undisclosed autoimmune disease. In a pooled analysis of all dose groups after eight weeks, a statistically significant mean reduction in disease activity of 56% was seen. No dose-limiting toxicity was reported after administration of doses up to eight mg/kg, and it is believed that the maximum tolerated dose was not reached. Genmab and Medarex are continuing to investigate potential development paths and also the competitive and commercial opportunities for this product.

**HuMax-EGFr (Anti-EGFr Antibody) *Head and Neck Cancers.*** Genmab is developing HuMax-EGFr, a fully human antibody targeting EGFr, a receptor molecule that has been found in excess on many types of tumor cells. According to Genmab, HuMax-EGFr is under development in head and neck cancer, and an ongoing Phase I/II clinical trial for the treatment of carcinoma of the head and neck has been completed. In January 2006, the FDA granted Fast Track designation to HuMax-EGFr for the treatment of patients with head and neck cancer who have previously failed standard therapies. In February 2006, Genmab announced that it expects to initiate a HuMax-EGFr Phase III trial in head and neck cancer in 2006.

**CNTO 95 (Anti-integrin receptors Antibody) *Cancer.*** In May 2005, Centocor announced that it is developing CNTO 95, a high affinity, fully human antibody targeting the  $\alpha$ v integrin receptors that are implicated in tumor-induced angiogenesis. Angiogenesis is the formation of new blood vessels and is believed to play an important role in tumor growth and metastasis. According to publicly available information, CNTO 95 is in a Phase I/II clinical trial alone and in combination with DTIC for advanced melanoma.

**MDX-1307 (Anti-Mannose Receptor/ $\beta$ hCG Antibody) *Colorectal, Pancreatic and/or Bladder Cancers.*** Our subsidiary, Celldex, is developing MDX-1307 (also known as  $\beta$ HCG-VAC), a fusion protein composed of a mannose receptor-specific human antibody conjugated to the beta chain of human chorionic gonadotropin, or  $\beta$ hCG. This therapeutic cancer vaccine is designed to induce antibody and cytotoxic T-cell responses directed at cancer cells in patients with  $\beta$ hCG-expressing tumors. An ongoing dose-escalation, multi-dose Phase I clinical trial is expected to enroll up to 18 patients with metastatic or locally advanced colorectal, pancreatic or bladder cancers. In September 2004, investigators at the Duke Comprehensive Cancer Center working with Celldex were awarded a two-year \$0.5 million grant from the Avon Foundation and the National Cancer Institute to initiate a Phase I clinical trial with MDX-1307 for the treatment of breast cancer.

**FG-3019 (Anti-CTGF) *Idiopathic Pulmonary Fibrosis, Diabetic Nephropathy and Pancreatic Cancer.*** FG-3019, being

developed by FibroGen, is a fully human therapeutic antibody that targets CTGF

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(connective tissue growth factor). According to publicly available sources, FG-3019 has completed a Phase I clinical trial for idiopathic pulmonary fibrosis and is also in Phase I clinical trials for the treatment of diabetic nephropathy and pancreatic cancer.

**MDX-1100 (Anti-IP-10 Antibody) *Inflammatory Diseases.*** We are developing MDX-1100, a fully human antibody that targets IP-10 (also known as CXCL10), a chemokine expressed in association with multiple inflammatory disease indications such as rheumatoid arthritis, inflammatory bowel disease and multiple sclerosis. The multi-center, single-dose, dose-escalation Phase I clinical trial is open to enroll up to 32 patients with ulcerative colitis. We acquired full rights to MDX-1100 as part of our acquisition of Ability Biomedical Corporation in August 2004.

**MEDI-545 and MDX-1333 (Anti-Type 1 IFN Antibodies) *Systemic Lupus Erythematosus.*** MedImmune is developing MEDI-545 (previously known as MDX-1103) and 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 IFN subtypes, and MDX-1333 is an antibody that is designed to block the receptor of Type 1 IFN. In November 2004, we announced a collaboration with MedImmune, whereby MedImmune will be responsible for 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. An IND for MEDI-545 was filed in October 2005.

**MDX-1303 (Anti-Anthrax Antibody) *Bacillus anthracis Infection.*** MDX-1303, also known as Valortim<sup>®</sup>, is a fully human antibody that we are co-developing with PharmAthene. MDX-1303 is designed to protect against inhalation anthrax by targeting a protein component of lethal toxins produced by the *Bacillus anthracis* bacterium known as the anthrax protective antigen. In preclinical studies, MDX-1303 both protected against infection and, when administered some time after exposure, induced recovery and survival in animals exposed to lethal doses of inhalation anthrax spores. A dose-escalation Phase I clinical trial is underway to evaluate the safety, tolerability and pharmacokinetics of MDX-1303 in healthy adults.

In 2004, we and PharmAthene received two grants from a division of the National Institutes of Health, or NIH, for up to \$7.2 million over three years to support our research and development of MDX-1303. In January 2006, the FDA granted Fast Track status for MDX-1303. Also in January 2006, we and PharmAthene procured \$2.05 million from the U.S. Department of Defense to support ongoing development of MDX-1303. In February 2006, orphan drug designation was received for the treatment of anthrax infection.

**MDX-1106 (Anti-PD-1 Antibody) *Cancer.*** MDX-1106 is a fully human antibody in preclinical development that we are co-developing with Ono Pharmaceuticals. MDX-1106 is designed to target PD-1, a receptor expressed on the surface of activated lymphocytes and is involved in tumor evasion of the immune system responses. We expect to file an IND on this product candidate for cancer in 2006.

**Other Product Candidates.** We are aware of a number of other antibody product candidates derived from our UltiMAb technology for which our partners have commenced Phase I clinical trials, including two Novartis antibodies for the treatment of autoimmune disease, two Amgen antibodies for undisclosed indications, an anti-TRAIL-R2 antibody (HGS-TR2J) being developed by Human Genome Sciences pursuant to a license with Kirin, Eli Lilly's antibody for an undisclosed indication, BMS-66513 by BMS for cancer, an undisclosed antibody being developed by Roche/Genmab for an undisclosed indication, another undisclosed antibody by an undisclosed partner, NI-0401 by NovImmune for autoimmune disease and an antibody for cancer being developed by ImClone. We are not aware of any additional information that has been made public regarding any of these Phase I clinical trials.

## **Our Human Antibody Partnering Business**

As of March 1, 2006, we have more than 40 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to enable other companies to use our UltiMAB Human Antibody Development System in their development and commercialization of new therapeutic and, in some cases, diagnostic products. We expect that a significant portion of our operating revenues over the next few years will come from licensing fees and milestone payments from our existing and future partners.

### ***BMS***

In January 2005, we announced the closing of a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. Under the terms of the collaboration, we and BMS have each granted the other certain intellectual property licenses and product rights on a worldwide basis in order 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 (also known as MDX-010), a fully human antibody product candidate developed using our UltiMAB Human Antibody Development System, that is antagonistic to CTLA-4. Ipilimumab is currently under investigation for the treatment of a broad range of cancers. The collaboration also includes the grant by us to BMS of a sub-license to MDX-1379, a gp100 peptide vaccine licensed by us from the U.S. Public Health Service, for use with ipilimumab for the treatment of metastatic melanoma. The FDA has granted orphan drug designation for ipilimumab for the treatment of high risk Stage II, Stage III and Stage IV melanoma, and we and BMS are currently conducting a Phase III clinical trial with ipilimumab and MDX-1379 combination therapy in Stage III and Stage IV metastatic melanoma patients, under a SPA agreement with the FDA, at multiple sites worldwide. This program has been granted Fast Track status by the FDA.

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

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

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

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

### *Pfizer*

In September 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 a total initial cash payment to us of \$80.0 million and purchased, through its wholly-owned subsidiary Pfizer Overseas Pharmaceuticals, a total of 4,827,808 unregistered shares of our common stock at a purchase price equal to \$6.21 per share for an aggregate purchase price of \$30.0 million at a small premium to market price at the time we entered into the collaboration. The shares were issued in a private placement pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. Pfizer also agreed to a two-year lock-up period with respect to any sales of such stock. Upon expiration of the lock-up period, such shares may be sold pursuant to the provisions of Rule 144 under the Securities Act. We have no future obligation to register such stock.

Under the Pfizer Amendment, we expect to use our UltiMAb Human Antibody Development System 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 pursuing the clinical testing of antibodies to CTLA-4, including our ipilimumab and Pfizer's ticalimumab (also known as CP-675,206) product candidates, both of which are currently in Phase III clinical trials for metastatic melanoma.

### *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. As of March 1, 2006, we had agreements with more than a dozen collaborators with whom we plan to jointly develop and commercialize human antibody products. 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 Human Antibody Development System. 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 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. As of March 1, 2006, we had more than two dozen licensing partnerships with various partners including industry leaders such as Abbott Laboratories, Amgen, Centocor, Eli Lilly, Human Genome Sciences, MedImmune, Novartis, Novo Nordisk, Pfizer and Schering AG.

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 will 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.

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

##### **Kirin**

In September 2002, we entered into a collaboration and license agreement with Kirin, which provides for us to exchange with Kirin certain cross-licenses for each other's technology for the development and commercialization of human antibody products. Pursuant to a letter of intent that was superseded by the collaboration and license agreement, we and Kirin developed the KM-Mouse®, a unique crossbred mouse which combines the traits of our HuMAB-Mouse with Kirin's TC Mouse. Under the collaboration and license agreement, we have exchanged cross-licenses with Kirin with respect to the KM-Mouse and other antibody-generating mice. In addition, certain of the cross-licenses granted under the collaboration and license agreement are subject to license, milestone and royalty payments by one party to the other. We are aware of one anti-TRAIL-R2 antibody (HGS-TR2J), currently in Phase I clinical trials, which is being developed by Human Genome Sciences pursuant to a license with Kirin. We expect to receive royalties on sales of this product, should commercialization occur.

Through December 31, 2005, we had not made any milestone payments to Kirin, although approximately \$2.8 million has been paid to Kirin as of December 31, 2005 representing a payment due Kirin as a result of our collaboration with Pfizer. Based on a total of three 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 2007, we may be required to make milestone payments to Kirin aggregating up to approximately \$12.75 million with respect to such products, or a maximum of approximately \$4.25 million per product. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

- whether or not a decision is made to request a license from Kirin;
- the type of license requested (research or commercial);
- the success and timing of development efforts and clinical trials of product candidates covered by any such licenses;
- the type of product developed (payment obligations differ depending on whether a product is an *ex vivo* therapeutic, *in vivo* therapeutic, research reagent or diagnostic 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, 2005, we had made milestone payments of approximately \$0.3 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of nine 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 2007, we may be obligated to make future milestone payments aggregating up to approximately \$59.9 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 I, Phase II and/or Phase III clinical trials or foreign equivalents;
- submission of BLA(s) or foreign equivalents; and
- receipt of marketing approval(s) to sell products in a particular country or region.





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

### Significant Partner Revenue

Revenue from partners representing 10% or more of total revenues for the years ended December 31, 2005, 2004 and 2003 is as follows:

| Partners | 2005 | 2004 | 2003 |
|----------|------|------|------|
| BMS      | 34 % | 4 %  |      |
| Pfizer   | 18 % | 20 % |      |
| Genmab   | 8 %  | 26 % | 48 % |
| Amgen    | 1 %  | 8 %  | 15 % |

Further information regarding revenues from partners is included in Notes 10 and 11 in the Notes to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

### Strategic Investments

#### *Genmab*

In August 2000, we entered into a binding memorandum of understanding, or the Genomics Agreement, with Genmab, a Danish biotechnology company in which we held, at the time, an equity interest of approximately 44%, pursuant to which we granted Genmab rights to make available our transgenic mouse technologies for multi-target (five or more targets) genomics partnerships to certain pharmaceutical and biotechnology companies whose headquarters are located in Europe. The Genomics Agreement had an initial term of five years with a right exercisable by Genmab to extend the term for an additional two years. The initial term of the agreement expired in August 2005 and was not extended. For each year of the agreement, we received \$2.0 million per year from Genmab. At Genmab's option, these amounts were paid in either cash or capital stock. During the years ended December 31, 2005, 2004 and 2003, we recognized \$1.3 million, \$2.0 million and \$2.0 million, respectively, of revenue from this agreement.

In October 2000, Genmab became a publicly listed company on the Copenhagen Stock Exchange. As a result of raising the equivalent of \$178.0 million (based on the 8.7695 DKK/USD exchange rate on the listing date of October 18, 2000) and subsequent investments in Genmab by other parties, our ownership interest in Genmab decreased to approximately 32%. In July 2004, Genmab completed a private placement of 5.6 million shares of its stock, resulting in a further reduction in our ownership interest to approximately 24.7%. 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 to approximately 22.2%, where it remained as of December 31, 2005. We accounted for our investment in Genmab under the equity method of accounting through January 31, 2006.

In February 2006, Genmab completed a private placement of 5.75 million shares of its stock. As a result of this offering, our ownership interest was reduced to approximately 18.9%. Beginning February 1, 2006, we expect to account for our investment in Genmab as a marketable security in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*.

### **IDM**

During the second half of the 1990s, the focus of our business shifted from humanized and murine monoclonal antibody-based products to fully human antibody development. As a result, in July 2000, we entered into an agreement with Immuno-Design Molecules, S.A., or IDM, whereby we licensed to IDM certain of our humanized and murine antibodies in exchange for equity units in IDM. In August 2005, IDM completed a share exchange with Epimmune Inc., a Delaware corporation traded on the Nasdaq, whereby IDM shareholders exchanged their IDM shares for shares of Epimmune. Epimmune subsequently changed its name to IDM Pharma, Inc., or IDM Pharma. As a result of the exchange, we currently hold an approximate 19.9% equity position in IDM Pharma. IDM Pharma's lead product candidate, Junovan, has completed Phase III clinical trials for the treatment of osteosarcoma, a bone cancer affecting adolescents.

### **Celldex**

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

In October 2005, Celldex acquired all of the issued and outstanding shares of capital stock of Lorantis Limited, or Lorantis, a privately held biotechnology company based in Cambridge, U.K. and substantially all of the assets of Alteris Therapeutics, Inc., or Alteris, a privately held biotechnology company based in Philadelphia, PA. The purchase price for the Lorantis capital stock consisted of 6.8 million shares of Celldex Class A common stock, and the purchase price for the Alteris assets consisted of 1.2 million shares of Celldex common stock, a cash payment of \$1.6 million and certain potential milestone and other payments. As a result of these transactions, our ownership percentage of Celldex was reduced to approximately 60%.

At the date of acquisition, in addition to cash of approximately \$30 million, Lorantis' assets included a pre-clinical program based upon the discovery of a fundamental immune mechanism, the Notch signaling pathway, that has been shown in preclinical studies to selectively modulate immune responses.

Through the acquisition of Alteris, Celldex obtained exclusive rights to ALT-110, a therapeutic cancer vaccine currently in an investigator-initiated Phase II clinical trial for the treatment of brain cancer and an investigator-initiated Phase I clinical trial for the treatment of prostate, gastric, non-small cell lung and ovarian cancers. ALT-110 is based on a variant of the epidermal growth factor receptor known as EGFRvIII. In addition, Celldex acquired several patent applications from Alteris covering the Rapid Identification of Alternative Splicing system, or RIAS, a proprietary technology platform for the discovery of new disease-specific targets.

## **Our Human Antibody Technology**

### ***The UltiMAb Technology Platform***

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.

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 do not require any humanization, a process that at times has proven to be challenging and time consuming, and can result in 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>-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.

To further enhance our ability to create products from genomics research, we have also coupled the UltiMAb Human Antibody Development System with other technologies, such as our proprietary Ultra-Potent Toxin, or UPT, technology for creating antibody immunoconjugates. Our UPT program includes a class of DNA alkylating agents, which have been designed to overcome multi-drug resistance. We believe this program provides us with a platform for generating cytotoxic drugs that specifically target various cancers.

#### *The UltiMAb Advantage*

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 are (i) 100% human, (ii) of a very high affinity, and (iii) can be produced and manufactured relatively quickly and efficiently.

We believe that our fully human antibody technologies offer the following advantages over other antibody technologies:

- *Fully Human Antibodies.* Unlike humanization techniques, our UltiMAb Human Antibody Development System generates antibodies with 100% human protein sequences, which we believe will permit the development of products with a favorable safety profile. Additionally, we believe fully human antibody-based products are likely to be eliminated less rapidly from the human body, potentially reducing the frequency and amount of dosing.

- *High Affinity Antibodies.* Our human antibody technology takes advantage of the human body's natural affinity maturation process (whereby antibodies evolve over time to have higher affinity to targets), creating antibodies that can have affinities up to 1,000 times higher than the chimeric or humanized antibodies now approved for sale in the U.S. Our high affinity antibodies have been generated against a wide range of target antigens. Our human antibodies are produced without the need for any subsequent engineering to make them more human—a process that at times has proven to be challenging and time consuming. Thus, we reduce the risk that an antibody's structure and function will be altered by such engineering.
- *Rapid Development Capabilities.* By combining our technology for creating fully human antibodies with our in-house development and clinical supply manufacturing expertise, we believe that we can rapidly progress from first generation of the antibody to the clinic.
- *Diverse Selection of Antibodies Responding to Many Disease Targets.* We believe that our technology has the potential to generate high affinity human antibodies of all isotypes and subclasses. In addition, we have been able to create large panels of monoclonal antibodies to many potentially medically relevant antigens. For a given antigen target, the ability to select a product candidate from a pool of multiple antibodies could be important in selecting the optimal antibody product candidate for development.
- *Flexibility for Our Partners.* Our human antibody technology can be used either in our laboratories or in the laboratories of our partners. This provides our partners with the flexibility to incorporate our technology into their research and development programs or to contract with us to produce antibodies for them.
- *Greater Certainty of Intellectual Property Rights.* 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. In contrast, various entities hold patents that may cover the chimerization or humanization of monoclonal antibodies. In addition, several companies and academic institutions have developed phage libraries for the creation of monoclonal antibodies, and a number of companies and academic research centers have received patents that may apply to the creation of phage-derived monoclonal antibodies.

#### **Our Research, Development and Manufacturing of Human Antibodies**

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 in Annandale and Bloomsbury, New Jersey, that 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 220 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 new 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 Cross License Agreement With Abgenix**

In 1994, prior to our acquisition of GenPharm International, Inc., Abgenix, Inc. and related entities brought a lawsuit against GenPharm relating to intellectual property issues involved in creating transgenic mice capable of generating fully human antibodies. GenPharm filed counterclaims, and the litigation was settled in March 1997 upon the execution of a patent cross-license and settlement agreement. Under the terms of this agreement, GenPharm granted a license, on a non-exclusive basis, 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. In exchange for this license, GenPharm received payments in 1997, and after our acquisition of GenPharm, we received payments, including interest, from Abgenix and its related parties, which totaled approximately \$38.6 million. Neither Abgenix nor any of its related entities have any further payment obligations to us under the agreement. Neither we nor GenPharm were required to make any payments to Abgenix or any related entity under the terms of the agreement. The agreement also provides us with a non-exclusive license to certain intellectual property held by Abgenix. In December 2005, Abgenix and Amgen announced their execution of a merger agreement which, subject to certain conditions, is expected to close by the end of April 2006. If the merger is completed, Amgen will gain access to the patents, patent applications, third-party licenses and inventions licensed to Abgenix under the cross-license agreement.

#### **Intellectual Property**

Proprietary protection for our products, processes and know-how is important to our business. Our policy 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.

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As of December 31, 2005, we hold an ownership interest in a total of 58 issued patents in the U.S. and 237 issued patents in foreign countries with respect to our UltiMab technology and products, our bispecific molecule technology and products, and our other technology and products.

Of these, 14 of our issued patents in the U.S. and 40 of our issued patents in foreign countries, including European countries, Japan, Korea, New Zealand and Australia, among others, relate to various aspects of our UltiMab technology. 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. These patents have expiration dates beginning in 2008, although the majority of the key HuMab-Mouse technology patents expire beginning in 2011. In addition to our UltiMab technology patents, we have two issued U.S. patents and 11 issued foreign patents that relate particularly to HuMab-Mouse products. We also have 38 related pending U.S. and foreign patent applications directed to various aspects of our UltiMab technology and 198 pending U.S. and foreign patent applications directed to various aspects of our UltiMab products. These include patent applications describing several of our particular human antibody product candidates, such as our anti-CTLA-4 (ipilimumab), anti-PSMA (MDX-070) and anti-CD30 (MDX-060) product candidates. We have been assigned patent rights from Northwest Biotherapeutics, Inc. relating to aspects of MDX-070. We have been assigned patent rights relating to MEDI-545 and MDX-1333 by Nufarm, B.V., Medisup International N.V., Pharma Pacific Pty. Ltd and Laboratoire Européen 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 relating to tumor-activated prodrugs and Ultra-Potent Toxins. A U.S. patent to our human anti-CTLA-4 antibody products issued in January 2006.

As of December 31, 2005, we had a total of 75 U.S. patent applications and 259 foreign patent applications pending.

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 intellectual property mentioned above. 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 have a license from medac GmbH relating to certain aspects of MDX-060. We have a non-exclusive license from Millennium Pharmaceuticals, Inc. relating to aspects of MDX-070.

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 U.S. and European Union; GenPharm® and Trans-Phage Technology® 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 I 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 II, 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 III, 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 II studies. These studies are often referred to as Phase I/II studies. Notwithstanding the foregoing, even if patients participate in initial human testing and a Phase I/II study carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase I and Phase II 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. 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 Biologic License Application, or 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 current good manufacturing practice, or cGMP, requirements.



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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 2006, the NDA or BLA review fee alone is \$767,000, 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.

Overall research, development and approval times depend on a number of factors, including the period of review at the FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA questions, the severity or life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials and the risks and benefits demonstrated in the clinical trials.

*Drugs and Biologics for Serious or Life-Threatening Illnesses.* 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 IV, studies as a condition of approval. In addition, the FDA may impose restrictions on distribution and/or promotion 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 (for example, 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. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information, the American Medical Association Drug Evaluations, or the U.S. Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

### **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 on 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 is Abgenix. As a result of the cross-license agreement with GenPharm (our wholly owned subsidiary since 1997), Abgenix offers to potential partners the use of its transgenic mouse known as XenoMouse® to generate fully human monoclonal antibodies. In December 2005, Abgenix and Amgen announced their execution of a merger agreement which, subject to certain conditions, is expected to close by the end of April 2006. If the merger is completed, Amgen will gain access to the patents, patent applications, third-party licenses and inventions licensed to Abgenix under the cross-license agreement.

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 of certain antibodies.

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) and XTL Biopharmaceuticals Ltd. each have developed technology that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies in functionally modified mice. Regeneron

claims to have developed VelocImmune mice, in which portions of the mouse immune genome have been humanized, generating mice with humanized immune systems that can generate fully human antibodies.

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 Cambridge Antibody Technology Group plc, or CAT, Dyax Corp. and MorphoSys AG to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, MedImmune, Amgen, Biogen Idec, Inc., Novartis, Genentech, Inc., PDL BioPharma, Inc., Abbott Laboratories, Wyeth and GlaxoSmithKline have generated therapeutic antibody-based products that are currently in development or on the market and 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, Johnson & Johnson, Wyeth, Amgen, Abbott, UCB Pharma, Biogen Idec, Abgenix, CAT, MorphoSys AG, Tanox, Inc., Genentech, 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 ticilimumab, an antibody to CTLA-4, in potential competition with our product candidate, ipilimumab. Ticilimumab is currently in Phase III clinical trials, and Pfizer has announced that it expects to file a BLA on the product in 2007. In addition, we are aware of a patent held by Pfizer to which we may need a license in order to manufacture commercial supplies of ipilimumab. Several of the foregoing companies are also licensees of our transgenic mouse technology. 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, have substantially greater experience than us in developing pharmaceutical products, undertaking preclinical testing and human clinical trials, obtaining FDA and other regulatory approvals of such products and the manufacturing and marketing of such products. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or other foreign 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, immunoconjugates monoclonal antibodies linked to toxins or radioactive isotopes are being developed by others, as well as by us. 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 underway for some time. Included in this group are interleukins such as IL-2 and IL-11, interferons, colony stimulating factors such as G-CSF and GM-CSF, clotting factors, growth hormones, erythropoietin, DNase, tPA, glucocerebrosidase, PDGF, and a number of other 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.



regulatory approval; dependence on key personnel; 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.

**Successful development of our products is uncertain.**

Based on public disclosures, as of March 1, 2006, regulatory applications, including INDs, have been submitted to the FDA or comparable foreign authorities, for 31 product candidates derived from our UltiMAB platform. Active product candidates employing our human antibody technology have not moved beyond clinical development. Neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA or comparable foreign authorities and/or commercialized. In addition, we are not aware of any commercialized fully human monoclonal antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond clinical development or demonstrate clinical safety and effectiveness.

Our 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:

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

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

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

**Our revenue and profit potential are unproven. No revenues have been generated from the commercial sale of our products and our products may not generate 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 an early stage of development 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, 2005, we had an accumulated deficit of approximately \$745.4 million. Our net loss was \$146.0 million for the year ended December 31, 2005. 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 products;
- establishing new collaborations; and
- new technologies.

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

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

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

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

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

- the timing of the commencement, completion or termination of partnership agreements;
- the introduction of new products and services by us, our partners or our competitors;
- delays in, or termination of, preclinical testing and clinical trials;

- changes in regulatory requirements for clinical trials;

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- 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 at risk of securities class action litigation.**

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. The risk is especially relevant for us because biotechnology companies have experienced greater than average price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could 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, by way of example:

- the size and complexity of research and development programs;
- the scope and results of preclinical testing and clinical trials;
- the retention of existing and establishment of further partnerships, if any;
- continued scientific progress in our research and development programs;
- the time and expense involved in seeking regulatory approvals;
- competing technological and market developments;
- the time and expense of filing and prosecuting patent applications and enforcing patent claims; and
- the cost of establishing 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 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.

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

We have \$150.0 million in aggregate principal amount of our 2.25% convertible senior notes outstanding, which, unless converted to shares of our common stock or redeemed, will mature in 2011. Our ability to make payments on these notes and our other obligations will depend on our future operating performance and ability to generate cash and may also depend on our ability to obtain additional debt or equity financing. Generally, during the last five years, our operating cash flows were negative and insufficient to cover our fixed charges. Our ability to generate sufficient operating cash flow to service our indebtedness, including the notes, and fund our operating requirements will depend on our ability, alone or with others, to successfully develop, manufacture, and obtain required regulatory approvals and market our product candidates, as well as other factors, including general economic, financial, competitive, legislative and regulatory conditions, some of which are beyond our control. If we are unable to generate sufficient operating cash flow to service our indebtedness and fund our operating requirements, we may need to obtain additional debt or equity financing to do so, which may not be available to us on satisfactory terms or at all. In addition, if new indebtedness is incurred, the risks relating to our ability to service our indebtedness that we face could intensify.

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

- limiting our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business;
- placing us at a competitive disadvantage relative to our competitors who have lower levels of debt;
- making us more vulnerable to a downturn in our business or the economy generally; and
- requiring us to use a substantial portion of our cash to pay principal and interest on our debt, instead of applying those funds to other purposes such as working capital and capital expenditures.

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

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

- the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices, or cGMPs, for use in clinical trials;
- the need or desire to modify our manufacturing processes;
- slower than expected rates of patient recruitment;
- modification of clinical trial protocols;
- the inability to adequately observe patients after treatment;



- changes in regulatory requirements for clinical trials;
- the lack of effectiveness during the clinical trials;
- unforeseen safety issues;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or clinical holds requiring suspension or termination of the trials.

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

Generally, our clinical trials, including our melanoma trials, 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 is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. The most common adverse events associated with our trials of ipilimumab have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related immune-mediated events, such as diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. Other than a very small number of fatalities, representing less than 1% of over 600 patients treated in all previous trials, which may or may not be attributable to our product candidate, most events resolved with treatment. We cannot assure you that additional safety issues will not arise with respect to our products in the future.

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

In addition, we are currently working out the final SPA details with the FDA for a single-arm monotherapy registrational study of our ipilimumab product candidate to enroll up to 150 second-line patients with metastatic melanoma previously treated with DTIC. A Phase III pivotal study of ipilimumab in combination with MDX-1379 (a melanoma peptide vaccine based on gp100) commenced enrollment of second-line patients in September 2004 and is currently ongoing. If the SPA for the monotherapy study is approved by the FDA, we may reallocate patients from the Phase III combination study to the new monotherapy study. Any such reallocations may delay the development of the combination therapy product candidate.

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

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

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

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

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

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

- establishment and demonstration of clinical efficacy and safety, especially as compared to conventional treatments;
- cost-effectiveness;
- alternative treatment methods;
- reimbursement policies of government and third-party payors; and
- marketing and distribution support for our product candidates.

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

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

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

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payors, the market for products employing our human antibody technology will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products. Such studies may require us to dedicate a significant amount of resources. Our project candidates may not be considered cost-effective. Third-party payors may not reimburse sales of products employing our human antibody technology, or enable us or our partners to sell them at profitable prices.

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

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

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

We may also encounter problems with the following:

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

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. We are currently pursuing late-stage clinical and commercial supply agreements with cGMP-compliant third-party manufacturers with available capacity to meet our internal production timetables. We have entered into clinical supply agreements with Lonza with respect to ipilimumab and MDX-060. As part of our collaboration with BMS, we assigned to BMS the clinical supply agreement with respect to ipilimumab. Our partner BMS is responsible for securing commercial supply agreements for ipilimumab and is currently in negotiations with respect to such arrangements. BMS may not be able to successfully consummate such arrangements. We do not currently have the capability to manufacture our product candidates under development in large commercial quantities and have no experience in commercial-scale manufacturing. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin producing antibodies under cGMP regulations. We cannot make assurances that we will be able to contract with such companies for clinical and/or commercial supply on acceptable terms or in a timely manner, if at all. Moreover, even if we are able to enter into clinical and/or commercial supply manufacturing arrangements with cGMP-compliant third-party manufacturers, we cannot assure you that such manufacturers will be able to produce products that are substantially equivalent to the product candidates that we have produced in our own facilities and used in our clinical trials. If such companies are not able to produce products that are substantially equivalent to our product candidates, the progress of our clinical trials and/or commercialization of our products may be delayed and our business, financial condition and results of operations may be materially harmed.

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

or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

**The development of 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 products generated through the use of our antibody technology. In particular, under the terms of our collaboration and co-promotion agreement with BMS, we have granted a license to commercialize our lead product candidate, 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 may cause us to incur substantial additional costs in order to develop and commercialize ipilimumab, which could have a material adverse effect on our business.

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

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

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

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

- our partners have significant discretion whether to pursue planned activities;
- we cannot control the quantity and nature of the resources our partners may devote to product candidates;
- our partners may not develop products generated using our antibody technology as expected; and
- business combinations or significant changes in a partner's business strategy may adversely affect that partner's willingness or ability to continue to pursue these product candidates.

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

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

Our licensing partners generally have the right to terminate our partnerships at any time. Our ability to continue our current partnerships and to enter into additional partnerships is dependent in large part on our ability to successfully demonstrate that our UltiMAB technology is an attractive method of developing





fully human antibody therapeutic products. Existing or potential partners may pursue alternative technologies, including those of our competitors, or enter into other transactions that could make a collaboration with us less attractive to them. For example, if an existing partner purchases or is purchased by a company that is one of our competitors, that company could be less willing to continue its collaboration with us and may, instead, become one of our competitors. For example, in December 2005, Abgenix and Amgen announced their execution of a merger agreement which, subject to certain conditions, is expected to close by the end of April 2006. Upon completion of the merger, Amgen will own Abgenix's XenoMouse technology. As a result, Amgen may be less willing to continue its collaboration with us and may, through the use of its newly acquired 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, we must consolidate the results of its operations in our financial statements.**

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, 2005, our share, net of minority interest, of Celldex's net loss included in our financial statements was approximately \$12.6 million.

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

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

We are exposed to equity price risk on our strategic investments in our publicly-traded partners, and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. As these investments are the result of strategic alliances with our collaborative partners, we typically do not attempt to reduce or eliminate our market exposure of these types of strategic investments. Under SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, these investments are designated as available-for-sale and are reported at fair value on our consolidated balance sheet. Unrealized holding gains and losses on available-for-sale securities are generally excluded from earnings and reported within other comprehensive income which is a separate component of shareholders' equity. Under our accounting policy, marketable equity securities are generally considered to be impaired if their fair value is less than our cost basis in such securities for more than six months, or some other

period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of available-for-sale securities is considered to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. During each of the years ended December 31, 2005 and 2003, no impairment charges were recorded related to the value of our investments in publicly traded companies. For the year ended December 31, 2004, we recorded impairment charges of \$0.2 million on investments in partners whose securities are publicly traded. 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, 2005, 2004 and 2003, we recorded impairment charges of approximately \$33.3 million, \$7.1 million and \$1.4 million, respectively, on our investments in privately-held companies. Approximately \$7.0 million of the 2004 impairment charge related to IDM. Approximately \$29.3 million of the 2005 impairment charge related to IDM prior to their share exchange with Epimmune. Future adverse changes in market conditions or adverse changes in operating results of these companies may also require an impairment charge in the future.

**We are dependent on our key personnel.**

We are highly dependent on the members of our scientific and management staff. If we are not able to retain any of these persons, our business may suffer. In particular, we depend on the services of Donald L. Drakeman, J.D., Ph.D., our President and Chief Executive Officer; Nils Lonberg, Ph.D., our Senior Vice President and Scientific Director; and Geoffrey M. Nichol, M.D., M.B.A., our Senior Vice President, Product Development. We maintain a key man life insurance policy for Dr. Drakeman in the amount of \$2.0 million and maintain key man life insurance policies in the amount of \$1.0 million for each of Dr. Lonberg and Dr. Nichol. We have entered into employment agreements with Dr. Drakeman and all of our other executive officers, which expire in January 2007. Thereafter, all of these agreements are automatically renewed for successive one (1) year terms unless we or the employee elect not to renew.

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

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

Our success depends in part on our ability to:

- apply for, obtain, protect and enforce patents;
- protect trade secrets;

- operate without infringing upon the proprietary rights of others; and
- in-license certain technologies.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued or enforceable. The patent position of biotechnology intellectual property involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide sufficient protection against competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed which is not covered by an issued patent. The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S.

In addition to patents, we rely on trade secrets and proprietary know-how. We seek protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide protection or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information, or breach of these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

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

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 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 harm our business.

Even though we have issued patents, filed applications and 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 technology include patents and applications that cover particular human antibodies. These patents do not cover all human antibodies.

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 products and business. These patents, patent applications, third party licenses and inventions form the basis of our HuMAb-Mouse technology. Abgenix has announced a potential merger with Amgen which, if completed, will give Amgen access to such patents, patent applications, third party licenses and inventions. Our business may suffer from the competition of these entities and their licensees and sublicensees.

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

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

Moreover, other parties could have blocking patent rights to products made using 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 such antibody. For example, we are aware of certain U.S. and European patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets, and to the method of manufacture and use of such products. In particular, we are aware of a patent held by Pfizer to which we may need a license in order to manufacture commercial supplies of ipilimumab. We are also aware of certain U.S. and foreign patents and patent applications held by third parties relating to anti-CTLA-4 antibodies, such as ipilimumab; anti-CD30 antibodies, such as MDX-060; anti-PSMA antibodies, such as MDX-070; anti-Type 1 IFN antibodies, such as MEDI-545 and MDX-1333; anti-IP10 antibodies, such as MDX-1100; anti-anthrax protective antigen antibodies, such as MDX-1303; anti-*C. difficile* antibodies, such as MDX-066; and antibodies that target the same disease antigen as MDX-018 (HuMax-Inflam), as well as other antibody products under development by us alone or with our collaborators.

With respect to third party patent rights, we are aware of a U.S. patent owned by Genentech, Inc. relating to the production of recombinant antibodies in host cells. Two separate re-examinations before the U.S. Patent and Trademark Office, or the USPTO were requested anonymously in May and December 2005. In the re-examination filed in May 2005, the USPTO rejected all of the patent claims, and Genentech recently filed its response following an interview with the USPTO. In January 2006, the USPTO ordered re-examination of the patent on the basis of the second request for re-examination, filed in December 2005, but has not yet taken any further action on this second request. If the claims are determined to be unpatentable during the re-examination, Genentech will have the opportunity to appeal, and the determination of unpatentability could be reversed. It is also possible that the claims might be confirmed as valid by the USPTO upon completion of the re-examination. The re-examination and appeal process could take several years each to complete.

We currently produce certain of our products and our partners' products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in the Genentech patent, and the patent survives the re-examination and 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 make and import recombinant antibodies using Genentech's techniques.

In addition to the Genentech patent, we are also aware of certain U.S. patents held by third parties relating to antibody expression in particular types of host cells, including CHO cells, and methods of culturing CHO cells in certain media, and to particular antibody formulations, which may be relevant to our current or future manufacturing techniques.

If our antibody products (or those antibody products of our partners using our human antibody technology) or their commercial use or production meet all of the requirements of any of the claims of the aforementioned patents or 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 products and/or actions in developing or selling human antibody products 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 products. Our failure to obtain a license to any technology that we may require may materially harm our business, financial condition and results of operations.

**We 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 products in clinical trials and the sale of products based on our technology. Product liability claims may be expensive to defend and may result in large judgments against us. We have obtained limited product liability coverage for our clinical trials, under which coverage limits are \$15 million per occurrence and \$15 million in the aggregate. Although we believe these coverage limits are adequate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. We intend to increase our coverage limits as we progress into additional late-stage clinical trials and to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for products in development. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

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

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

therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. The most common adverse events associated with our melanoma trials of ipilimumab have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related immune-mediated adverse events, such as diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. Almost all of these adverse events responded to medical therapy. In a very small number of instances (less than 1% of over 600 patients treated), fatalities not directly related to disease progression have occurred during the course of these trials such fatalities may or may not be attributable to our product. Any of these events or any other adverse events in any of our other clinical trials could result in a product liability claim. Any such claims against us, regardless of their merit, could result in significant awards against us, which could materially harm our business, financial condition and results of operations.

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

The development of biotechnology and pharmaceutical products is a highly competitive business subject to significant and rapid technological change. We face competition in several different forms. First, our human antibody generation activities currently face competition from several competitors with similar technology to ours as well as distinctly different technologies. Second, the actual products being developed by us or by our partners also face actual and potential competition. Developments by our competitors may render our human antibody technology 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 products or have successfully commercialized antibody products. Many of these companies are addressing the same diseases and 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. We compete directly with Abgenix, with respect to the generation of fully human antibodies from transgenic mice. In December 2005, Abgenix and Amgen announced their execution of a merger agreement which, subject to certain conditions, is expected to close by the end of April 2006. Upon completion of the merger, Amgen will own Abgenix's XenoMouse technology and may engage in direct competition with us in the area of generating fully human monoclonal antibodies for antibody-based therapeutics. In addition, we have entered into agreements with each of Kirin and Genmab, respectively, that grant these companies licenses to our proprietary transgenic mouse technology platform, enabling them to compete with us in offering antibody generation and development services in certain markets.

We have also entered into license agreements with Pfizer which enable it to compete with us in the generation and development of antibodies to CTLA-4. Pfizer is developing ticilimumab (also known as CP-675,206), a fully human antibody generated by using transgenic mouse technology substantially similar to our HuMAb-Mouse technology that targets the immune receptor CTLA-4. According to publicly available information, a first-line Phase III clinical trial comparing ticilimumab alone to chemotherapy alone for metastatic melanoma was initiated by Pfizer in December 2005. Pfizer has disclosed that it expects to file a BLA with respect to ticilimumab in 2007.

Xenerex Biosciences and XTL Biopharmaceutical, Ltd. have developed technology that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies in functionally modified mice. Regeneron claims to have developed VelocImmune mice, in which portions of the mouse immune genome have been humanized, generating mice with humanized immune systems that can generate fully human antibodies. Numerous additional companies are developing therapeutic products comprising

human antibody components. Furthermore, several companies are developing, or have developed, technologies that do not involve immunization of animals for creating antibodies comprising human antibody sequences. For example, phage display technology is being used by companies, such as CAT, Dyax and MorphoSys to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, MedImmune, Amgen, Biogen Idec, Novartis, Genentech, PDL BioPharma, Wyeth, Abbott Laboratories and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market and that are derived from recombinant DNA that comprise human antibody components.

Other technologies can also be applied to the treatment of the diseases that we or our partners are pursuing. For example, immunoconjugates monoclonal antibodies linked to toxins or radioactive isotopes are being developed by others, as well as by us. 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 underway for some time. Included in this group are interleukins such as IL-2 and IL-11, interferons, colony stimulating factors such as G-CSF and GM-CSF, clotting factors, growth hormones, erythropoietin, DNase, tPA, glucocerebrosidase, PDGF, and a number of other similar biological agents. Continuing development of new chemical entities and other drugs by pharmaceutical and other biotechnology companies carries with it the potential discovery of agents for treating disease indications also targeted by drugs that we or our partners are developing.

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

- developing products;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing and marketing products.

Accordingly, our competitors may obtain patent protection, receive FDA approval or commercialize products before we or our partners do. If we or our partners commence commercial product sales, we or our partners will be competing against companies with greater 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 instead of us that are more effective than ours.

Our competitive strategy includes seeking orphan drug designation for eligible products (i.e., certain products for diseases with small patient populations). 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.

We have obtained orphan drug designation for each of ipilimumab and MDX-1379 for specified metastatic melanoma patient populations, and therefore each is eligible for orphan drug exclusivity if approved first. The FDA's approach with respect to orphan drug status for antibody products is uncertain, particularly with respect to whether two antibody products against the same disease target would be considered to be the same for orphan drug purposes under current law and regulations. Furthermore, we



are not aware of established FDA policies or precedent for how orphan drug exclusivity applies in circumstances where two or more compounds with orphan drug designations are approved for combination therapy. The FDA may not grant us exclusivity for the ipilimumab and MDX-1379 combination therapy, or may permit others to receive approval for differing combinations of similar compounds despite any orphan drug exclusivity we receive, depending on FDA's assessment of the chemical similarity of the other drugs to Medarex's products. Even if we receive orphan drug exclusivity, the FDA may permit others to market similar or different compounds for different uses or it may permit others to market similar compounds for treating metastatic melanoma. We therefore may not receive any meaningful protection for ipilimumab, MDX-1379 or our other products based on orphan drug exclusivity.

In addition, Pfizer could obtain orphan drug designation for ticilimumab for specific patient populations, including metastatic melanoma and, if they are first to receive approval by the FDA, could obtain market exclusivity with respect to such populations, thereby blocking Medarex and BMS from obtaining approval to sell ipilimumab, whether as a monotherapy or combination therapy with MDX-1379, for such patient populations, including metastatic melanoma.

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

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

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

- adversely affect the successful commercialization of any drugs that we or our partners develop;
- impose additional costs on us or our partners;
- diminish any competitive advantages that we or our partners may attain; and
- adversely affect our receipt of revenues or royalties.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example,

manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. If we, our partners or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things:

- delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;
- warning letters;
- fines;
- import and/or export restrictions;
- product recalls or seizures;
- injunctions;
- total or partial suspension of production;
- civil penalties;
- withdrawals of previously approved marketing applications or licenses;
- recommendations by the FDA or other regulatory authorities against governmental contracts; and
- criminal prosecutions.

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

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

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

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

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

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results;
- the product candidate was not effective in treating the specified disease or condition;
- the product candidate had harmful side effects on humans or presented unacceptable safety risks;
- the governing regulatory authorities (such as the FDA) denied approval to the product candidate altogether or denied a commercially important indicated use;
- the product candidate was not economical for us to manufacture; and/or
- the product candidate was not cost effective in light of alternative therapies.

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

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

We will depend on our own manufacturing facilities and/or on those of our partners and other third parties to manufacture products generated through the use of our human antibody technology. Before commercializing a new drug, manufacturers must demonstrate compliance with the applicable current good manufacturing practices, or cGMP, requirements which include quality control and quality assurance requirements as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of our technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. We, our partners or third party contract manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements, may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and/or civil or criminal sanctions.

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

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

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to FDA's current good manufacturing practice requirements. Application holders must obtain FDA approval for product, manufacturing, and labeling changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the 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. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval.

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

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

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

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

**Our operations involve hazardous materials and are subject to environmental, health and safety controls and regulations.**

As a biopharmaceutical company, we are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with environmental, health and safety regulations may be substantial. Our business activities involve the controlled use of hazardous materials and we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources and may materially harm our business, financial condition and results of operations.

**Our stock price may be volatile.**

Historically, there has been significant volatility in the market prices of biotechnology companies' securities. During the two-year period ended December 31, 2005, the sale prices of our common stock ranged between \$4.37 and \$14.35. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- fluctuations in our operating results;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- published reports by securities analysts;
- progress with clinical trials;
- governmental regulation;
- developments in patent or other proprietary rights;
- developments in our relationship with collaborative partners;
- public concern as to the safety and effectiveness of our products; and
- general market conditions.

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 February 28, 2006, we had 16,665,756 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 \$8.58 per share and we had reserved 3,940,137 shares of common stock for issuance pursuant to future grants of options under our equity incentive plans. We have filed registration statements on Form S-8 under the Securities Act covering all of these shares. Shares issued pursuant to these plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

In addition, as of that date, there were 41,168 shares reserved for issuance pursuant to a deferred compensation program. The shares reserved for the deferred compensation program will be issued in various amounts over various periods of time during the next three years. We have filed a registration statement on Form S-8 under the Securities Act covering those shares. Shares issued pursuant to this

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

As of February 28, 2006, we had reserved 766,184 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 under the Securities Act covering all of those shares. All shares issued under this plan, other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

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

As of February 28, 2006, we had 10,936,935 shares of common stock reserved for the issuance pursuant to the conversion of the \$150.0 million aggregate principal amount of our outstanding 2.25% Convertible Senior Notes due May 15, 2011. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or redemption by us at a conversion rate of 72.9129 shares per each \$1,000 principal amount of the notes (\$13.72 per share), subject to adjustment.

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

As of February 28, 2006, we had 111,964,174 shares of common stock outstanding, of which 9,477,928 are restricted securities as that term is defined in Rule 144 under the Securities Act. Under certain circumstances, these restricted securities may be sold without registration pursuant to such rule. We are unable to predict the effect that sales made under Rule 144 or pursuant to any registration may have on the market price of our common stock. The sale of a significant number of additional securities, or even the possibility thereof, may lower the market price of our common stock.

In addition, we have filed a shelf registration statement on Form S-3 under the Securities Act relating to the sale of up to \$294.59 million of any of the following securities:

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

We have filed a registration statement on Form S-3 under the Securities Act relating to our \$150.0 million 2.25% Convertible Senior Notes due May 15, 2011, and up to 10,936,935 shares of our common stock which may be issued upon conversion of the notes. The notes and the shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144.

We have filed a registration statement on Form S-4 under the Securities Act to register shares of our common stock having a maximum aggregate offering price of \$12.0 million. Such shares are freely tradable without restriction or further registration under the Securities Act. This registration statement on Form S-4 under the Securities Act is currently available for the sale of up to \$7.7 million of our common stock.

We have also filed registration statements on Form S-3 under the Securities Act that relate to the sale by certain selling securityholders of up to 21,875,353 shares of our common stock. These shares are included in the 111,964,174 shares of our common stock outstanding as of February 28, 2006 mentioned

above, and were issued upon the conversion of our 4.25% Convertible Senior Notes due August 15, 2010 in connection with the provisional redemption of such notes in January 2005. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144.

**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 February 28, 2006, \$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 written 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/<br>Owned | Square<br>Feet | Use                            | Lease<br>Expiration<br>Date |
|------------------------|------------------|----------------|--------------------------------|-----------------------------|
| Annandale, New Jersey  | Leased           | 45,000         | Laboratory, 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**

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

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

None.



**PART II****Item 5. Market for Registrant's Common Equity and Related Shareholder Matters**

Our common stock is traded on The NASDAQ National 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 National Market:

|                                     | <b>Common Stock<br/>Price</b> |            |
|-------------------------------------|-------------------------------|------------|
|                                     | <b>High</b>                   | <b>Low</b> |
| <b>Year ended December 31, 2004</b> |                               |            |
| First Quarter                       | \$ 9.93                       | \$ 6.28    |
| Second Quarter                      | \$ 11.13                      | \$ 6.51    |
| Third Quarter                       | \$ 8.41                       | \$ 4.37    |
| Fourth Quarter                      | \$ 11.55                      | \$ 7.06    |
| <b>Year ended December 31, 2005</b> |                               |            |
| First Quarter                       | \$ 10.87                      | \$ 6.88    |
| Second Quarter                      | \$ 8.82                       | \$ 6.65    |
| Third Quarter                       | \$ 10.50                      | \$ 8.22    |
| Fourth Quarter                      | \$ 14.35                      | \$ 7.45    |

The number of shares of our common stock outstanding as of February 28, 2006 was 111,964,174. As of February 28, 2006, there were approximately 600 record holders of our common stock. As of March 22, 2005, the record date for our last Annual Meeting of Shareholders held on May 19, 2005, there were approximately 600 record holders of common stock (which includes individual holders) and approximately 42,753 beneficial shareholders 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 Related to Stockholder Matters.



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

Currently, 31 antibody product candidates generated from our UltiMab Human Antibody Development System are in human clinical trials, or have had regulatory applications submitted for such trials<sup>(1)</sup>. In 2006, we expect at least 11 Phase III clinical trials to be underway relating to five of the most advanced product candidates in which Medarex has an economic interest through co-promotion/profit sharing rights, royalties and/or equity ownership. In addition, our partner Genmab A/S has announced that it expects to initiate multiple Phase III trials for two additional product candidates in 2006. Four of the five product candidates currently in Phase III trials were generated through the use of our UltiMab® technology and include:

- ipilimumab (also known as MDX-010), which we are developing jointly with Bristol-Myers Squibb Company, or BMS, for the treatment of metastatic melanoma and other cancers;
- golimumab (also known as CNTO 148) under development by Centocor, Inc. (a subsidiary of Johnson & Johnson) for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis;
- CNTO 1275 for the treatment of psoriasis, also under development by Centocor; and
- zanolimumab (also known as HuMax-CD4 ), being developed by Genmab A/S for the treatment of T-cell lymphoma.

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

Medarex is committed to building value by developing a diverse pipeline of antibody products to address the world's unmet healthcare needs. In addition to the five antibody candidates currently in Phase III trials, multiple product candidates in Phase II, Phase I and preclinical testing are being developed by Medarex either alone or jointly with or separately by our partners, including Amgen, Inc., BMS, Centocor,

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

Eli Lilly and Company, Genmab, ImClone Systems Incorporated, MedImmune, Inc., Novartis Pharma AG, Novo Nordisk A/S and Schering 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 important treatments for a wide range of diseases.

In addition to our UltiMab Human Antibody Development System, 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 our partners. We intend to add sales and marketing and additional manufacturing capabilities as needed.

A portion of our revenue is derived from licensing our fully human antibody technology to pharmaceutical and biotechnology companies. The terms of these license agreements typically include potential license fees and a series of potential milestone payments commencing upon the initiation of clinical trials and continuing through commercialization. These payments may total \$7.0 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, 2005, we had an accumulated deficit of approximately \$745.4 million. Over the next several years, we expect to incur substantial expenses as we continue to identify, develop and manufacture our potential products, invest in research, move forward with our product development and prepare to commercialize our product(s). Our commitment of resources to research and the continued development and potential commercialization of our product candidates will require substantial additional funds. Our operating expenses may also increase as we invest in research or acquire additional technologies, as additional potential product candidates are selected for clinical development and as some of our earlier stage product candidates move into later stage clinical development. In addition, we may incur significant milestone payment obligations as our products progress towards commercialization. In the absence of substantial revenues from new corporate collaborations or other sources, we will incur substantial operating losses and may be required to raise additional funds through debt or equity financings or delay, reduce or eliminate certain of our research and development programs.

#### **Critical Accounting Policies**

The methods, estimates and judgments we use in applying our most critical accounting policies have a significant impact on the results we report in our consolidated financial statements. We evaluate our estimates and judgments on an on-going basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions

form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could materially change our reported results. We believe the following accounting policies are the most critical to us, in that they are important to the portrayal of our financial statements and they require our most difficult, subjective or complex judgments in the preparation of our consolidated financial statements.

### ***Revenue Recognition***

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

- We sell antibodies primarily to partners in the United States and overseas. Revenue from these sales is recognized when the antibodies are shipped and we have no further obligations related to the development of the antibodies.
- We receive research fees from the licensing of our proprietary technologies for research and development performed by our customers and partners. Revenue from these research fees is recognized generally over the term of the respective license period beginning only after both the license period has begun and the technology has been delivered.
- We receive fees for product development services (including manufacturing) we perform for our customers and partners. These fees are recognized ratably over the entire period during which the services are performed.
- Revenue from milestone payments is recognized when each milestone is achieved, when collectibility of such milestone payment is assured and we have no future performance obligations relating to that event. Milestone payments are triggered either by the results of our research efforts or by the efforts of our partners and include such events as submission of an Investigational New Drug Application, or IND, commencement of Phase I, II or III clinical trials, submission of a Biologic License Application, or BLA, and regulatory approval of a product. Milestone payments are substantially at risk at the inception of an agreement.
- Revenue arrangements that include multiple deliverables are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.
- Revenues derived from reimbursements of costs associated with the development of product candidates are recorded in compliance with EITF Issue 99-19, Reporting Revenue Gross as a Principal Versus Net as an Agent ( EITF 99-19 ). According to the criteria established by EITF 99-19, in transactions where we act as a principal, with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we believe we have met the criteria to record revenue for the gross amount of the reimbursements.
- Grant revenues are recognized as we provide the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

### ***Investments***

Our investment policy calls for investments in fixed income high grade securities such as U.S. corporate debt securities, U.S. treasury obligations and money market funds for which we believe there is not a significant risk of loss. Our primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return consistent with these two objectives. However, in the course of our business, we have made and may continue to make investments in companies (both public and private) as part of our strategic collaborations. Investments in companies whose securities are publicly traded (other than Genmab) are classified as marketable securities on our consolidated balance sheets. The fair market value of investments in our partners whose securities are publicly traded (other than Genmab) represented approximately 2.6% of total marketable securities as of December 31, 2005 and approximately 0.9% of total marketable securities as of December 31, 2004.

Under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, our marketable securities are classified as available-for-sale securities and are carried at fair value. Marketable securities will include those securities of debt and publicly traded equity securities accounted for under the cost method. These securities trade on listed exchanges; therefore, fair value is readily available. These securities are also subject to an impairment charge when we believe an investment has experienced a decline in value that is other than temporary. Under our accounting policy, a decline in the value of our investments is deemed to be other than temporary and such investments are generally considered to be impaired if their value is less than our cost basis for more than six (6) months, or some other applicable period in light of the facts and circumstances surrounding the investments.

In addition, in connection with our collaborative partnering business, we sometimes make strategic investments in the securities of companies that are privately held. Investments in our partners whose equity is not publicly traded are classified in a separate line item in our consolidated balance sheet entitled "Investments in, and advances to, other partners" and were \$6.4 million as of December 31, 2005. These securities are carried at original investment cost and adjusted for other than temporary impairment charges, if any. Because these securities are not listed on a financial exchange, the value of these investments is inherently more difficult to estimate than investments in public companies. We value these investments by using information acquired from industry trends, management of these companies, 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.

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

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

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

- a significant negative industry or economic trend.

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

#### ***Acquired In-Process Technology***

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.

#### **Results of Operations**

##### ***Years Ended December 31, 2005, 2004 and 2003***

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

Contract and license revenues totaled \$30.2 million, \$9.1 million and \$5.8 million for the years ended December 31, 2005, 2004 and 2003, respectively. Contract and license revenues for 2005 increased by \$21.1 million or 231% as compared to 2004. This increase relates principally to a total of approximately \$13.8 million of increased revenue recognized from our collaborations with Pfizer, BMS, Lilly and the National Institutes of Health, or NIH, in accordance with an NIH grant we received, as well as \$4.0 million in milestone payments received from our contract and licensing business. Contract and license revenues for 2004 increased by \$3.3 million or 56% as compared to 2003. This increase relates principally to approximately \$2.4 million of revenue recognized from our collaboration agreement with Pfizer which was executed in September 2004 and approximately \$0.6 million of revenue from the NIH in accordance with a grant we received in 2004. Because contract and license revenues depend to a large extent on the product development efforts of our partners and licensees, our 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 \$4.1 million, \$3.4 million and \$5.3 million for the years ended December 31, 2005, 2004 and 2003, respectively. Contract and license revenues from Genmab for 2005 increased by \$0.7 million or 21% as compared to 2004. This increase is primarily the result of payments received from Genmab for the licensing of European and Asian rights to develop and commercialize antibodies raised against the CD4 antigen, partially offset by a decrease in antibody exclusive licenses granted to Genmab in 2005 as compared to 2004. Contract and license revenues from Genmab for 2004 decreased by \$1.9 million or 37% as compared to 2003. This decrease relates principally to fewer research licenses and antibody exclusive licenses requested by and granted to Genmab in 2004 as compared to 2003.

**Reimbursement of Development Costs**

Revenues derived from the reimbursement of costs associated with the development of our product candidates are recorded in compliance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus as an Agent* ( EITF 99-19 ). Reimbursement of development costs were \$17.2 million in 2005 and related primarily to the development of ipilimumab with BMS. There were no such reimbursements in 2004 and 2003.

**Research and Development Expenses**

Research and development expenses for our products in development were \$135.8 million, \$122.0 million and \$95.5 million for the years ended December 31, 2005, 2004 and 2003, respectively. Research and development expenses in 2005 increased by \$13.8 million, or 11% as compared to 2004 and research and development expenses in 2004 increased by \$26.5 million, or 28% as compared to 2003. Historically, due to the limited number of our product candidates in clinical trials, we have not accounted for our research and development expenses on a project-by-project basis. 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, |            |           |
|---------------------|-------------------------|------------|-----------|
|                     | 2005                    | 2004       | 2003      |
| Research            | \$ 46,207               | \$ 53,284  | \$ 37,495 |
| Product Development | 89,640                  | 68,723     | 57,964    |
| Total               | \$ 135,847              | \$ 122,007 | \$ 95,459 |



### **Research Costs**

Research costs in 2005 decreased by \$7.1 million, or 13% as compared to 2004. Research costs in 2004 increased by \$15.8 million, or 42% as compared to 2003. The changes in research costs primarily relate to the following.

- Personnel costs in 2005 were \$14.7 million, an increase of \$1.5 million or 11% as compared to 2004. Personnel costs in 2004 were \$13.2 million, an increase of \$0.5 million or 3% as compared to 2003. The increased personnel costs are primarily attributable to staff needed to support higher levels of new product development opportunities, the continued development of our UltiMAb® system, and the performance of contract services for our collaborative partners. Personnel costs include primarily salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase as we continue to increase our research activities.
- An \$8.5 million expense representing a liability to Gilead Sciences, Inc., or Gilead, for the reduction of future royalty obligations relating to certain intellectual property rights regarding anti-CTLA-4 product candidates in 2004 for which no comparable expenses were incurred in 2005 or 2003. The total consideration of \$8.5 million is being paid to Gilead in eight equal quarterly installments. As of December 31, 2005, approximately \$2.1 million (two installments) remained due to Gilead under this obligation (see further discussion under the section herein entitled *Other Liquidity Matters* ).
- License and technology access fees in 2005 were \$5.4 million, a decrease of \$1.5 million or 22% as compared to 2004. License and technology access fees in 2004 were \$6.9 million, an increase of \$3.8 million or 125% as compared to 2003. 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 2005 costs are payments to Genentech, Inc. and the Mayo Foundation for Medical Education and Research. Included in the 2004 costs are payments to diaDexus, Inc., Pharma Pacific Pty Ltd. and Kirin Brewery Co., Ltd., or Kirin, for licenses to certain technologies. We expect license fees, including funds paid to certain partners, to increase in the future.
- Supply costs in 2005 were \$6.2 million, an increase of \$1.1 million or 23% as compared to 2004. Supply costs in 2004 were \$5.1 million, a decrease of \$0.1 million or 1% as compared to 2003. The increased supply costs in 2005 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.

### **Product Development Costs**

Product development costs in 2005 increased by \$20.9 million, or 30% as compared to 2004. Product development costs in 2004 increased by \$10.8 million, or 19% as compared to 2003. The increases in product development costs primarily relate to the following:

- Contract manufacturing costs in 2005 were \$10.3 million, an increase of \$1.2 million or 12% as compared to 2004. Contract manufacturing costs in 2004 were \$8.1 million, an increase of \$7.4 million or 1091% as compared to 2003. The increase in third party contract manufacturing costs primarily represents production and packaging expenses for a Phase III pivotal trial of ipilimumab in combination with MDX-1379, which began in the third quarter of 2004 and certain MDX-060 manufacturing costs. 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 2005 were \$25.6 million, an increase of \$2.7 million or 12% as compared to 2004. Personnel costs in 2004 were \$22.9 million, an increase of \$2.3 million or 11% as compared to 2003.



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.

- Supply costs in 2005 were \$5.1 million, an increase of \$0.5 million or 10% as compared to 2004. Supply costs in 2004 were \$4.6 million, a decrease of \$1.1 million or 19% as compared to 2003. The increases in 2005 costs reflect production of clinical material for phase I and phase II trials for certain of our product candidates. In 2003 we completed a change to our method of production which resulted in comparatively lower supply costs in 2004. Included in these costs are materials, chemicals and disposables associated with the manufacture of material for clinical trials. We expect these costs to increase as we continue to expand our product development efforts and increase our clinical trial activities.
- Clinical research fees in 2005 were \$11.5 million, an increase of \$6.8 million or 145% as compared to 2004. This increase resulted primarily from the continued enrollment of patients in the Phase III clinical trial for ipilimumab in combination with MDX-1379 and the initiation of additional sites for this trial. As of December 31, 2005 sites participating in this Phase III clinical trial are located in North America, Europe and Latin America. The continued enrollment of patients in the Phase III trial and the initiation of additional sites resulted in increased monitoring costs and increased investigator site fees. Clinical research fees in 2004 were \$4.7 million, the same as 2003. These costs represented the conclusion of certain Phase II clinical trials for ipilimumab offset by the initiation of the Phase III clinical trial for ipilimumab in combination with MDX-1379 which began in the third quarter of 2004. Clinical research fees include clinical investigator site fees, external trial monitoring costs and data accumulation costs. We expect expenses related to clinical trials to increase in the future as we continue to develop our therapeutic product pipeline.
- An expense of \$6.4 million for 2005 representing the reimbursement of our share (35%) of the BMS costs for the development of ipilimumab. No comparable expense was incurred in 2004 or 2003. 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 I        | 1-2 Years                   |
| Phase II       | 1-2 Years                   |
| Phase III      | 2-4 Years                   |

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

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

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

We continue to explore new collaborative arrangements that may affect future spending for research and development. As part of our partnering strategy, a significant portion of the research and development expenses incurred in connection with products using our technology is expected to be borne by our partners. We believe this allows us to participate in the research and development of substantially more potential product candidates than we could develop on our own if we bore the entire cost of development. Products using our technology are currently in various stages of development from preclinical to Phase III. The successful development of these product candidates is dependent on many factors, including among other things, the efforts of our partners, unforeseen delays in, or expenditures relating to, preclinical development, clinical testing, manufacturing or regulatory approval, failure to receive 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 \$28.1 million, \$24.3 million and \$21.7 million for the years ended December 31, 2005, 2004 and 2003, respectively. General and administrative expenses increased by \$3.8 million in 2005, or 15% as compared to 2004. The 2005 increase was primarily attributable to the operations of Celldex Therapeutics, Inc., or Celldex, including the write-off of deferred offering costs (legal, accounting and printing) of \$1.9 million. Such costs were written off in 2005 as a result of Celldex terminating its initial public offering and withdrawing its registration statement with the Securities and Exchange Commission due to unfavorable market conditions. General and administrative expenses increased by \$2.6 million in 2004, or 12% as compared to 2003. The 2004 increase is primarily attributable to increased personnel costs of \$1.1 million, and increased legal fees of \$1.0 million primarily as a result of the completion of the negotiation and execution of a series of agreements with Pfizer and our collaboration and license agreement with BMS. 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, 2005 related to acquisition of all of the outstanding capital stock of Lorantis Limited, a privately held biotechnology company based in Cambridge, U.K. and the acquisition of substantially all assets of Alteris Therapeutics, Inc., 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.

Acquisition of in-process technology for the year ended December 31, 2004 related to our acquisition of all of the outstanding capital stock not already owned by us of Ability Biomedical Corporation, a privately held Canadian biotechnology company, in August 2004. The total cost of the acquisition (including transaction costs), discussed more fully under the section herein entitled *Liquidity and Capital Resources*, was \$5.7 million, of which approximately \$5.5 million of in-process research and development

was determined not to be technologically feasible and had no alternative future uses at the time of acquisition, and, as a result, was charged to operations as acquisition of in-process technology during 2004.

Acquisition of in-process technology for the year ended December 31, 2003 related to an amended and restated license agreement with Kyowa Hakko Kogyo Co. Ltd., or the Kyowa License, that we entered into during the fourth quarter of 2003. Under the terms of the Kyowa License we received certain intellectual property rights relating to the development and commercialization of our Ultra-Potent Toxin technology. The Kyowa License was the result of a renegotiation of a pre-existing license agreement with respect to Ultra-Potent Toxin technology between Kyowa and Corixa Corporation, or Corixa, whose license agreement we acquired as part of our May 2002 asset acquisition from Corixa. Upon the execution of the Kyowa License, we paid Kyowa a total of \$4.0 million and also made a final payment to Corixa in the amount of \$2.5 million.

#### ***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, 2005, 2004 and 2003. Genmab is an affiliated company and during these periods was accounted for using the equity method of accounting (see Note 11 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 \$6.3 million, \$19.8 million and \$15.0 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Equity in net loss of affiliate in 2005 decreased by \$13.5 million, or 68% as compared to 2004. The decrease was primarily related to the suspension of our share of Genmab's net losses for a portion of 2005. See Note 11 to the consolidated financial statements for further explanation. Equity in net loss of affiliate in 2004 increased by \$4.8 million or 32% as compared to 2003. This increase reflects an increase in Genmab's net loss as a result of its expanded research and development efforts offset, in part, by a reduction in our ownership percentage, resulting from Genmab's 2004 private placement of its ordinary shares (discussed below), and therefore a reduction of our share of Genmab's net loss for the second half of 2004.

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.

In July 2004, Genmab completed a private placement of 5.6 million shares of its stock. As a result of this private placement, our ownership percentage of Genmab was reduced from approximately 30.9% to 24.7%. The difference between our proportionate share of the equity and our carrying value after completion of the private placement was approximately \$9.7 million and was accounted for in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investment in Common Stock*, and Staff Accounting Bulletin No. 51, *Accounting for Sales of Stock by a Subsidiary* increasing our investment in Genmab and capital in excess of par value.

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 expect to account for our investment in Genmab as a marketable security in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*.

***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 \$14.7 million, \$7.2 million and \$12.3 million for the years ended December 31, 2005, 2004 and 2003, respectively. Interest, dividend income and realized gains in 2005 increased by \$7.6 million, or 106% as compared to 2004. Included in interest, dividend income and realized gains for the year ended December 31, 2005 is a gain on the sale of common stock of one of our partners of approximately \$3.3 million and included in interest, dividend income and realized gains for the year ended December 31, 2004 is a gain on the sale of common stock of one of our partners of approximately \$1.7 million. Excluding the impact of these gains, interest and dividend income in 2005 would have increased by \$6.1 million. This increase primarily relates a higher average balance and higher returns on our investment portfolio as well as decreased amortization of premiums on debt securities. Interest and dividend income in 2004 decreased by \$6.9 million, or 56% (excluding the \$1.7 million gain discussed above) as compared to 2003. This decrease primarily relates to lower returns on our investment portfolio as well as increased amortization of premiums on debt securities. We anticipate lower interest and dividend income in the future as we continue to fund our operations and capital expenditures from our cash reserves.

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

We recorded impairment charges of \$0, \$0.2 and \$0 million for the years ended December 31, 2005, 2004 and 2003, respectively, related to investments in certain of our partners (other than Genmab) whose securities are publicly traded. The 2004 impairment charge was the result of losses on one of these 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 \$33.3 million, \$7.1 million and \$1.4 million for the years ended December 31, 2005, 2004 and 2003, 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. The 2004 impairment charge is primarily comprised of a \$7.0 million impairment related to our investment in IDM. The amount of the IDM impairment charge was calculated as the difference between the per share price received by IDM in a December 2004 private placement of its equity securities and our cost basis. 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 4.50% Convertible Subordinated Notes issued in June 2001, or the 4.50% notes, our 4.25% Convertible Senior Notes issued in July 2003, or the 4.25% notes, and our 2.25% Senior Subordinated Notes issued in May 2004, or the 2.25% notes. Interest expense was \$4.2 million, \$12.8 million and \$11.8 million for the years ended December 31, 2005, 2004 and 2003, respectively. Interest expense in 2005 decreased by \$8.6 million, or 67% as compared to 2004. This decrease reflects the January 2005 conversion of all of our 4.25% Notes (\$146.986 million) into a total of 21,875,353 shares of our common stock. Interest expense in

2004 increased by \$1.1 million, or 9% as compared to 2003. The increase reflects a full year of interest expense on our 4.25% notes and the addition of approximately seven months of interest expense on our 2.25% notes, offset, in part, by a decrease in interest expense resulting from the redemption, repurchase and cancellation of the 4.50% notes in June and July 2004. 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 for the year ended December 31, 2005 of \$4.4 million represents 40% of Celldex's net loss for the period from October 12, 2005 through December 31, 2005. 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 15 to the consolidated financial statements) our ownership percentage was reduced from 100% to approximately 60%. Celldex's results of operations for 2005 have been consolidated for reporting purposes and the \$4.4 million (the portion of Celldex's net loss for the period from October 12, 2005 through December 31, 2005 not attributable to us) is recorded as a reduction of our expenses.

#### ***Debt Conversion Expense***

Debt conversion expense of \$10.2 million for the year ended December 31, 2004 related to the make-whole payment associated with the December 2004 decision calling for the redemption of our 4.25% notes. Such amount was accrued as of December 31, 2004 and was paid in January 2005 (see further information under the section entitled *Cash Provided By Financing Activities*). There were no comparable charges for the years ended December 31, 2005 and 2003.

#### ***Net Loss on Extinguishment of Debt***

In connection with a private placement of \$150.0 million of our 2.25% notes (see further discussion under the section entitled *Liquidity and Capital Resources*) we repurchased and redeemed \$142.0 million in aggregate principal amount of our 4.50% notes for cancellation in January 2005. As a result of this repurchase and cancellation we recorded a loss on the early extinguishment of debt of approximately \$4.5 million for the year ended December 31, 2004.

In January 2004, we and certain holders of our 4.50% notes completed an exchange and cancellation of \$33.0 million in aggregate principal amount of the 4.50% notes, for the issuance of \$21.986 million in aggregate principal of a new series of 4.25% notes and, in connection therewith, we recorded a gain of approximately \$0.3 million for 2004. We calculated the gain in accordance with EITF 96-19, *Debtor's Accounting for a Modification or Exchange of Debt Instruments*. EITF 96-19 requires that the gain on the early extinguishment of debt be computed using the fair value of the newly issued convertible debt which, at the time of the debt exchange, was trading at a premium to the principal amount of the notes. We classified the premium associated with the newly issued 4.25% notes of approximately \$10.2 million as capital in excess of par value in accordance with APB 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants*.

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

Our provision for income taxes of \$0.4 million, \$31 thousand and \$0.1 million for the years ended December 31, 2005, 2004 and 2003, respectively, relates primarily to the New Jersey alternative minimum tax assessment.

***Cumulative Effect of a Change in Accounting Principle***

Cumulative effect of a change in accounting principle for the year ended December 31, 2003 was \$0.8 million. Effective January 1, 2003, we changed our method of accounting for asset retirement obligations in accordance with SFAS No. 143, *Accounting for Asset Retirement Obligations*. Previously, we were not required to recognize amounts related to asset retirement obligations. Under SFAS No. 143, we now recognize asset retirement obligations in the period in which they are incurred if a reasonable estimate of a fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately \$1.4 million, recognition of an asset retirement obligation liability of approximately \$2.2 million and a cumulative effect of a change in accounting principle of approximately \$0.8 million.

**Liquidity and Capital Resources**

We require cash to fund our operations, to make capital expenditures and strategic investments, and to pay debt service on our convertible notes. Since inception, we have financed our operations through the sale of our securities in public and private placements, sales of our products for research purposes, development and manufacturing services, technology transfer and license fees and milestone payments. We expect to continue to fund our cash requirements from these sources in the future. In 2003, 2004, and 2005, we received net proceeds of \$331.5 million from sales of our equity and debt securities.

At December 31, 2005 and 2004, we had \$351.3 million and \$374.5 million, respectively, in cash, cash equivalents and marketable securities. Approximately \$25.2 of cash and cash equivalents included in the December 31, 2005 balance relates to Celldex and is consolidated for accounting purposes. We primarily invest our cash equivalents and marketable securities in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

***Cash Used in Operating Activities***

Cash used in operating activities was \$88.9 million, \$6.0 million and \$89.3 million for the years ended December 31, 2005, 2004 and 2003, respectively. This reflects an increase of \$82.9 million in 2005 as compared to 2004 and a decrease of \$83.3 million in 2004 as compared to 2003.

The 2005 increase is primarily due to a decrease in deferred contract revenue (approximately \$72.9 million) resulting from less up-front payments associated with collaborations in 2005 as compared to 2004. The 2004 decrease is primarily due to an increase in deferred contract revenue (approximately \$99.1 million) resulting from the up-front payments associated with collaborations with each of Pfizer and MedImmune, Inc., offset in part, by higher research and development expenses (approximately \$26.5 million). The increase in research and development expenses resulted primarily from higher personnel costs, expenses related to our facilities, third-party research and contract manufacturing costs, and the costs of clinical trials. All of these costs were higher as result of our increased clinical trial and product development activities.

We have incurred and will continue to incur significant costs in the area of research and development, including preclinical and clinical trials, as our products are developed. We plan to spend significant amounts to progress our current products through the clinical trial and commercialization process as well as to develop additional product candidates on our own or with our partners. As our products progress through the clinical trial process, we may be obligated to make significant milestone payments on certain of our products. We also expect to incur future facility costs as a result of our continued capital expansion, renovations and replacements. 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 \$84.1 million in 2005. Net cash used in investing activities was \$33.8 million in 2004 and \$22.6 million in 2003, respectively. Cash was provided by and used in investing activities primarily as follows:

- Capital expenditures of \$9.3 million, \$9.1 million and \$8.9 million in 2005, 2004 and 2003, 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 and \$3.2 million in 2005 and 2003, respectively. 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). The net sales of marketable securities in 2003 were the result of funding operations and capital expenditures offset by the net proceeds received (\$121.2 million) from the sale of our 4.25% notes in July 2003.
- Net purchases of marketable securities in 2004 were \$27.9 million. The 2004 net purchases were the result of the proceeds received from the Pfizer collaboration (\$110.0 million), the MedImmune collaboration (\$15.0 million) and the net proceeds (\$145.2 million) received for the private placement of our 2.25% notes, offset in part, by sales of marketable securities (\$242.6 million) to fund operations and capital expenditures as well as to repurchase and redeem our 4.50% notes as discussed further in the section entitled *Cash Provided by Financing Activities*.
- Net cash of approximately \$29.7 million provided through the acquisition of Lorantis by Celldex (see further explanation in the section entitled *Other Liquidity Matters*).

We expect 2006 capital expenditures to be approximately \$15.0 million representing the purchase of machinery and scientific equipment and additional investment in lab automation.

***Cash Provided by Financing Activities***

Cash provided by financing activities was \$31.1 million, \$31.6 million and \$123.0 million in 2005, 2004 and 2003, respectively. In 2005, cash provided by financing activities consisted primarily of proceeds received (\$25.0 million) from the sale of common stock to BMS in connection with our collaboration. In 2004, cash provided by financing activities consisted primarily of \$145.2 million in net proceeds received from the sale of our 2.25% notes in May 2004 and \$31.8 million from sales of common stock primarily to Pfizer (\$30.0 million) and the issuance of common stock under our employee stock purchase plan (\$1.1 million), offset in part, by the repurchase, redemption and cancellation of our 4.50% notes (\$144.6 million). In 2003, cash provided by financing activities consisted primarily of \$121.2 million in net proceeds received from the sale of our 4.25% notes in July 2003 and \$0.9 million from the issuance of common stock under our employee stock purchase plan.

In July 2003, we completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended of \$125 million in aggregate principal amount of our 4.25% notes to qualified institutional investors. The 4.25% notes were initially convertible into shares of our common stock at the rate of 148.8261 shares per each \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$6.72 per share, subject to anti-dilution adjustments. Interest was payable on February 15 and August 15 of each year. The first interest payment was made on February 15, 2004.

The 4.25% notes were scheduled to mature on August 15, 2010 and were redeemable at our option on or after August 15, 2006, or earlier if the price of our common stock exceeded specified levels. We received net proceeds from the private placement of the 4.25% notes of approximately \$121.2 million (after deducting the initial purchasers' discounts and offering expenses). As of December 31, 2004, we had purchased U.S. Treasury security strips to collateralize the notes in an amount sufficient to pay the four interest payments due on the 4.25% notes in 2005 and 2006. Such amount was classified as segregated securities in the current assets section of our December 31, 2004, consolidated balance sheet.

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. We accrued the \$10.2 million make-whole payment in the quarter ended December 31, 2004, at the time the redemption was announced.

In January 2004, we and certain holders of our 4.50% notes completed an exchange and cancellation of \$33.0 million in aggregate principal amount of the 4.50% notes, for the issuance of \$21.986 million in aggregate principal of a new series of 4.25% notes due August 15, 2010. As a result of this exchange and cancellation, our total convertible debt was reduced by \$11.014 million.

In May 2004, we completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended, of \$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 20, 2009. 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 private placement 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.

In June 2001, we issued \$175 million of our 4.50% notes. The 4.50% notes were scheduled to mature on July 1, 2006. Concurrent with the private placement of the 2.25% notes described above, we repurchased approximately \$65.6 million in aggregate principal amount of our 4.50% notes for cancellation during the second quarter of 2004. On July 1, 2004, we completed the redemption and cancellation of the remaining balance of our 4.50% notes of approximately \$76.4 million for approximately \$77.7 million plus accrued interest of approximately \$1.7 million.

#### ***Other Liquidity Matters***

As of December 31, 2005, we had federal net operating loss (NOL) carryforwards of approximately \$438.2 million. These NOL carryforwards will expire in the years 2006-2025 (as more fully described in Note 5 to the consolidated financial statements), if not utilized. During 2000 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, 2005

the amount of NOL subject to the limitation was \$43.1 million and the amount not subject to limitation was \$395.1 million.

In July 2004, we entered into an amendment to a collaboration and license agreement with Gilead, referred to herein as the Gilead Amendment. Under the terms of the Gilead Amendment, we agreed to pay Gilead a total of \$8.5 million in eight equal quarterly installments of \$1.063 million, payable at our election, in cash, registered shares of our common stock or a combination thereof, in exchange for (i) a reduction of certain future royalty payment obligations payable by us to Gilead, and (ii) an expansion of the scope of certain licenses from Gilead to us relating to certain intellectual property rights regarding anti-CTLA-4 products. The first of these payments was paid on August 2, 2004 through the issuance of 185,622 shares of our common stock to Gilead. The second payment was made on October 1, 2004 in cash. The third, fourth, fifth and sixth payment (all made in 2005) were also made in cash. The seventh payment was made on January 3, 2006 in cash. The remaining payment will be made on April 3, 2006.

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.

Upon achievement of certain development milestones with respect to our anti-IP-10 antibody program, but no later than September 4, 2007, we may be required to pay the former shareholders of Ability Biomedical an additional amount of approximately \$3.65 million in cash and/or common stock subject to fluctuations in currency exchange rates. In lieu of such additional payment, we also have the option to revert to the original joint collaboration agreement with the former shareholders of Ability Biomedical whereby each party would be responsible for 50% of the costs associated with the anti-IP-10 antibody.

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 total initial 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. These shares were issued in a private placement pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, or the Securities Act. The purchase price represented a small premium to market price at the time we entered into the collaboration. Pfizer agreed to a two-year lock-up with respect to the sales of such stock. We have no further obligation to register such stock.

In January 2005, we announced the closing of a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. Under the terms of the collaboration, we and BMS each granted the other certain intellectual property licenses and product rights on a worldwide basis in order to enable us to collaborate in research and development of certain therapeutic antibody-based 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 developed using our UltiMab Human Antibody Development System. Ipilimumab is currently under investigation for the treatment of a broad range of cancers. The collaboration also includes the grant by us to BMS of a sub-license to MDX-1379, a gp100 peptide vaccine licensed by us from the U.S. Public Health Service, for use with ipilimumab for the treatment of metastatic melanoma. We and BMS are currently conducting a Phase III clinical trial with ipilimumab and MDX-1379 combination therapy in Stage III and Stage IV metastatic melanoma patients at multiple sites worldwide.

As part of the collaboration, we and BMS committed to an initial multi-year budget of approximately \$192.0 million to fund the development of ipilimumab as a potential treatment for a broad range of cancers. BMS is responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the 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 could receive up to \$205.0 million from BMS if all regulatory milestones are met, plus up to an additional \$275.0 million in sales-related milestones. We will also have the option to co-promote any products in the U.S., and, if we elect to exercise this option and have participated in the funding of the applicable Phase II clinical trial(s), we will receive 45% of any profits from commercial sales. In the event we choose not to exercise our co-promotion rights, BMS will have exclusive commercial rights in the U.S. and will pay us royalties on commercial sales. Outside the U.S., BMS will have exclusive commercial rights and will pay us royalties on commercial sales.

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

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

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

The purchase price for substantially all of the Alteris assets consisted of 1.2 million shares of Celldex common stock (valued at \$6.0 million) and approximately \$1.6 million in cash. Celldex may be required to pay Alteris up to \$5.0 million upon obtaining the first approval for commercial sale of an EGFRvIII product. In addition, Celldex may be required to pay an amount equal to 20% of any upfront fees or milestone payments received from a certain unrelated third-party licensee, in the event that within 12 months of the closing, Celldex enters into a license agreement with such third party for any EGFRvIII-derived product developed using the technology acquired from Alteris.

**Contractual Obligations**

Our material contractual obligations under lease, debt and research funding agreements for the next five years, and thereafter, as of December 31, 2005, are as follows:

|   | Payments Due by Period                |                  |                  |                   | Total             |
|---|---------------------------------------|------------------|------------------|-------------------|-------------------|
|   | Less Than<br>1 Year<br>(in thousands) | 1-3 Years        | 4-5 Years        | After<br>5 Years  |                   |
| <b>Contractual Obligations(1)</b>         |                                       |                  |                  |                   |                   |
| Convertible notes(2)                      | \$ 3,375                              | \$ 6,750         | \$ 6,750         | \$ 150,000        | \$ 166,875        |
| Research funding(3)                       | 47,649                                | 5,300            | 50               |                   | 52,999            |
| Operating leases and other                | 6,803                                 | 8,194            | 3,975            | 3,070             | 22,042            |
| <b>Total contractual cash obligations</b> | <b>\$ 57,827</b>                      | <b>\$ 20,244</b> | <b>\$ 10,775</b> | <b>\$ 153,070</b> | <b>\$ 241,916</b> |

(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 funding for Less than 1 year includes up to \$40.1 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 2006. 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 2006. The amounts that we actually spend during 2006 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**

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

Through December 31, 2005, we have not made any milestone payments to Kirin although approximately \$2.8 million has been paid to Kirin as of December 31, 2005 representing a payment due Kirin as a result of our collaboration with Pfizer. Based on a total of three products we are developing which use or, we believe may use, Kirin technology that (i) are currently in clinical trials, or (ii) we



anticipate may enter clinical trials through the end of 2007, we may be required to make milestone payments to Kirin aggregating up to approximately \$12.75 million with respect to such products, or a maximum of approximately \$4.25 million per product. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

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

We have also entered into a number of other agreements that contain licenses of third-party technology which may be used together with our own platform technologies for the generation, development and/or manufacture of our antibody products. In addition, we have entered into other third-party agreements that contain licenses associated with antibody products that target specific antigens. Many of these agreements contain milestone payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of our products currently under development trigger such milestone payments. Through December 31, 2005, we had made milestone payments of approximately \$0.3 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of nine 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 2007, we may be obligated to make future milestone payments aggregating up to approximately \$59.9 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 I, Phase II and/or Phase III clinical trials or foreign equivalents;
- submission of BLA(s) or foreign equivalents; and
- receipt of marketing approval(s) to sell products in a particular country or region.

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

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

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





2.25% notes are converted into shares of our common stock on or before their maturity date, we will have use of that portion of the principal amount of the notes to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We cannot assure you that we will be able to raise such additional funds. We may be unable to raise sufficient funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

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

In December 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends Statement No. 95, *Statement of Cash Flows*. Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Historically, in accordance with SFAS 123 and SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, we had elected to follow the disclosure only provisions of Statement No. 123 and, accordingly, continue to account for share based compensation under the recognition and measurement principles of APB Opinion No. 25 and related interpretations. Under APB 25, when stock options are issued with an exercise price equal to the market price of the underlying stock price on the date of grant, no compensation expense is recognized in the financial statements, and compensation expense is only disclosed in the footnotes to the financial statements. We are required to adopt Statement No. 123(R) beginning January 1, 2006. We have selected the Black-Scholes option valuation method and the modified prospective transition method available under Statement 123(R). Although we have not yet determined the impact of Statement 123(R), we believe the non-cash expense for 2006 related to Statement 123(R) will be in the range of \$17.0 million to \$18.0 million.

#### **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.

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

**Item 8. Consolidated Financial Statements and Supplementary Data**

**Index to Consolidated Financial Statements**

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**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, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2005. 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. The financial statements of Genmab A/S (a corporation in which the Company has an 22% interest at December 31, 2005), have been audited by other auditors whose report for December 31, 2004 and the two year period then ended has been furnished to us, and our opinion on the consolidated financial statements, insofar as it relates to the amounts included for Genmab A/S, is based solely on the report of the other auditors. In the consolidated financial statements, the Company's investment in Genmab A/S represents 0.7% and 0.3% of total assets as of December 31, 2005 and 2004, respectively, and the Company's equity in the net loss of Genmab A/S represents 4% in 2005, 10% in 2004, and 12% in 2003 of pre-tax loss.

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 and the report of other auditors provide a reasonable basis for our opinion.

In our opinion based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Medarex, Inc. and subsidiaries at December 31, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2003, the Company adopted Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations.

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, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 3, 2006 expressed an unqualified opinion thereon.

MetroPark, New Jersey  
March 3, 2006

/s/ ERNST & YOUNG LLP

**MEDAREX, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share data)

|  | December 31,<br>2005 | 2004       |
|--|----------------------|------------|
| <b>ASSETS</b>  |                      |            |
| Current assets:  |                      |            |
| Cash and cash equivalents  | \$ 90,602            | \$ 64,843  |
| Marketable securities  | 260,705              | 309,664    |
| Segregated securities  |                      | 12,301     |
| Prepaid expenses and other current assets  | 31,608               | 6,708      |
| Total current assets   | 382,915              | 393,516    |
| Property, buildings and equipment:   |                      |            |
| Land   | 6,795                | 6,795      |
| Buildings and leasehold improvements   | 82,338               | 77,995     |
| Machinery and equipment  | 54,130               | 45,898     |
| Furniture and fixtures   | 4,553                | 4,290      |
|  | 147,816              | 134,978    |
| Less accumulated depreciation and amortization   | (61,832 )            | (45,098 )  |
|  | 85,984               | 89,880     |
| Investment in Genmab   | 3,255                | 1,657      |
| Investment in IDM  |                      | 41,206     |
| Investments in, and advances to, other partners  | 6,400                | 10,482     |
| Segregated securities  | 2,033                | 1,700      |
| Other assets   | 6,289                | 10,904     |
| Total assets   | \$ 486,876           | \$ 549,345 |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>   |                      |            |
| Current liabilities:   |                      |            |
| Trade accounts payable   | \$ 4,939             | \$ 4,998   |
| Accrued liabilities  | 27,905               | 32,148     |
| Deferred contract revenue - current  | 20,872               | 15,260     |
| Total current liabilities  | 53,716               | 52,406     |
| Deferred contract revenue - long-term  | 106,827              | 86,691     |
| Other long-term liabilities  | 4,032                | 5,873      |
| 4.25% Convertible senior notes due August 15, 2010   |                      | 146,986    |
| 2.25% Convertible senior notes due May 15, 2011  | 150,000              | 150,000    |
| Minority interest  | 11,590               |            |
| 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; 111,773,230 shares issued and 111,687,930 outstanding at December 31, 2005 and 85,865,333 shares issued and 85,673,693 shares outstanding at December 31, 2004 |                      |            |
|  | 1,118                | 859        |
| Capital in excess of par value   | 908,151              | 699,380    |
| Treasury stock, at cost 85,300 shares in 2005 and 191,640 shares in 2004   | (215 )               | (482 )     |
| Deferred compensation  | (599 )               | 372        |
| Accumulated other comprehensive income   | (2,351 )             | 6,649      |
| Accumulated deficit  | (745,393 )           | (599,389 ) |
| Total shareholders' equity   | 160,711              | 107,389    |
| Total liabilities and shareholders' equity   | \$ 486,876           | \$ 549,345 |

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, |               |               |
|---|---------------------------------|---------------|---------------|
|   | 2005                            | 2004          | 2003          |
| Sales   | \$                              | \$            | \$ 25         |
| Contract and license revenues                                   | 30,226                          | 9,119         | 5,833         |
| Contract and license revenues from Genmab                       | 4,067                           | 3,355         | 5,316         |
| Reimbursement of development costs                              | 17,162                          |               |               |
| Total revenues  | 51,455                          | 12,474        | 11,174        |
| Costs and expenses:   |                                 |               |               |
| Cost of sales   |                                 |               | 3             |
| Research and development  | 135,847                         | 122,007       | 95,459        |
| General and administrative                                      | 28,054                          | 24,314        | 21,727        |
| Acquisition of in-process technology                            | 8,447                           | 5,455         | 6,500         |
| Total costs and expenses  | 172,348                         | 151,776       | 123,689       |
| Operating loss  | (120,893 )                      | (139,302 )    | (112,515 )    |
| Equity in net loss of affiliate                                 | (6,323 )                        | (19,791 )     | (14,997 )     |
| Interest, dividend income and realized gains                    | 14,740                          | 7,161         | 12,311        |
| Impairment loss on investments in partners                      | (33,347 )                       | (7,309 )      | (1,400 )      |
| Interest expense  | (4,233 )                        | (12,845 )     | (11,777 )     |
| Minority interest Celldex                                       | 4,410                           |               |               |
| Debt conversion expense   |                                 | (10,151 )     |               |
| Net loss on extinguishment of debt                              |                                 | (4,241 )      |               |
| Pre tax loss  | (145,646 )                      | (186,478 )    | (128,378 )    |
| Provision for income taxes                                      | 358                             | 31            | 69            |
| Loss before cumulative effect of change in accounting principle | (146,004 )                      | (186,509 )    | (128,447 )    |
| Cumulative effect of change in accounting principle             |                                 |               | (830 )        |
| Net loss  | \$ (146,004 )                   | \$ (186,509 ) | \$ (129,277 ) |
| Basic and diluted net loss per share:                           |                                 |               |               |
| Loss before cumulative effect of change in accounting principle | \$ (1.32 )                      | \$ (2.29 )    | \$ (1.64 )    |
| Cumulative effect of change in accounting principle             |                                 |               | (0.01 )       |
| Net loss  | \$ (1.32 )                      | \$ (2.29 )    | \$ (1.65 )    |
| Weighted average number of common shares outstanding            |                                 |               |               |
| basic and diluted   | 110,309                         | 81,494        | 78,314        |

See notes to these consolidated financial statements.

**MEDAREX, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY**  
(Dollars in thousands)

|   | Common stock<br>Number of<br>shares | Amount | Capital<br>in excess<br>of par value | Treasury Stock<br>Number of<br>shares | Amount  | Deferred<br>Compensation | Accumulated<br>other<br>comprehensive<br>income (loss)<br>Deficit | Accumulated | Total<br>shareholders<br>equity |
|---|-------------------------------------|--------|--------------------------------------|---------------------------------------|---------|--------------------------|---|-------------|---------------------------------|
| Balance at December 31, 2002  | 77,725,376                          | 777    | 630,279                              | (795,392)                             | (2,001) | 1,311                    | 5,380   | (283,603)   | 352,143                         |
| Issuance of common stock for exercise of options and grant of restricted shares         | 441,397                             | 4      | 1,467                                |                                       |         | 442                      |   |             | 1,913                           |
| Withdrawal from executive deferred compensation plan                                    |                                     |        |                                      | 301,876                               | 759     | (759)                    |   |             |                                 |
| Issuance of common stock for asset acquisition and license agreements, net              | 1,158,352                           | 12     | 7,088                                |                                       |         |                          |   |             | 7,100                           |
| Issuance of common stock under the employee stock purchase plan                         | 175,955                             | 2      | 950                                  |                                       |         |                          |   |             | 952                             |
| Net loss  |                                     |        |                                      |                                       |         |                          |   | (129,277)   | (129,277)                       |
| Other comprehensive income (loss)   |                                     |        |                                      |                                       |         |                          |   |             |                                 |
| foreign currency translation adjustment   |                                     |        |                                      |                                       |         |                          | 2,766   |             | 2,766                           |
| unrealized loss on securities   |                                     |        |                                      |                                       |         |                          | (1,586)   |             | (1,586)                         |
| Comprehensive loss  |                                     |        |                                      |                                       |         |                          |   |             | (128,097)                       |
| Balance at December 31, 2003  | 79,501,080                          | 795    | 639,784                              | (493,516)                             | (1,242) | 994                      | 6,560   | (412,880)   | 234,011                         |
| Issuance of common stock for exercise of options and grant of restricted shares         | 201,450                             | 2      | 869                                  |                                       |         | 138                      |   |             | 1,009                           |
| Stock based compensation Celldex  |                                     |        | 254                                  |                                       |         |                          |   |             | 254                             |
| Issuance of vested restricted stock units under deferred compensation plan              |                                     |        | 722                                  |                                       |         |                          |   |             | 722                             |
| Withdrawal from executive deferred compensation plan                                    |                                     |        |                                      | 301,876                               | 760     | (760)                    |   |             |                                 |
| Issuance of common stock as partial consideration for acquisition of Ability Biomedical | 731,823                             | 7      | 4,274                                |                                       |         |                          |   |             | 4,281                           |
| Issuance of common stock in connection with license agreements, net                     | 426,547                             | 5      | 2,556                                |                                       |         |                          |   |             | 2,561                           |
| Issuance of common stock under the employee stock purchase plan                         | 176,625                             | 2      | 1,067                                |                                       |         |                          |   |             | 1,069                           |
| Issuance of common stock in connection with Pfizer collaboration                        | 4,827,808                           | 48     | 29,952                               |                                       |         |                          |   |             | 30,000                          |
| Premium associated with convertible notes exchange                                      |                                     |        | 10,154                               |                                       |         |                          |   |             | 10,154                          |
| Appreciation of equity method investee  |                                     |        | 9,748                                |                                       |         |                          |   |             | 9,748                           |
| Net loss  |                                     |        |                                      |                                       |         |                          |   | (186,509)   | (186,509)                       |
| Other comprehensive income (loss)   |                                     |        |                                      |                                       |         |                          |   |             |                                 |
| foreign currency translation adjustment   |                                     |        |                                      |                                       |         |                          | 724   |             | 724                             |
| unrealized loss on securities   |                                     |        |                                      |                                       |         |                          | (635)   |             | (635)                           |
| Comprehensive loss  |                                     |        |                                      |                                       |         |                          |   |             | (186,420)                       |
| Balance at December 31, 2004  | 85,865,333                          | 859    | 699,380                              | (191,640)                             | (482)   | 372                      | 6,649   | (599,389)   | 107,389                         |
| Issuance of common stock for exercise of options and grant of restricted shares         | 919,067                             | 9      | 4,626                                |                                       |         | (94)                     |   |             | 4,541                           |
| Stock based compensation Celldex  |                                     |        | 898                                  |                                       |         | (610)                    |   |             | 288                             |
| Issuance of vested 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  |                                     |        |                                      |                                       |         |                          |   | (146,004)   | (146,004)                       |
| Other comprehensive income (loss)   |                                     |        |                                      |                                       |         |                          |   |             |                                 |
| foreign currency translation adjustment   |                                     |        |                                      |                                       |         |                          | (610)   |             | (610)                           |
| unrealized loss on securities   |                                     |        |                                      |                                       |         |                          | (8,390)   |             | (8,390)                         |

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|                              |             |          |            |          |          |         |           |             |            |
|------------------------------|-------------|----------|------------|----------|----------|---------|-----------|-------------|------------|
| Comprehensive loss           |             |          |            |          |          |         |           |             | (155,004)  |
| Balance at December 31, 2005 | 111,773,230 | \$ 1,118 | \$ 908,151 | (85,300) | \$(215 ) | \$(599) | \$(2,351) | \$(745,393) | \$ 160,711 |

See notes to these consolidated financial statements.

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**MEDAREX, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

|   | <b>For the Year Ended</b> |               |               |
|---|---------------------------|---------------|---------------|
|   | <b>December 31,</b>       |               |               |
|   | <b>2005</b>               | <b>2004</b>   | <b>2003</b>   |
| <b>Operating activities:</b>  |                           |               |               |
| Net loss  | \$ (146,004 )             | \$ (186,509 ) | \$ (129,277 ) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                           |               |               |
| Cumulative effect of change in accounting principle                         |                           |               | 830           |
| Depreciation  | 12,737                    | 12,020        | 10,650        |
| Amortization  | 5,627                     | 8,914         | 4,613         |
| Loss on sale of equipment   |                           | 105           |               |
| Stock options and awards to employees                                       | 194                       | 1,203         | 773           |
| Write-off of deferred offering costs - Celldex                              | 978                       |               |               |
| Non cash revenue - Genmab   |                           | (1,166 )      | (834 )        |
| Licenses fees paid with stock   |                           | 2,560         |               |
| Acquisition of in-process technology  | 8,447                     | 5,455         | 6,100         |
| Equity in net loss of Genmab  | 6,323                     | 19,791        | 14,997        |
| Impairment losses on investments in partners and other assets               | 36,120                    | 7,309         | 1,400         |
| Gain on exchange of convertible debt  |                           | (325 )        |               |
| Loss on redemption convertible debt   |                           | 4,566         |               |
| Gain on sale of partners' stock   | (3,315 )                  | (1,664 )      | (1,530 )      |
| Minority interest - Celldex   | (4,410 )                  |               |               |
| Changes in operating assets and liabilities                                 |                           |               |               |
| Other current assets  | (24,900 )                 | (458 )        | 3,799         |
| Trade accounts payable  | (59 )                     | 2,801         | (489 )        |
| Accrued liabilities   | (6,400 )                  | 20,769        | 214           |
| Deferred contract revenue   | 25,748                    | 98,649        | (497 )        |
| Net cash used in operating activities                                       | (88,914 )                 | (5,980 )      | (89,251 )     |
| <b>Investing activities:</b>  |                           |               |               |
| Purchase of property and equipment  | (9,312 )                  | (9,074 )      | (8,890 )      |
| Proceeds from sale of land and equipment                                    |                           | 600           |               |
| Increase in investments and advances to affiliates and partners             |                           | (581 )        | (1,000 )      |
| Decrease (increase) in segregated cash                                      |                           | 3,195         | (15,896 )     |
| Investment in Lorantis, net of acquired cash                                | 29,742                    |               |               |
| Investment in Alteris, net of acquired cash                                 | (2,208 )                  |               |               |
| Purchase of marketable securities   | (56,108 )                 | (270,500 )    | (121,191 )    |
| Sales and maturities of marketable securities                               | 121,999                   | 242,573       | 124,407       |
| Net cash provided by (used in) investing activities                         | 84,113                    | (33,787 )     | (22,570 )     |
| <b>Financing activities:</b>  |                           |               |               |
| Cash received from sales of securities and exercise of stock options, net   | 31,061                    | 31,850        | 2,091         |
| Proceeds from sale of convertible subordinated notes, net                   |                           | 145,217       | 121,239       |
| Repurchase of 4.50% convertible notes                                       |                           | (144,585 )    |               |
| Deferred offering costs - Celldex   |                           | (692 )        |               |
| Debt exchange costs   |                           | (100 )        |               |
| Principal payments under capital lease obligations                          | (9 )                      | (78 )         | (323 )        |
| Net cash provided by financing activities                                   | 31,052                    | 31,612        | 123,007       |
| Effect of exchange rate differences on cash and cash equivalents            | (492 )                    |               |               |
| Net increase (decrease) in cash and cash equivalents                        | 25,759                    | (8,155 )      | 11,186        |
| Cash and cash equivalents at beginning of period                            | 64,843                    | 72,998        | 61,812        |
| Cash and cash equivalents at end of period                                  | \$ 90,602                 | \$ 64,843     | \$ 72,998     |
| <b>Non-cash investing and financing activities:</b>                         |                           |               |               |
| Issuance of common stock for intangible assets                              | \$                        | \$            | \$ 7,100      |
| <b>Supplemental disclosures of cash flow information</b>                    |                           |               |               |
| <b>Cash paid during period for:</b>   |                           |               |               |
| Income taxes  | \$ 365                    | \$ 3          | \$ 108        |
| Interest  | \$ 5,717                  | \$ 10,789     | \$ 11,841     |

See notes to these consolidated financial statements.





**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2005, 2004 and 2003**

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

**1. Organization and Description of Business**

Medarex, Inc. ( Medarex or the Company ), incorporated in July 1987, is a biopharmaceutical company developing therapeutic products for cancer, inflammation, autoimmune disorders and other life-threatening and debilitating diseases based on its proprietary technology. The Company's therapeutic products are currently under development and will need the approval of the U.S. Food and Drug Administration ( FDA ) prior to commercial distribution in the United States.

The Company's financial statements consolidate all of its subsidiaries, including those that it controls and those in which it holds a majority voting interest. As of December 31, 2005, Medarex owns approximately 60% of the outstanding common stock of Celldex Therapeutics, Inc. ( Celldex ) (see Note 15). As of December 31, 2005, the Company has significant investments in Genmab A/S ( Genmab ) (see Note 11) and IDM Pharma, Inc. ( IDM Pharma ) (see Note 12). The Company's operations constitute one business segment. All significant intercompany balances and transactions have been eliminated in consolidation.

**2. Significant Accounting Policies**

***Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The Company invests its cash in deposits with major financial institutions, money market funds and notes issued by the U. S. government.

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

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

In addition, the Company has investments in several of its partners whose securities are not publicly traded. These investments are accounted for under the cost basis. Because these securities are not publicly traded, the Company values these investments by using information acquired from industry trends, management of these companies, such companies' financial statements, and other external sources. Specifically, the Company's determination of any potential impairment of the value of privately held securities includes an analysis of the following for each company on a periodic basis: review of interim and

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year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financings, and potential strategic alternatives. Based on the information acquired through these sources, the Company records an investment impairment charge when it believes an investment has experienced a decline in value that is considered to be other than temporary.

The Company recorded investment impairment charges of \$0, \$0.2 million and \$0 related to investments in partners whose securities are publicly traded for the years ended December 31, 2005, 2004 and 2003, respectively. In addition, the Company recorded investment impairment charges of \$33.3 million, \$7.1 million and \$1.4 million in partners whose securities are privately held for the years ended December 31, 2005, 2004 and 2003, respectively. Approximately \$29.3 million, \$7.1 million and \$0 of investments impairment charges for the years ended December 31, 2005, 2004 and 2003, respectively, related to the Company's investment in Immuno-Design Molecules, S.A. (IDM) prior to its business combination with Epimmune, Inc. (Epimmune) (see Note 12).

***Segregated Securities***

Segregated securities primarily represent U.S. treasury security strips which collateralized interest payments related to the Company's 4.25% convertible senior notes which were due August 15, 2010 and all of which were converted into shares of common stock in January 2005 (see Note 6).

***Financial Instruments***

The fair values of cash and cash equivalents, marketable securities, accounts payable, accrued liabilities and convertible subordinated notes payable are not materially different from their carrying amounts as of December 31, 2005 and 2004. Receivables from partners are concentrated primarily in the pharmaceutical and biotechnology industries. Although the Company's partners are concentrated primarily within these two industries, management considers the likelihood of material credit risk as remote.

***Property, Buildings and Equipment***

Property, buildings and equipment are stated at cost. Depreciation is determined using straight-line methods over the estimated useful lives of the various asset classes. Useful lives for buildings and building improvements, furniture and fixtures and machinery and equipment principally range from fifteen to thirty years, five years and three to five years, respectively. Leasehold improvements are amortized over the estimated useful lives of the assets or the initial lease terms, whichever is shorter.

***Impairment of Long-Lived Assets***

Long-lived assets and certain identifiable intangible assets to be held and used are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to

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their estimated fair values. Long-lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

***Transactions in Equity Method Investee Stock***

At the time an equity method investee sells its stock to unrelated parties at a price in excess of its book value, the Company's net investment in that equity method investee increases proportionately to its equity basis in the equity method investee. If at that time the equity method investee is a newly-formed start-up, a research and development or a development stage company, the Company's proportionate share of the equity method investee's equity resulting from the additional equity raised is accounted for as an increase to capital in excess of par value under Accounting Principles Board ( APB ) Opinion No. 18 and Staff Accounting Bulletin ( SAB ) No. 51.

***Foreign Currency Translation***

Investments in foreign affiliates accounted for under the equity method have been translated into U.S. dollars in accordance with the Financial Accounting Standards Board ( FASB ) Statement No. 52, *Foreign Currency Translation*. All asset and liability accounts have been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year. The gains and losses resulting from the changes in exchange rates from year to year have been reported in other comprehensive income (loss). As of December 31, 2005, the accumulated unrealized foreign exchange translation gain included in other comprehensive income was approximately \$4.9 million.

***Revenue Recognition***

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

- The Company sells antibodies primarily to partners in the United States and overseas. Revenue from these sales is recognized when the antibodies are shipped and the Company has no further obligations related to the development of the antibodies.
- Fees received from the licensing of the Company's proprietary technologies for research and development performed by its customers and partners is recognized generally over the term of the respective license period beginning after both the license period has begun and the technology has been delivered.
- Fees received for product development services are recognized ratably over the period during which the services are performed.
- Milestone payments are recognized as revenue upon the achievement of mutually agreed milestones, provided that (i) the milestone event is substantive and its achievement is not

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

- Revenue arrangements that include multiple deliverables are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.
- Revenues derived from reimbursements of costs associated with the development of product candidates are recorded in compliance with EITF Issue 99-19, Reporting Revenue Gross as a Principal Versus Net as an Agent ( EITF 99-19 ). According to the criteria established by EITF 99-19, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company believes it has met the criteria to record revenue for the gross amount of the reimbursements.
- Grant revenues are recognized as the Company provides the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

***Research and Development***

Research and development costs are expensed as incurred 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. Costs to acquire technologies that are utilized in research and development that have no alternative future use are expensed as incurred.

***Use of Estimates***

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

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***Stock-Based Compensation***

At December 31, 2005, the Company's stock awards are governed by its 2005 Equity Incentive Plan, as amended, which is described more fully in Note 8. The Company accounts for its stock awards plan under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. The following table illustrates the effect on net loss per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

|  | Year ended December 31 |               |               |
|--|------------------------|---------------|---------------|
|  | 2005                   | 2004          | 2003          |
| Net loss, as reported  | \$ (146,004 )          | \$ (186,509 ) | \$ (129,277 ) |
| Add: Non-cash employee compensation  | 194                    | 1,203         | 773           |
| Deduct: Total stock-based employee compensation expense determined under fair value method | (17,701 )              | (14,797 )     | (11,303 )     |
| Pro forma net loss   | \$ (163,511 )          | \$ (200,103 ) | \$ (139,807 ) |
| Loss per share:  |                        |               |               |
| Basic and diluted, as reported   | \$ (1.32 )             | \$ (2.29 )    | \$ (1.65 )    |
| Basic and diluted, pro forma   | \$ (1.48 )             | \$ (2.46 )    | \$ (1.79 )    |

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

|                                 | 2005       | 2004    | 2003    |
|---------------------------------|------------|---------|---------|
| Expected dividend yield         | 0          | % 0     | % 0     |
| Expected stock price volatility | 99.1       | % 55.0  | % 64.0  |
| Risk-free interest rate         | 4.29       | % 3.60  | % 2.75  |
| Expected life of options        | 6.25 years | 5 years | 5 years |

***Income Taxes***

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

***Net Loss Per Share***

Basic and diluted net loss per share are calculated in accordance with SFAS No. 128, *Earnings Per Share*. Basic net loss per share is based upon the number of weighted average shares of common stock outstanding. Diluted net loss per share is based upon the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding. Potential shares of common stock result

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from the assumed exercise of outstanding stock options, which are included under the treasury stock method as well as the assumed conversion of convertible senior notes. Potentially dilutive securities have been excluded from the computation of diluted net loss per share for all years presented, as their effect is antidilutive. A summary of such potentially dilutive securities is as follows:

|                   | Year ended December 31 |            |            |
|-------------------|------------------------|------------|------------|
|                   | 2005                   | 2004       | 2003       |
| Convertible notes | 10,936,935             | 29,161,546 | 13,818,457 |
| Stock options     | 3,191,712              | 3,087,816  | 729,386    |
|                   | 14,128,647             | 32,249,362 | 14,547,843 |

***Asset Retirement Obligations***

Effective January 1, 2003, the Company changed its method of accounting for asset retirement obligations in accordance with SFAS No. 143, *Accounting for Asset Retirement Obligations*. Previously, the Company was not required to recognize amounts related to asset retirement obligations. Under SFAS No. 143, the Company now recognizes asset retirement obligations in the period in which they are incurred if a reasonable estimate of fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset.

The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately \$1.4 million, recognition of an asset retirement obligation liability of approximately \$2.2 million and a cumulative effect of a change in accounting principle of approximately \$0.8 million. Adoption of SFAS No. 143 had no material impact on net loss before the cumulative effect of adoption in the year ended December 31, 2003.

***Reclassifications***

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

***Impact of Recently Issued Accounting Pronouncements***

In December 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends Statement No. 95, *Statement of Cash Flows*. Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Historically, in accordance with SFAS 123 and SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, the Company had elected to follow the disclosure only provisions of Statement No. 123 and, accordingly, continues to account for share-based compensation under the recognition and measurement principles of APB Opinion No. 25 and related interpretations. Under APB 25, when stock options are issued with an exercise price equal to the market price of the underlying stock price on the date of grant, no compensation expense is recognized in the financial statements, and compensation expense is only disclosed in the footnotes to the financial statements. The Company is required to adopt Statement No. 123(R) beginning January 1, 2006. The Company selected the Black-Scholes option valuation method

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and the modified prospective transition method available under Statement 123(R). Although the Company has not yet determined the final impact of Statement 123(R), the Company believes the non-cash expense for 2006 related to Statement 123(R) will be in the range of \$17.0 million to \$18.0 million.

### 3. Available for Sale Investments

Available for sale investments consist of the following as of December 31:

|  | 2005      |                    |                    | 2004        |                    |                    | Unrealized<br>Loss | Fair Value  |            |
|--|-----------|--------------------|--------------------|-------------|--------------------|--------------------|--------------------|-------------|------------|
|  | Cost      | Unrealized<br>Gain | Unrealized<br>Loss | Cost        | Unrealized<br>Gain | Unrealized<br>Loss |                    |             |            |
| Money market funds<br>(included in cash and<br>cash equivalents) | \$ 62,315 |                    |                    | \$ 62,315   | \$ 57,984          | \$ 1               | \$ (2 )            | \$ 57,983   |            |
| U.S. Treasury<br>Obligations                                     | 41,938    |                    | (342 )             | 41,596      | 32,746             | 2                  | (201 )             | 32,547      |            |
| U.S. Corporate Debt<br>Securities                                | 214,105   | 32                 | (1,851 )           | 212,286     | 275,131            | 23                 | (1,267 )           | 273,887     |            |
| Equity Securities  | 11,940    |                    | (5,117 )           | 6,823       | 674                | 2,556              |                    | 3,230       |            |
|  |           | \$ 330,298         | \$ 32              | \$ (7,310 ) | \$ 323,020         | \$ 366,535         | \$ 2,582           | \$ (1,470 ) | \$ 367,647 |

The Company's available for sale investments have the following maturities at December 31, 2005:

|  |            |
|--|------------|
| Due in one year or less                  | \$ 205,374 |
| Due after one year, less than five years | 117,646    |
| Due after five years                     |            |

For the years ended December 31, 2005, 2004 and 2003, realized gains totaled \$3.3 million, \$2.3 million and \$2.1 million, respectively, and realized losses totaled \$0, \$0 and \$0.1 million, respectively. The cost of securities sold is based on the specific identification method.

Unrealized loss positions for which other-than-temporary impairments have not been recognized at December 31, 2005, is summarized as follows:

|                                 | Fair<br>Value | Unrealized<br>Loss |
|---------------------------------|---------------|--------------------|
| Purchased less than one year    | \$ 127,136    | \$ (6,398 )        |
| Purchased greater than one year | 106,978       | (912 )             |
|                                 | \$ 234,114    | \$ (7,310 )        |

Unrealized losses in the portfolio relate to an equity security (approximately \$5.1 million) and various debt securities including U.S. treasury obligations, asset backed securities and corporate bonds (approximately \$2.2 million). For the equity security, the unrealized loss was due to a temporary decline in the value of the security. For the debt securities, the unrealized losses were primarily due to increases in interest rates. The Company has concluded that unrealized losses in its investment securities are not other-than-temporary and the Company has the ability to hold securities to maturity date or the recovery period.



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**4. Balance Sheet Detail**

Other current assets consist of the following as of December 31:

|                                   | <b>2005</b> | <b>2004</b> |
|-----------------------------------|-------------|-------------|
| Interest and dividends receivable | \$ 1,893    | \$ 2,198    |
| Employee receivables              | 520         | 488         |
| Prepaid insurance                 | 2,067       | 2,011       |
| Receivables from partners         | 22,416      | 915         |
| Other                             | 4,712       | 1,096       |
|                                   | \$ 31,608   | \$ 6,708    |

Other assets consist of the following as of December 31:

|  | <b>2005</b> | <b>2004</b> |
|--|-------------|-------------|
| Deferred debt issuance costs, net of accumulated amortization of \$1,111 in 2005 and \$1,249 in 2004 | \$ 3,586    | \$ 7,477    |
| Patents, net of accumulated amortization of \$3,571 in 2005 and \$2,651 in 2004                      | 1,436       | 2,356       |
| Acquired workforce, net of accumulated amortization of \$705 in 2005 and \$612 in 2004               |             | 93          |
| Deferred offering costs Celldex  |             | 978         |
| Acquired technology Celldex, net of accumulated amortization of \$29 in 2005                         | 1,267       |             |
|  | \$ 6,289    | \$ 10,904   |

Accrued liabilities consist of the following as of December 31:

|   | <b>2005</b> | <b>2004</b> |
|---|-------------|-------------|
| Accrued convertible debt redemption expense | \$          | \$ 10,151   |
| Accrued construction and equipment costs    | 312         | 330         |
| Accrued interest                            | 450         | 2,793       |
| Accrued compensation                        | 6,740       | 5,902       |
| Accrued contract manufacturing              | 28          | 1,984       |
| Accrued license and royalty fees            | 3,143       | 6,313       |
| Accrued professional fees                   | 2,993       | 1,280       |
| Due to Essex Chemical Corp.                 | 667         | 667         |
| Accrued clinical trial expenses             | 2,917       | 928         |
| Accrued partner reimbursements              | 6,439       |             |
| Other                                       | 4,216       | 1,800       |
|   | \$ 27,905   | \$ 32,148   |

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**5. Taxes**

The provision (benefit) for income taxes is as follows:

|               | Year ended December 31 |       |       |
|---------------|------------------------|-------|-------|
|               | 2005                   | 2004  | 2003  |
| Federal       |                        |       |       |
| Current       | \$                     | \$    | \$    |
| Deferred      |                        |       |       |
| Total federal |                        |       |       |
| State         |                        |       |       |
| Current       | 333                    | 21    | 34    |
| Deferred      |                        |       |       |
| Total state   | 333                    | 21    | 34    |
| Foreign       |                        |       |       |
| Current       | 25                     | 10    | 35    |
| Deferred      |                        |       |       |
| Total foreign | 25                     | 10    | 35    |
| Total         | \$ 358                 | \$ 31 | \$ 69 |

The current foreign tax provision relates to foreign withholding taxes. The current state tax provision is attributable to the New Jersey alternate minimum tax assessment.

A reconciliation of the provision for income taxes and the amount computed by applying the federal income rate of 34% to loss before provision for income tax is as follows:

|  | Year ended December 31 |              |              |
|--|------------------------|--------------|--------------|
|  | 2005                   | 2004         | 2003         |
| Computed at statutory rate                           | \$ (49,542 )           | \$ (63,403 ) | \$ (43,649 ) |
| State income taxes, net of federal tax effect        | (8,594 )               | (10,832 )    | (7,733 )     |
| Minority interest Celldex                            | (1,477 )               |              |              |
| In-process technology                                | 359                    | 1,836        |              |
| Loss of foreign subsidiary                           | 770                    | 64           | 24           |
| Foreign withholding taxes                            | 17                     | 7            | 23           |
| Research and development credit carryforward benefit | (3,068 )               | (2,922 )     | (2,876 )     |
| Other  | 51                     | 54           | 74           |
| Other change in deferred tax valuation reserve       | 61,842                 | 75,227       | 54,206       |
|  | \$ 358                 | \$ 31        | \$ 69        |

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The components of deferred tax assets and liabilities consist of the following as of December 31:

|   | 2005       | 2004       |
|---|------------|------------|
| Deferred tax assets:                                  |            |            |
| Net operating loss carryforwards                      | \$ 170,414 | \$ 165,789 |
| Accrued compensation                                  | 25         | 1,196      |
| Research and development capitalized for tax purposes | 4,217      | 4,217      |
| Deferred revenue                                      | 38,835     | 116        |
| Research credits                                      | 12,656     | 10,505     |
| Impairment loss on investments                        | 42,546     | 25,615     |
| License fees capitalized for tax purposes             | 6,265      | 6,117      |
| In-process technology capitalized for tax purposes    | 11,269     | 9,671      |
| Accrued debt make-whole payment                       |            | 4,059      |
| Accrued royalty                                       | 2,692      | 814        |
| Cumulative effect asset retirement obligation         | 332        | 332        |
| Other   | 1,896      | 856        |
|   | 291,147    | 229,287    |
| Deferred tax asset valuation allowance                | (291,147 ) | (229,287 ) |
| Net deferred tax assets                               | \$         | \$         |

At December 31, 2005, approximately \$18.9 million of gross deferred tax assets related to net operating loss ( NOL ) carryforwards representing tax benefits associated with the exercise of non-qualified stock options and the disqualifying disposition of stock acquired with incentive stock options. Such benefits, when realized, are credited to additional paid-in capital.

At December 31, 2005, the Company had federal NOL carryforwards of approximately \$438.2 million. The NOL carryforwards expire in 2006 (\$0.8 million), 2007 (\$4.0 million), 2008 (\$5.5 million), 2009 (\$7.6 million), 2010 (\$6.4 million), 2011 (\$7.0 million), 2012 (\$9.6 million), 2018 (\$20.9 million), 2019 (\$3.0 million), 2020 (\$13.5 million), 2021 (\$19.2 million), 2022 (\$87.6 million), 2023 (\$109.8 million), 2024 (\$94.4 million) and 2025 (\$48.9 million). The Company determined that an ownership change under Section 382 of the Internal Revenue Code of 1986, as amended, occurred during 1998. The effect of the ownership change is the imposition of a \$3.2 million annual limitation on the use of NOL carryforwards attributable to periods before the change. At December 31, 2005, the amount of NOL subject to the limitation was \$43.1 million and the amount not subject to limitation was \$395.1 million.

The Company had federal research tax credit carryforwards at December 31, 2005 of approximately \$11.7 million which expire between 2006 and 2025. As a result of the 1998 ownership change under Section 382, the use of approximately \$1.4 million of these carryforwards is subject to limitation.

At December 31, 2005, the Company had state NOL carryforwards of approximately \$280.3 million. These NOL carryforwards will expire in varying amounts between 2006 and 2014.

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**6. Convertible Notes**

***4.50% Convertible Subordinated Notes***

On June 26, 2001, the Company completed a public offering of \$175.0 million of 4.50% Convertible Subordinated Notes due 2006 (the 4.50% Notes). The 4.50% Notes were convertible into shares of common stock at a ratio of 34.6789 shares per each \$1,000 principal amount of the notes (\$28.84 per share), subject to adjustment, and were scheduled to mature in July 2006.

The Company was obligated to pay interest on the 4.50% Notes on January 1 and July 1 of each year. Interest payable per \$1,000 principal amount of notes for each subsequent interest period was \$22.50. Interest was calculated on the basis of a 360-day year consisting of twelve 30-day months. The 4.50% Notes were either repurchased and cancelled or redeemed and cancelled in 2004 (See Note 7).

***4.25% Convertible Senior Notes***

On July 23, 2003, the Company completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended (the Securities Act), of \$125.0 million of 4.25% Convertible Senior Notes due August 15, 2010 (the 4.25% Notes) to qualified institutional investors. The 4.25% Notes were initially convertible into shares of the Company's common stock at the rate of 148.8261 per each \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$6.72 per share, subject to anti-dilution adjustments. As of December 31, 2004, the Company had a total of 21,875,353 shares of common stock reserved for issuance pursuant to the conversion of all of its 4.25% Notes.

In January 2004, the Company and certain holders of its 4.50% Notes completed an exchange and cancellation of \$33.0 million principal amount of the 4.50% Notes for the issuance of \$21.986 million in aggregate principal of a new series of the Company's 4.25% Notes, in a limited number of transactions. As a result of this exchange and cancellation, the Company's total convertible debt was reduced by \$11.014 million. In addition, the Company recorded a gain on the early extinguishment of debt of approximately \$0.3 million in connection with the exchange and cancellation. Such gain is included within net loss on the extinguishment of debt for the year ended December 31, 2004 in the Company's consolidated statement of operations.

The Company paid interest on the 4.25% Notes on February 15 and August 15 of 2004. Interest payable per \$1,000 principal amount of the 4.25% Notes for the period from the issue date to February 15, 2004 was approximately \$23.85. Interest payable per \$1,000 amount of the 4.25% Notes for the August 15, 2004 interest payment was \$21.25.

The Company received net proceeds from the private placement of the 4.25% Notes of approximately \$121.3 million (after deducting the initial purchasers' discounts and offering expenses). As of December 31, 2004, the Company had purchased U.S. Treasury security strips to collateralize the notes in an amount sufficient to pay the four interest payments on the 4.25% Notes due in 2005 and 2006. Such amount has been classified as segregated securities in the current assets section of the Company's December 31, 2004 consolidated balance sheet.

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In January 2005, the Company completed the provisional redemption of all of its outstanding 4.25% Notes which was previously announced in December 2004. Prior to the redemption date, holders of all of the outstanding 4.25% Notes (\$146.986 million) converted their notes into a total of 21,875,353 shares of the Company's common stock. In connection with the redemption, the Company paid approximately \$12.5 million in cash representing primarily the make-whole payment of \$10.2 million as well as accrued interest of \$2.3 million. The Company accrued the \$10.2 million make-whole payment in the quarter ended December 31, 2004, at the time the redemption was announced. In connection with the completion of this transaction, unamortized debt issuance costs of approximately \$3.2 million were reclassified to capital in excess of par value at the time the 4.25% Notes were converted to common stock.

***2.25% Convertible Senior Notes***

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

The Company pays interest on the 2.25% Notes on May 15 and November 15 of each year beginning on November 15, 2004. Interest payable per \$1,000 principal amount of the 2.25% Notes for the period from issue date to November 15, 2004 was approximately \$12.00. Interest payable per \$1,000 amount of the 2.25% Notes for each subsequent interest payment is \$11.25.

The Company received net proceeds from the private placement of the 2.25% Notes of approximately \$145.2 million (after deducting the initial purchasers' discounts and offering expenses).

On or after May 20, 2009, the Company may redeem the 2.25% Notes, in whole or in part, at its option at a redemption price expressed as a percentage of principal amount, of 100.6% for the period between May 20, 2009 and May 15, 2010 and 100.3% for the 12 month period beginning on May 15, 2010. As of December 31, 2005, the Company had 10,936,935 shares of common stock reserved for issuance pursuant to the conversion of the 2.25% Notes.

The holders of the 2.25% Notes have the option, subject to certain conditions, to require the Company to repurchase the notes in the event of a change in control, as defined in the indenture at a price equal to 100% of the principal amount of the notes plus accrued and unpaid interest to the date of repurchase. The Company may pay the repurchase price in cash or, at the Company's option, in shares of its common stock. Payments made in shares of the Company's common stock will be valued at 95% of the average of the closing sales prices of the Company's common stock for the five trading days immediately preceding the third trading day prior to the repurchase date.

**7. Debt Repurchase and Cancellation**

During 2004 the Company repurchased, redeemed and cancelled the entire outstanding principal amount of its 4.50% Notes (\$142.0 million).

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The total charge associated with the Company's repurchase, redemption and cancellation of its 4.50% Notes for the year ended December 31, 2004 was \$4.5 million.

## 8. Stock Options

The Company's stock awards are governed by its 2005 Equity Incentive Plan, as amended (the "Plan"). The purchase price of stock options under the Plan is determined by the Compensation and Organization Committee of the Board of Directors of the Company (the "Committee"). The term is fixed by the Committee, but no incentive stock option is exercisable after 10 years from the date of grant. Stock options generally vest over a four year period. At December 31, 2005, a total of 4,081,085 shares were available for future grants under the Plan.

In January 2003, the Company's Board of Directors approved a stock option exchange program. Under this program, eligible employees and eligible officers were given the opportunity to cancel one or more stock options previously granted to them in exchange for new stock options to be granted at least six months and one day from the date the old options are cancelled (the "grant date"), provided that the individual is still employed by the Company on such date. Eligible employees refers to current Company employees who are not executive officers and who hold options to purchase the Company's stock with an exercise price of \$10.00 or more. Eligible officers refers to executive officers (excluding the President and Chief Executive Officer and the former Executive Vice President) who hold options to purchase the Company's stock with an exercise price of \$25.00 or more. Members of the Company's Board of Directors were not eligible to participate in the program. The participation deadline for the program was March 7, 2003. Eligible Employees and Eligible Officers elected to exchange a total of 2,309,401 shares of common stock underlying eligible options. The number of shares subject to the new options was determined based on the old options' exercise price. Specifically, if the exercise price of the old options was between \$10.00 and \$24.99 per share, then the exchange ratio was equal to 0.67 of a share. If the exercise price of the old options was \$25.00 per share or higher, then the exchange ratio was equal to 0.50 of a share. The Company issued 1,313,919 replacement options with an exercise price of \$6.33 on September 8, 2003.

A summary of the Company's stock option activity and related information for the years ended December 31, 2005, 2004 and 2003 is as follows:

|   | 2005                       |  | 2004                       |  | 2003                       |  |
|---|----------------------------|--|----------------------------|--|----------------------------|--|
|   | Common<br>Stock<br>Options | Weighted<br>Average<br>Exercise<br>Price | Common<br>Stock<br>Options | Weighted<br>Average<br>Exercise<br>Price | Common<br>Stock<br>Options | Weighted<br>Average<br>Exercise<br>Price |
| Outstanding at beginning of year                                  | 14,245,187                 | \$ 7.84                                  | 11,629,594                 | \$ 8.32                                  | 9,935,072                  | \$ 13.64                                 |
| Granted   | 3,888,462                  | 9.78                                     | 3,141,325                  | 5.80                                     | 5,018,019                  | 6.43                                     |
| Exercised   | (919,067 )                 | (4.88 )                                  | (201,450 )                 | (3.88 )                                  | (451,897 )                 | 2.52                                     |
| Canceled  | (410,854 )                 | (7.05 )                                  | (324,282 )                 | (7.53 )                                  | (2,871,600 )               | 24.25                                    |
| Outstanding at end of year  | 16,803,728                 | 8.47                                     | 14,245,187                 | 7.84                                     | 11,629,594                 | 8.32                                     |
| Exercisable at end of year  | 9,534,573                  | 8.82                                     | 7,372,351                  | 9.21                                     | 5,093,394                  | 10.04                                    |
| Weighted average fair value of<br>options granted during the year |                            | \$ 7.95                                  |                            | \$ 2.99                                  |                            | \$ 3.63                                  |

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Stock options outstanding at December 31, 2005 are summarized as follows:

| Range of Exercise Price | Outstanding<br>Options at<br>December 31, 2005 | Weighted Average<br>Remaining<br>Contractual Life | Weighted<br>Average<br>Exercise Price | Exercisable<br>Options at<br>December 31, 2005 | Weighted<br>Average<br>Exercise Price |
|-------------------------|--|---|---------------------------------------|--|---------------------------------------|
| \$ 1.47 to \$ 5.61      | 4,580,127                                      | 6.55  | \$ 4.01                               | 2,826,842                                      | \$ 4.05                               |
| \$ 5.70 to \$ 6.37      | 3,266,949                                      | 6.94  | 6.35                                  | 2,896,195                                      | 6.35                                  |
| \$ 6.46 to \$9.88       | 3,816,402                                      | 7.99  | 7.27                                  | 2,003,347                                      | 7.23                                  |
| \$ 9.90 to \$11.89      | 3,346,200                                      | 9.66  | 9.91                                  | 17,095   | 10.41                                 |
| \$12.50 to \$53.41      | 1,794,050                                      | 5.40  | 22.10                                 | 1,791,094                                      | 22.11                                 |
|                         | 16,803,728                                     |   |                                       | 9,534,573                                      |                                       |

## 9. Deferred Compensation

The Company maintains deferred compensation programs, under which each of the Company's executive officers elected to have a portion of his 2005, 2004 and 2003 bonuses, which were otherwise payable in cash, converted to restricted stock units representing shares of the Company's common stock. Participants in the deferred compensation programs could elect to defer up to 50% of their respective bonuses. The number of restricted stock units awarded upon such conversion was determined by dividing (i) the amount of the bonus to be converted by (ii) the fair market value of the Company's common stock on the grant date. Participants in the deferred compensation programs elected to defer receipt of the common stock portion of their bonuses until the earlier of three years from the grant date or the participant's termination from the Company. The bonus portion deferred by each of the participants is matched on a 1:1 basis by the Company and 25% of the match vested as of the respective grant dates. So long as a participant remains employed by the Company, an additional 25% of the Company's matching contribution vests on each anniversary of the respective grant dates for the next three years. All benefits under the deferred compensation programs are distributed in a single payment and will be paid exclusively in the form of shares of the Company's common stock. The Company's matching contribution was approximately \$0.5 million, \$0.3 million and \$0.1 million for the years ended, December 31, 2005, 2004 and 2003, respectively.

## 10. Collaboration Agreements

### *Kirin*

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

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Through December 31, 2005, the Company has not made any milestone payments to Kirin. However, approximately \$2.8 million has been paid to Kirin as of December 31, 2005 representing a payment due Kirin as a result of the Company's collaboration with Pfizer. Based on a total of three products the Company is developing, which use or the Company believes may use Kirin technology and that (i) are currently in clinical trials, or (ii) the Company anticipates may enter clinical trials through the end of 2007, the Company may be required to make milestone payments to Kirin aggregating up to approximately \$12.75 million with respect to such products, or a maximum of approximately \$4.25 million per product. The Company's future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

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

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

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

***Bristol-Myers Squibb Collaboration***

In January 2005, the Company announced the closing of a collaboration and co-promotion agreement and a related securities purchase agreement with BMS, pursuant to which the Company and BMS each granted the other certain intellectual property licenses and product rights on a worldwide basis in order to enable the parties to collaborate in research and development of ipilimumab for the treatment of cancer and other diseases, and, in the event that further development work is successful, to commercialize any resulting products. In particular, the collaboration includes a grant by the Company to BMS of a license to commercialize ipilimumab, a fully human antibody product developed using the Company's UltiMAb Human Antibody Development System, that is antagonistic to cytotoxic T-lymphocyte antigen 4 (CTLA-4). Ipilimumab is currently under investigation for the treatment of a broad range of cancers and other diseases. The collaboration also includes the grant by the Company to BMS of a license to MDX-1379, a gp100 peptide vaccine, for use with ipilimumab for the treatment of metastatic melanoma.



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As part of the collaboration, the two companies have committed to an initial multi-year budget of approximately \$192.0 million to fund their development of ipilimumab as a potential treatment for a broad range of cancers. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the United States and Europe, with the remaining 35% to be paid by the Company. The parties will share equally the costs of any clinical trials of products intended solely for regulatory approval in the United States, and BMS will be fully responsible for all development efforts that relate solely to regulatory approval in Europe and other parts of the world. Approximately \$14.7 million of the Company's revenue for the year ended December 31, 2005 represented the reimbursement of 65% of the Company's costs associated with the development of ipilimumab recorded in accordance with EITF 99-19. The Company's 35% share of the BMS development costs for the year ended December 31, 2005 was approximately \$6.4 million.

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

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

*Pfizer*

In September 2004, the Company entered into a series of agreements with Pfizer, Inc. The first agreement amended the Company's 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 the Company to Pfizer and a cross-license of certain patents and patent applications solely relating to the companies' 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 total initial cash payment to the Company of \$80.0 million and purchased 4,827,808 unregistered shares of the Company's common stock at a purchase price equal to \$6.21 per share for an aggregate purchase price of \$30.0 million. The purchase price represented a small premium to market price at the time the Company entered into the collaboration.

The Company accounts for revenue arrangements that include multiple deliverables in accordance with Emerging Issues Task Force No. 00-21, *Accounting for Revenue Arrangements with Multiple Arrangements* (EITF 00-21).

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The Company has concluded that because the Pfizer collaboration contains multiple deliverables (licenses to technology and research services) EITF 00-21 applies. The Company considers the arrangement with Pfizer to be a single unit of accounting under EITF 00-21 for purposes of recognizing the initial \$80.0 million payment. For the years ended December 31, 2005 and 2004, the Company recognized \$9.3 million and \$2.6 million of revenue under the agreements with Pfizer.

***MedImmune***

In November 2004, the Company entered into an exclusive license and collaboration agreement with MedImmune, Inc. to develop antibodies targeting interferon-alpha and the type I interferon receptor 1. The collaboration focuses on two fully human antibodies, MEDI-545 (MDX-1103) and MDX-1333, that are currently in clinical and preclinical development, respectively, by MedImmune and the Company for the treatment of autoimmune diseases.

Under the terms of the agreement, the Company received a payment of \$15.0 million from MedImmune and has the ability to receive potential milestone payments for product candidates developed by the collaboration that enter into clinical development. MedImmune is fully responsible for all development costs up to the point of initiating pivotal trials of any product candidates. At that point, the Company has a choice for each potential product candidates. The Company can elect to enter into a profit sharing arrangement in the United States whereby the Company will pay its proportionate share of the future development costs and reimburse MedImmune for a proportionate share of MedImmune's previous development costs plus interest. In addition, the Company would also have the option to enter into a co-promotion relationship with MedImmune in the United States for each such product. In the alternative, the Company can elect to forego any further funding for the product candidates, and MedImmune will be responsible for all costs of development and commercialization. In that case, the Company will be entitled to milestone payments and substantial royalties on any sales in the United States. The Company is also entitled to milestone payments and substantial royalties on any product sales in the rest of the world.

***Gilead***

In July 2004, the Company entered into an amendment to a Collaboration and License Agreement with Gilead Sciences, Inc. (the successor in interest to NeXstar Pharmaceuticals, Inc.), referred to herein as the Gilead Amendment. Under the terms of the Gilead Amendment, the Company agreed to pay Gilead a total of \$8.5 million in eight equal quarterly installments of \$1.063 million, payable at the Company's election, in cash, registered shares of its common stock or a combination thereof, in exchange for (i) a reduction of certain future royalty payment obligations, payable by the Company to Gilead, and (ii) an expansion of the scope of certain licenses from Gilead to the Company relating to certain intellectual property rights regarding anti-CTLA-4 products. The first of these payments was paid on August 2, 2004 through the issuance of 185,622 shares of the Company's common stock to Gilead. The second payment was made on October 1, 2004 in cash. The third, fourth, fifth and sixth payments (all made in 2005) were also in cash. The seventh payment was made on January 3, 2006 in cash. The remaining payment will be made on April 3, 2006.

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*Kyowa Hakko Kogyo Co., Ltd.*

In October 2003, the Company entered into an Amended and Restated License Agreement with Kyowa Hakko Kogyo Co., Ltd., (the Kyowa License ). Under the terms of the Kyowa License, the Company received certain intellectual property rights relating to the development and commercialization of our Ultra-Potent Toxin technology. As partial consideration for these rights, the Company paid Kyowa a total of \$4.0 million, \$3.6 million of which was paid through the issuance of 552,020 shares of our common stock with the balance of \$0.4 million paid in cash, representing applicable withholding taxes.

The Kyowa License was the result of the renegotiation of a pre-existing license agreement with respect to Ultra-Potent Toxin technology between Kyowa Hakko and Corixa Corporation ( Corixa ) which license agreement the Company acquired as part of the purchase of certain assets of Corixa in May 2002. Under the terms of the Corixa Asset Purchase Agreement, upon the execution of the Kyowa License, the Company was required to make a final payment to Corixa of \$2.5 million, which was paid through the issuance of 353,807 shares of the Company s common stock. The Company has no further obligation to Corixa in connection with the Asset Purchase Agreement.

The total amount of the payments to Kyowa Hakko and Corixa in 2003 of \$6.5 million was charged to operations as in-process research and development.

## 11. Transactions with Genmab

In August 2000, the Company entered into a binding memorandum of understanding, or the Genomics Agreement, with Genmab, pursuant to which the Company granted Genmab rights to market its transgenic mouse technologies for multi-target (five or more targets) genomics partnerships to certain pharmaceutical and biotechnology companies whose headquarters are located in Europe.

The Genomics Agreement had an initial term of five years with a right exercisable by Genmab to extend the term for an additional two years. The initial term of the agreement expired in August 2005 and was not extended. For each year of the agreement, the Company received \$2.0 million per year from Genmab. At Genmab s option, these amounts were paid in either cash or capital stock. During the years ended December 31, 2005, 2004 and 2003, the Company recognized \$1.3 million, \$2.0 million and \$2.0 million, respectively, of revenue from this agreement.

As of January 1, 2003, the Company owned approximately 31.3% of the outstanding stock of Genmab. In July 2003, the Company received 246,914 shares of Genmab stock valued at \$2.0 million representing payment for the fourth of five annual payments under the August 2000 Genomics Agreement between the Company and Genmab (described above). The Company s ownership percentage in Genmab increased to approximately 32.0% as a result of the receipt of the 246,914 shares of Genmab stock.

In July 2004 Genmab completed a private placement of 5.6 million shares of its stock. As a result of this private placement, the Company s ownership percentage of Genmab was reduced to approximately 24.7%. The difference between the Company s proportionate share of the equity and its carrying value at the time the private placement was completed was approximately \$9.7 million and was accounted for in accordance with APB Opinion No.18, *The Equity Method of Accounting for Investment in Common Stock*, and Staff Accounting Bulletin No. 51, *Accounting for Sales of Stock by a Subsidiary*. This transaction is

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reflected as an increase to capital in excess of par value in the Company's consolidated financial statements as of and for the year ended December 31, 2004.

During the first quarter of 2005, the remaining basis of the Company's investment in Genmab was reduced to zero and accordingly, recognition of the Company's share of Genmab's net losses for the remainder of the first quarter of 2005, the second quarter of 2005 and a portion of the third quarter of 2005 was suspended.

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, the Company's ownership percentage in Genmab was reduced to approximately 22.2%. The difference between the Company's proportionate share of the equity and its carrying value after completion of Genmab's sale of stock to the corporate partner was approximately \$8.0 million and was also accounted for in accordance with APB Opinion No.18, *The Equity Method of Accounting for Investment in Common Stock*, and Staff Accounting Bulletin No. 51, *Accounting for Sales of Stock by a Subsidiary*. This transaction is reflected as an increase to capital in excess of par value in the Company's consolidated financial statements as of and for the year ended December 31, 2005.

As a result of the increase in carrying value of the Company's investment in Genmab of approximately \$8.0 million in August 2005 and in accordance with EITF 02-18, *Accounting for Subsequent Investments in an Investee after Suspension of Equity Method Loss Recognition*, the Company was required to resume the recognition of its share of Genmab's net losses in the third quarter of 2005. In accordance with the equity method of accounting, the Company will continue to record its proportionate share of Genmab's net losses in the future until such time when the Company's carrying value of its investment in Genmab has been reduced to zero or when the Company's ownership percentage in Genmab has been reduced to less than 20% (see Note 19).

The Chairman of the Company's board of directors is also on the board of directors of Genmab. In addition, the President and Chief Executive Officer of the Company, who is also a member of the board of directors of the Company, and the President and Chief Executive Officer of Genmab are husband and wife. The President and Chief Executive Officer of Genmab and the Chief Scientific Officer of Genmab have consulting agreements with the Company. No services were rendered under these consulting agreements for the years ended December 31, 2005, 2004 and 2003.

As of December 31, 2005, the market value of the Company's investment in Genmab was approximately \$157.2 million.

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Summary financial information for Genmab is as follows as of and for the years ended December 31, 2005, 2004 and 2003:

|                         | 2005       | 2004       | 2003       |
|-------------------------|------------|------------|------------|
| Current Assets          | \$ 209,226 | \$ 217,582 | \$ 178,596 |
| Non Current Assets      | 7,473      | 15,044     | 19,487     |
| Current Liabilities     | 37,504     | 12,796     | 12,606     |
| Non Current Liabilities | 2,290      | 3,833      | 3,117      |
| Revenue                 | 15,946     | 750        | 10,500     |
| Gross Profit            | 15,946     | 750        | 10,500     |
| Net Loss                | (62,479 )  | (70,787 )  | (47,613 )  |

## 12. Transactions with Immuno-Designed Molecules S.A. ( IDM )

In December 2004, IDM completed a private placement of its equity securities at a per share price which was less than the Company's cost basis in IDM. As a result, the Company recorded a non-cash investment impairment charge of approximately \$7.0 million during the fourth quarter of 2004.

The Company's equity ownership in IDM was approximately 8% as of December 31, 2004. As of December 31, 2004, the Company held 503,400 Class A shares, 713,576 Class B shares and 192,278 units, each unit comprising one Class B share and 19 warrants allowing each to purchase one convertible or redeemable bond into one Class B share. If the warrants were exercised and converted or redeemed, the Company would own an additional 3,653,282 Class B shares of IDM. The warrants were exercisable between September 2002 and September 2010, for bonds that in turn are convertible into or redeemable in Class B shares six months after the exercise.

On August 16, 2005 Epimmune, Inc. and IDM announced the completion of their previously announced business combination. In connection with the business combination all of the Company's Class A shares, Class B shares and units of IDM were converted into approximately 2.6 million shares of common stock of the combined entity, IDM Pharma, Inc. ( IDM Pharma ), a publicly traded company. As of December 31, 2005, the Company's investment in IDM Pharma is included within marketable securities in the Company's consolidated balance sheet.

The Company's President and Chief Executive Officer is on the board of directors of IDM Pharma.

## 13. Commitments and contingencies

The Company is obligated under non-cancelable operating leases for laboratory, production and office space in New Jersey and California. These leases expire on various dates between September 2008 and February 2013. The Company is also obligated under certain research and license agreements. A summary of the Company's commitments as of December 31, 2005 is as follows:

|                  | 2006      | 2007     | 2008     | 2009     | 2010     | 2011     |
|------------------|-----------|----------|----------|----------|----------|----------|
| Operating leases | \$ 6,803  | \$ 4,281 | \$ 3,913 | \$ 2,373 | \$ 1,602 | \$ 1,529 |
| Research funding | 7,549     | 3,025    | 2,275    | 25       | 25       |          |
| Total            | \$ 14,352 | \$ 7,306 | \$ 6,188 | \$ 2,398 | \$ 1,627 | \$ 1,529 |

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The Company incurred rent expense of \$4.0 million in 2005, \$3.9 million in 2004 and \$3.5 million in 2003.

The Company has secured a bank letter of credit pursuant to the requirements of its Annandale, New Jersey lease. This letter of credit in the amount of \$1.3 million is fully cash collateralized and the cash is categorized as segregated securities in the consolidated balance sheets.

The Company has entered into a number of other agreements that contain in-licenses of third-party technology (in addition to Kirin see Note 10) which may be used together with the Company's own platform technologies for the generation, development and/or manufacture of its antibody products. In addition, the Company has entered into other third-party agreements that contain in-licenses associated with antibody products that target specific antigens. Many of these agreements contain milestones payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of the Company's products currently under development trigger such milestone payments. Through December 31, 2005, the Company had made milestone payments under these agreements of approximately \$0.3 million. In addition, under the agreements the Company currently has in place (other than with Kirin), based on a total of nine products the Company is developing for which milestones are potentially due and that (i) are now in clinical trials, or (ii) which the Company anticipates may enter clinical trials before the end of 2007, the Company may be obligated to make future milestone payments aggregating up to approximately \$59.9 million with respect to such products. In general, potential milestone payments for 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 milestone payments per product include:

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

In addition, the licenses above may trigger royalty payments in connection with the commercialization of certain of the Company's products. Whether the Company will be obligated to make milestone or royalty payments in the future is subject to the success of its product development efforts and, accordingly, is inherently uncertain.

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

#### **14. Segment Information**

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

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**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2005, 2004 and 2003**  
**(Dollars in thousands, unless otherwise indicated, except share data)**

Revenue from partners representing 10% or more of total revenues for the years ended December 31, 2005, 2004 and 2003 is as follows:

| <b>Partners</b> | <b>2005</b> | <b>2004</b> | <b>2003</b> |
|-----------------|-------------|-------------|-------------|
| BMS             | 34 %        | 4 %         |             |
| Genmab          | 8 %         | 26 %        | 48 %        |
| Pfizer          | 18 %        | 20 %        |             |
| Amgen           | 1 %         | 8 %         | 15 %        |

**15. Celldex Therapeutics, Inc.**

In March 2004, the Company assigned or licensed to Celldex certain intellectual property related to the Company's vaccine technology, including the rights to MDX-1307, one of the Company's product candidates for the treatment of cancer, as well as the Investigational New Drug Application (IND), associated with this product candidate which became effective in February 2004.

In order to complement its technology and its internal clinical pipeline, in October 2005, Celldex completed the acquisition of all of the issued and outstanding shares of capital stock of Lorantis Limited (Lorantis), a privately held biotechnology company based in Cambridge, U.K. and substantially all of the assets of Alteris Therapeutics, Inc. (Alteris), a privately held biotechnology company based in Philadelphia, PA. As a result of the Lorantis acquisition and the Alteris asset acquisition, the Company's ownership percentage of Celldex was reduced from 100% to approximately 60%.

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 addition, Celldex may be required to pay an amount equal to 20% of any upfront fees or milestone payments received from a certain unrelated third-party licensee, in the event that within 12 months of the closing, Celldex enters into a license agreement with such third party for any EGFRvIII-derived product developed using the technology acquired from Alteris.

The total cost of the Lorantis acquisition was \$34.6 million, of which \$0.5 million represented transaction costs. The total cost of the Alteris asset acquisition was \$8.2 million, of which \$0.6 million represented transaction costs. These amounts have been allocated as follows based upon independent third party valuations using the income approach:

|  | <b>Lorantis</b> | <b>Alteris</b> | <b>Total</b> |
|--|-----------------|----------------|--------------|
| Net current assets (primarily cash and cash equivalents) | \$ 30,297       | \$             | \$ 30,297    |
| Fixed assets   | 2,717           | 6              | 2,723        |
| Acquired technology                                      |                 | 1,296          | 1,296        |
| In-process research and development                      | 1,541           | 6,906          | 8,447        |
|  | \$ 34,555       | \$ 8,208       | \$ 42,763    |

**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2005, 2004 and 2003**  
**(Dollars in thousands, unless otherwise indicated, except share data)**

The total in-process research and development of \$8.4 million was determined not to be technologically feasible and had no alternative future uses. The developed technology is being amortized over its estimated useful life of 11 years.

The value of the acquired in-process research and development was determined by estimating the related probability-adjusted net cash flows, which were then discounted to a present value using a rate of 27.5%. The discount rate was based upon Celldex's weighted average cost of capital taking into account the risk associated with the technologies acquired. The projected cash flows for such projects were based on estimated revenues and operating profits related to such projects considering the development of each of the technologies acquired, the time and resources needed to develop the technologies, the estimated life of each potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound and obtaining FDA and other regulatory approvals.

The results of operations for the Lorantis acquisition and the Alteris asset acquisition are included in the consolidated statement of operations from October 12, 2005.

The unaudited pro-forma results of operations for the years ended December 31, 2005 and 2004, assuming the acquisition of Lorantis and the Alteris asset acquisition took place on January 1, 2004, are as follows:

|                                      | <b>Year Ended December 31</b> |             |
|--------------------------------------|-------------------------------|-------------|
|                                      | <b>2005</b>                   | <b>2004</b> |
| Total revenue                        | \$ 51,593                     | \$ 12,525   |
| Net loss                             | (145,621 )                    | (192,247 )  |
| Basic and diluted net loss per share | \$ (1.32 )                    | \$ (2.36 )  |

The pro-forma information does not include the write-off of in-process technology of \$8.4 million which is not expected to recur in the future. The pro-forma unaudited financial results are not necessarily indicative of the results of operations that would have occurred had the Lorantis acquisition and the Alteris asset acquisition taken place at the beginning of the periods presented nor are they intended to be indicative of results that may occur in the future.

## 16. Acquisition of Ability Biomedical Corporation

On August 5, 2004, the Company completed the acquisition of all of the outstanding capital stock not already owned by the Company of Ability Biomedical Corporation, a privately held Canadian biotechnology company. Pursuant to such acquisition, the Company acquired Ability Biomedical's intellectual property related to IP-10, a protein believed to be associated with a variety of immune disorders, including multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, chronic obstructive pulmonary disease and type I diabetes.

The purchase price consisted of 731,823 shares of Medarex common stock (valued at approximately \$4.3 million), cash payments of approximately \$0.6 million and transaction costs of approximately \$0.2 million. In addition, the Company had owned shares of Ability Biomedical prior to the acquisition, which were valued at approximately \$0.6 million, therefore the total cost of the acquisition was \$5.7 million. During the 60-day period following the issuance of shares of the Company's common stock to the Ability Biomedical shareholders in connection with the acquisition, certain shareholders sold all of the shares



**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2005, 2004 and 2003**  
**(Dollars in thousands, unless otherwise indicated, except share data)**

issued to them for an amount less than the amount due to them under the share purchase agreement while certain other shareholders sold shares issued to them for an amount greater than the amount due them under the share purchase agreement. In accordance with the share purchase agreement, the Company received approximately \$0.1 million representing 50% of the difference between the actual proceeds received and the amount due under the share purchase agreement. Such amount is included within additional (payments) receipts related to asset acquisitions in the Company's consolidated statement of operations for the year ended December 31, 2004.

Upon achievement of certain development milestones with respect to the Company's anti-IP-10 antibody program, but no later than September 4, 2007, the Company may be required to pay the former shareholders of Ability Biomedical an additional amount of approximately \$3.65 million in cash and/or common stock subject to fluctuations in currency exchange rates. In lieu of such additional payment, the Company also has the option to revert to the original joint collaboration agreement with the former shareholders of Ability Biomedical whereby each party would be responsible for 50% of the costs associated with the anti-IP-10 antibody.

The total cost of the acquisition was \$5.7 million. This amount has been allocated as follows:

|  |               |
|--|---------------|
| In-process technology                            | \$ 5.4        |
| Net assets (primarily cash and cash equivalents) | 0.3           |
|  | <b>\$ 5.7</b> |

The assets and liabilities assumed have been recorded at their estimated fair market values at the date of acquisition. Since technological feasibility of the in-process research and development costs have not yet been established and the technology had no alternative future use at the acquisition date, the in-process research and development costs of \$5.4 million were immediately written-off and included in the results of operations for the year ended December 31, 2004.

## **17. Employee Benefit Plans**

### ***Employee Stock Purchase Plan***

In May 2002, the Company adopted an Employee Stock Purchase Plan (the "ESPP") which currently authorizes the issuance of 1,500,000 shares of its common stock pursuant to purchase rights granted to eligible employees of the Company. The ESPP provides a means by which employees purchase common stock of the Company through payroll deductions of up to 10% of their base compensation. At the end of each of two purchase periods during the calendar year, the Company uses accumulated payroll deductions to purchase, on behalf of participating employees, shares of common stock at a price equal to the lower of 85% of the fair market value of a share of common stock (i) on July 1, 2004 or (ii) at the end of each six month purchase period. The purchase periods under the ESPP end on June 30 and December 31 of each year. Generally all employees, including executive officers, who work at least 20 hours per week and five months per year may participate in the ESPP. Employees who are deemed to own greater than 5% of the combined voting power of all classes of stock of the Company are not eligible for participation in the ESPP. During the years ended December 31, 2005, 2004 and 2003, 234,254, 176,625 and 175,955 shares of common stock were issued under the ESPP resulting in net proceeds to the Company of \$1.4 million, \$1.1

**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2005, 2004 and 2003**  
**(Dollars in thousands, unless otherwise indicated, except share data)**

million and \$1.0 million, respectively. As of December 31, 2005, the Company had reserved 766,184 shares of common stock for issuance pursuant to the ESPP.

***Employee Savings Plan***

The Company maintains a 401(k) savings plan. Employees may contribute up to 15% of their annual salaries. The Company may make matching contributions of up to 4% of a participant's annual salary. During 2005, 2004 and 2003, the Company made contributions to the plan totaling \$0.7 million, \$0.6 million and \$0.6 million, respectively.

**18. Quarterly Financial Information - Unaudited**

The following is a summary of the quarterly results of operations for the years ended December 31, 2005 and 2004:

| <b>2005</b>                            | <b>March 31,</b> | <b>June 30,</b> | <b>September 30,</b> | <b>December 31,</b> | <b>Total</b> |
|--|------------------|-----------------|----------------------|---------------------|--------------|
| Contract and license revenues          | \$ 6,532         | \$ 11,716       | \$ 7,621             | \$ 8,424            | \$ 34,293    |
| Reimbursement of development costs     | 1,979            | 6,821           | 3,045                | 5,317               | 17,162       |
| Total revenue                          | 8,511            | 18,537          | 10,666               | 13,741              | 51,455       |
| Loss before provision for income taxes | (46,838 )        | (30,662 )       | (23,005 )            | (45,141 )           | (145,646 )   |
| Net loss                               | (46,896 )        | (30,800 )       | (23,095 )            | (45,213 )           | (146,004 )   |
| Basic and diluted net loss per share   | \$ (0.44 )       | \$ (0.28 )      | \$ (0.21 )           | \$ (0.41 )          | \$ (1.32 )   |

  

| <b>2004</b>                            | <b>March 31,</b> | <b>June 30,</b> | <b>September 30,</b> | <b>December 31,</b> | <b>Total</b> |
|--|------------------|-----------------|----------------------|---------------------|--------------|
| Contract and license revenues          | \$ 1,929         | \$ 1,910        | \$ 3,682             | \$ 4,953            | \$ 12,474    |
| Total revenue                          | 1,929            | 1,910           | 3,682                | 4,953               | 12,474       |
| Loss before provision for income taxes | (30,954 )        | (43,550 )       | (54,825 )            | (57,149 )           | (186,478 )   |
| Net loss                               | (30,960 )        | (43,553 )       | (55,007 )            | (56,989 )           | (186,509 )   |
| Basic and diluted net loss per share   | \$ (0.39 )       | \$ (0.55 )      | \$ (0.68 )           | \$ (0.66 )          | \$ (2.29 )   |

(1) Includes acquisition of in-process technology of \$8,447.

**19. Subsequent Events**

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

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Genmab A/S:

In our opinion, the accompanying consolidated balance sheet and the related consolidated statements of operations, shareholders' equity and cash flows (not presented herein) present fairly, in all material respects, the financial position of Genmab A/S and its subsidiaries (a development stage company) at December 31, 2004, and the results of their operations and their cash flows for the years ended December 31, 2004 and 2003 and, cumulatively, for the period from June 11, 1998 (date of inception) to December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers

Statsautoriseret Revisionsinteressentskab  
Copenhagen, Denmark, February 8, 2005

/s/ JENS RØDER

State Authorized Public Accountant

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**Item 9.** Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

**Item 9A.** Controls and Procedures

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

*Management's Annual Report on Internal Control Over Financial Reporting:* Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Medarex; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on its assessment and those criteria, our management has concluded that we maintained effective internal control over financial reporting as of December 31, 2005.

Our independent auditors have issued an attestation report on our management's assessment of Medarex's internal control over financial reporting. That report appears on page 75 of this annual report.

*Changes in Internal Controls Over Financial Reporting:* Such evaluation did not identify any significant changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders  
Medarex, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting in Item 9A that Medarex, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Medarex, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Medarex, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Medarex, Inc. maintained, in all respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Medarex, Inc. and subsidiaries as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2005 and our report dated March 3, 2006 expresses an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey  
March 3, 2006

**Item 9B. Other Information**

None

**PART III**

**Item 10. Directors and Executive Officers of the Registrant**

**Identification of Directors and Executive Officers**

The information required by this Item will be reported in our definitive Proxy Statement for the Annual Meeting of Shareholders which we expect will be filed on or before April 28, 2006, or the Proxy Statement, under the heading Proposal 1 Election of Directors, and is incorporated herein by reference.

**Compliance with Section 16(a) of the Exchange Act**

The information required by this Item will be reported in the Proxy Statement under the heading Ownership of Company Stock Section 16(a) Beneficial Ownership Reporting Compliance, and is incorporated herein by reference.

**Code of Ethics**

The information required by this Item will be reported in the section entitled Proposal 1 Election of Directors Corporate Governance Standards of Integrity in the Proxy Statement and is incorporated herein by reference.

**Item 11. Executive Compensation**

The information required by this Item will be reported in the Proxy Statement under the headings Proposal 1 Election of Directors Executive Compensation, Proposal 1 Election of Directors Information Regarding the Board and its Committees Compensation of Directors, and Proposal 1 Election of Directors Stock Price Performance Graph, and is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters**

The information required by this Item will be reported in the Proxy Statement under the headings Ownership of Company Stock Medarex Stock Owned by Principal Shareholders and Management, Equity Compensation Plan Information and Equity Compensation Plans Not Approved by Shareholders, and is incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions**

The information required by this Item will be reported in the Proxy Statement under the heading Proposal 1 Election of Officers Certain Relationships and Related Transactions, and is incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services**

The information required by this Item will be reported in the Proxy Statement under the heading Proposal 2 Ratification of the Appointment of Independent Registered Public Accounting Firm, and is incorporated herein by reference.

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**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

**Item  
Number**

- (a).1.(a) Consolidated Financial Statements **Medarex, Inc.**  
Report of Independent Registered Public Accounting Firm.  
Consolidated Balance Sheets as of December 31, 2005 and 2004.  
Consolidated Statements of Operations for the Years Ended December 31, 2005, 2004 and 2003.  
Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2005, 2004 and 2003.  
Consolidated Statements of Cash Flows for the Years Ended December 31, 2005, 2004 and 2003.  
Notes to Consolidated Financial Statements.
- (a).1.(b) Consolidated Financial Statements **Genmab A/S (A development stage company)**  
Report of Independent Registered Public Accounting Firm.
- (a).2. Financial Statement Schedules.  
All financial statement schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are either not required under the related instructions or are inapplicable because the required information is included in the consolidated financial statements or related notes thereto.
- (a).3. Exhibits.
- 2.1(1) Certificate of Merger, dated June 15, 1989, including Plan of Merger.
- 2.3(28) Amended and Restated Agreement and Plan of Reorganization among the Registrant, Medarex Acquisition Corp. and GenPharm International, Inc., dated as of May 5, 1997, together with Exhibits thereto.
- 3.1(56) Restated Certificate of Incorporation of the Registrant.
- 3.2(64) Amended and Restated By-laws of the Registrant.
- 4.1(1) Form of Specimen of Common Stock Certificate.
- 4.2(74) Form of Rights Agreement (including Form of Rights Certificate).
- 4.3(75) Indenture dated as of May 3, 2004 between Registrant and Wilmington Trust Company, as trustee.
- 4.4(76) Registration Rights Agreement dated as of May 3, 2004 by and among Registrant, Goldman, Sachs & Co. and J.P. Morgan Securities, Inc.
- 10.3(1) 1991 Employee Stock Option Plan.
- 10.29(2) Employment Agreement between the Registrant and Dr. Donald L. Drakeman, dated January 5, 2004.
- 10.30(77) Employment Agreement between the Registrant and Dr. Nils Lonberg, dated January 5, 2004.
- 10.31(77) Employment Agreement between the Registrant and W. Bradford Middlekauff, dated January 5, 2004.

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- 10.32(77) Employment Agreement between the Registrant and Dr. Geoffrey M. Nichol, dated January 5, 2004.
- 10.33(77) Employment Agreement between the Registrant and Dr. Ronald A. Pepin, dated January 5, 2004.
- 10.34(77) Employment Agreement between the Registrant and Christian S. Schade, dated January 5, 2004.
- 10.40(77) Form of Employee Incentive Stock Option Agreement.
- 10.41(77) Form of Employee Nonqualified Stock Option Agreement.
- 10.42(77) Form of Non-Employee Director Nonqualified Stock Option Agreement.
- 10.51(8) 1992 Employee Stock Option Plan.
- 10.52(10) Lease of Registrant's Laboratory Facility (Annandale, New Jersey).
- 10.53(11) Amendment to Lease of Registrant's Laboratory Facility (Annandale, New Jersey).
- 10.61(9) 1995 Stock Option Plan.
- 10.73(23)\*\* Release and Settlement Agreement, dated March 26, 1997, among Cell Genesys, Inc., Abgenix, Inc., Xenotech, L.P., Japan Tobacco, Inc. and GenPharm International, Inc.
- 10.74(24)\*\* Cross License Agreement, effective as of March 26, 1997, among Cell Genesys, Inc., Abgenix, Inc., Xenotech, L.P., Japan Tobacco, Inc. and GenPharm International, Inc.
- 10.75(25)\*\* Interference Settlement Procedure Agreement, effective as of March 26, 1997, among Cell Genesys, Inc., Abgenix, Inc., Xenotech, L.P., Japan Tobacco, Inc. and GenPharm International, Inc.
- 10.84(36)\*\* Shareholders Agreement dated February 25, 1999, among Medarex, Inc., GenPharm International, Inc., BankInvest, BI Asset Management, Fondsmaglerselskab A/S and certain other investors.
- 10.85(37)\*\* Evaluation and Commercialization Agreement dated as of February 25, 1999, among Medarex, Inc., GenPharm International, Inc. and Genmab.
- 10.86(30) Medarex, Inc. Executive Deferred Savings Plan.
- 10.87(39) Agreement of Lease dated July 7, 1999, between McCarthy Associates Limited and the Registrant.
- 10.88(40) Medarex, Inc. 1997 Stock Option Plan.
- 10.89(41) Medarex, Inc. 1999 Stock Option Plan.
- 10.104(57) Medarex, Inc. 2000 Stock Option Plan.
- 10.105(58) Medarex, Inc. 2000 Non-Director/Officer Employee Stock Option Plan.
- 10.106(59) Medarex, Inc. 2001 Non-Director/Officer Employee Stock Option Plan.
- 10.107(60) Medarex, Inc. 2001 Stock Option Plan.
- 10.108(61) Medarex, Inc. 2002 Employee Stock Purchase Plan.
- 10.109(62) Medarex, Inc. 2002 New Employee Stock Option Plan.
- 10.110a(65) Medarex, Inc. 2004 New Employee Stock Option Plan.
- 10.110b(63)\*\* Collaboration and License Agreement, dated September 4, 2002, between the Registrant, GenPharm International, Inc. and Kirin Brewery Co., Ltd.



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|--------------|--|
| 10.111(79)   | Medarex, Inc. 2004 Restricted Stock Unit Award and Deferred Compensation Program, as amended.  |
| 10.112(80)   | Medarex, Inc. Second 2004 Restricted Stock Unit Award and Deferred Compensation Program, as amended.                                     |
| 10.113(66)** | License Agreement dated September 15, 2004, between the Registrant and Pfizer, Inc.  |
| 10.114(67)** | Cross-License Agreement dated September 15, 2004 between the Registrant and Pfizer, Inc.   |
| 10.115(68)** | License and Royalty Agreement dated April 4, 2003, between the Registrant and Pfizer, Inc.   |
| 10.116(69)** | Collaborative Research Agreement dated April 4, 2003 between the Registrant and Pfizer, Inc.   |
| 10.117(70)** | Amendment No. 1 dated September 15, 2004 between the Registrant and Pfizer, Inc.   |
| 10.118(71)   | Securities Purchase Agreement dated September 15, 2004 between the Registrant and Pfizer, Inc.   |
| 10.119(72)** | Collaboration and Co-Promotion Agreement dated November 7, 2004, between the Registrant and Bristol-Myers Squibb Company.                |
| 10.120(73)   | Securities Purchase Agreement dated November 7, 2004 between the Registrant Bristol-Myers Squibb Company.                                |
| 10.121(78)   | Medarex, Inc. 2005 Equity Incentive Plan, as amended.  |
| 21           | Subsidiaries of the Registrant.  |
| 23.1         | Consent of Ernst & Young LLP.  |
| 23.2         | Consent of PriceWaterhouseCoopers.   |
| 24           | Power of Attorney (contained on the signature page hereto).  |
| 31.1         | Rule 13a-14(a) Certification of Chief Executive Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2         | Rule 13a-14(a) Certification of Chief Financial Officer of the Company in accordance with Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1*        | Section 1350 Certification of Chief Executive Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002.   |
| 32.2*        | Section 1350 Certification of Chief Financial Officer of the Company in accordance with Section 906 of the Sarbanes-Oxley Act of 2002.   |

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(1) Incorporated by reference to the identically numbered exhibit to the Registrant's Registration Statement on Form S-1 (File No. 33-39956) filed on April 12, 1991.

(2) Incorporated by reference to Exhibit No. 10.1 to the Registrant's Statement on Form S-3, as Amended (File No. 333-108325) filed on January 30, 2004.

(8) Incorporated by reference to the identically numbered exhibit to the Registrant's Annual Report on Form 10-K filed on March 15, 1993.

(9) Incorporated by reference to the identically numbered exhibit to the Registrant's Annual Report on Form 10-K filed on February 23, 1996.

- (10) Incorporated by reference to the identically numbered exhibit to the Registrant's Quarterly Report on Form 10-Q filed on May 17, 1993.
- (11) Incorporated by reference to the identically numbered exhibit to the Registrant's Quarterly Report on Form 10-Q filed on August 13, 1993.
- (23) Incorporated by reference to Exhibit Number 10.44 to Cell Genesys, Inc.'s Annual Report on Form 10-K/A filed on April 30, 1997.
- (24) Incorporated by reference to Exhibit Number 10.45 to Cell Genesys, Inc.'s Annual Report on Form 10-K/A filed on April 30, 1997.
- (25) Incorporated by reference to Exhibit Number 10.46 to Cell Genesys, Inc.'s Annual Report on Form 10-K/A filed on April 30, 1997.
- (28) Incorporated by reference to Exhibit Number 2.1 to the Registrant's Current Report on Form 8-K filed on June 17, 1997.
- (30) Incorporated by reference to Exhibit Number 10.82 to the Registrant's Quarterly Report on Form 10-Q filed on August 13, 1999.
- (36) Incorporated by reference to Exhibit Number 10.80 to the Registrant's Current Report on Form 8-K filed on August 11, 1999.
- (37) Incorporated by reference to Exhibit Number 10.81 to the Registrant's Current Report on Form 8-K filed on August 11, 1999.
- (39) Incorporated by reference to Exhibit Number 10.83 to the Registrant's Quarterly Report on Form 10-Q filed on August 13, 1999.
- (40) Incorporated by reference to Exhibit Number 10.84 to the Registrant's Quarterly Report on Form 10-Q filed on August 13, 1999.
- (41) Incorporated by reference to Exhibit Number 10.85 to the Registrant's Quarterly Report on Form 10-Q filed on August 13, 1999.
- (52) Incorporated by reference to Exhibit Number 10.10 to the Registrant's Current Report on Form 8-K filed on January 26, 2000.
- (56) Incorporated by reference to Exhibit Number 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 12, 2003.
- (57) Incorporated by reference to Exhibit Number 10.1 to the Registrant's Registration Statement on Form S-8 (File Number 333-39084) filed on June 12, 2000.
- (58) Incorporated by reference to Exhibit No. 10.1 to Registrant's Registration Statement on Form S-8 (File Number 333-55222) filed on February 8, 2001.

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(59) Incorporated by reference to Exhibit No. 10.1 to Registrant's Registration Statement on Form S-8 (File Number 333-55224) filed on February 8, 2001.

(60) Incorporated by reference to Exhibit No. 10.1 to Registrant's Registration Statement on Form S-8 (File Number 333-72154) filed on October 24, 2001.

(61) Incorporated by reference to Exhibit No. 10.1 to Registrant's Registration Statement on Form S-8 (File Number 333-91394) filed on June 28, 2002.

(62) Incorporated by reference to Exhibit No. 10.1 to Registrant's Registration Statement on Form S-8 (File Number 333-101698) filed on December 6, 2002.

(63) Incorporated by reference to Exhibit No. 10.1 to Registrant's Current Report on Form 8-K filed on September 18, 2002.

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- (64) Incorporated by reference to Exhibit No. 99.2 to Registrant's Current Report on Form 8-K filed on July 29, 2005.
- (65) Incorporated by reference to Exhibit 10.1 to Registrant's Registration Statement on Form S-8 (File Number 333-121387) filed on December 17, 2004.
- (66) Incorporated by reference to Exhibit 99.2 to Registrant's Current Report on Form 8-K filed on November 8, 2004.
- (67) Incorporated by reference to Exhibit 99.3 to Registrant's Current Report on Form 8-K filed on November 8, 2004.
- (68) Incorporated by reference to Exhibit 99.5 to Registrant's Current Report on Form 8-K filed on November 8, 2004.
- (69) Incorporated by reference to Exhibit 99.6 to Registrant's Current Report on Form 8-K filed on November 8, 2004.
- (70) Incorporated by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K filed on November 8, 2004.
- (71) Incorporated by reference to Exhibit 99.4 to Registrant's Current Report on Form 8-K filed on November 8, 2004.
- (72) Incorporated by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K filed on January 24, 2005.
- (73) Incorporated by reference to Exhibit 99.2 to Registrant's Current Report on Form 8-K filed on January 24, 2005.
- (74) Incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed on May 25, 2001.
- (75) Incorporated by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K filed on May 4, 2004.
- (76) Incorporated by reference to Exhibit 4.2 to Registrant's Current Report on Form 8-K filed on May 4, 2004.
- (77) Incorporated by reference to the identically numbered exhibit to Registrant's Annual Report on Form 10-K filed on March 16, 2005.
- (78) Incorporated by reference to Exhibit 99.1 to Registrant's Current Report on Form 8-K filed on January 20, 2006.
- (79) Incorporated by reference to Exhibit 99.2 to Registrant's Current Report on Form 8-K filed on January 20, 2006.
- (80) Incorporated by reference to Exhibit 99.3 to Registrant's Current Report on Form 8-K filed on January 20, 2006.

\* This certification accompanies this Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

\*\* Confidential treatment has been granted with respect to specified portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

Management contract or compensatory plan or arrangement required to be filed (and/or incorporated by reference) as an exhibit to this Annual Report on Form 10-K pursuant to Item 15(c) of Form 10-K.



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 15, 2006.

MEDAREX, Inc.  
 By: */s/ DONALD L. DRAKEMAN*  
 Donald L. Drakeman  
*President and Chief Executive Officer*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Donald L. Drakeman, Director, President and Chief Executive Officer, and Christian S. Schade, Senior Vice President and Chief Financial Officer, and each of them, his true and lawful attorneys-in-fact and agents, with the full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated and on the dates indicated.

**Principal Executive Officer and Director:**

|   |  |                     |
|---|--|---------------------|
| Director, President and<br>Chief Executive Officer<br><b>Principal Financial and<br/>                 Accounting Officer</b><br>Senior Vice President and<br>Chief Financial Officer<br><b>Directors:</b> | <i>/s/ DONALD L. DRAKEMAN</i><br><b>Donald L. Drakeman</b>                     | Date March 15, 2006 |
|   | <i>/s/ CHRISTIAN S. SCHADE</i><br><b>Christian S. Schade</b>                   | Date March 15, 2006 |
|   | <i>/s/ IRWIN LERNER</i><br><b>Irwin Lerner</b><br><b>Chairman of the Board</b> | Date March 15, 2006 |
|   | <i>/s/ MICHAEL A. APPELBAUM</i><br><b>Michael A. Appelbaum</b>                 | Date March 15, 2006 |
|   | <i>/s/ PATRICIA M. DANZON</i><br><b>Patricia M. Danzon</b>                     | Date March 15, 2006 |
|   | <i>/s/ RONALD J. SALDARINI</i><br><b>Ronald J. Saldarini</b>                   | Date March 15, 2006 |
|   | <i>/s/ CHARLES R. SCHALLER</i><br><b>Charles R. Schaller</b>                   | Date March 15, 2006 |
|   | <i>/s/ JULIUS A. VIDA</i><br><b>Julius A. Vida</b>                             | Date March 15, 2006 |