

MEDAREX INC  
Form 10-K  
March 16, 2005

# 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

For the fiscal year ended December 31, 2004

Commission File No. 0-19312

MEDAREX, INC.

(Exact name of registrant as specified in its charter)

**New Jersey**  
(State of Incorporation)  
**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	Name of Each Exchange on Which Registered
Common Stock (\$0.01 par value)	The Nasdaq Stock Market, Inc. under symbol MEDX

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

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 an accelerated filer (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 \$540.8 million as of June 30, 2004, 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 5,089,221 shares

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held by directors, officers and shareholders whose ownership exceeded 5% of the Registrant's outstanding Common Stock as of June 30, 2004. 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, 2005, the registrant had outstanding 110,529,979 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 19, 2005 (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. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in Risk Factors,

Management's Discussion and Analysis of Financial Condition and Results of Operations and Business as well as those discussed elsewhere in this Annual Report. Actual events or results may differ materially from those discussed 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, 22 antibody products generated from our UltiMAb Human Antibody Development System are in human clinical trials<sup>(1)</sup>. Eight of these products are in Phase II or Phase III clinical trials. The 22 antibodies are designed to treat a wide range of diseases, such as cancer, rheumatoid arthritis and other inflammatory, autoimmune and infectious diseases. The most advanced of these products is MDX-010 (Phase III, Phase II and Phase I clinical trials), which we are developing jointly with Bristol-Myers Squibb Company, or BMS, for the treatment of metastatic melanoma and other cancers. Four of these antibody products are fully owned by Medarex and its affiliates: MDX-060 for lymphomas (Phase II clinical trial), MDX-070 for prostate cancer (Phase II clinical trial), MDX-214 for cancer (Phase I/II clinical trial) and MDX-1307 for genitourinary and breast cancers (Phase I clinical trial). We are developing MDX-066 (Phase I clinical trial) jointly with The Massachusetts Biologic Laboratories of the University of Massachusetts Medical School, or MBL, for the treatment of *Clostridium difficile* associated diarrhea. Another antibody, MDX-018 (Phase I/II clinical trial), is being jointly developed with Genmab A/S for autoimmune disease, and three additional antibodies are being developed separately by Genmab: HuMax -CD4 (Phase II clinical trials) for T-cell lymphomas, HuMax-EGFr (Phase I/II clinical trial) for head and neck cancer and HuMax-CD20 (Phase I/II clinical trial) for lymphomas. Genmab and Amgen, Inc. are developing AMG 714 (Phase II clinical trial) for rheumatoid arthritis. Additionally, other licensing partners, including Novartis Pharma AG, Eli Lilly and Company, and Centocor, Inc. (a subsidiary of Johnson & Johnson), are developing a total of ten antibody products, for inflammatory and/or autoimmune diseases and cancer, that are currently in clinical trials. Human Genome Sciences, Inc. has also announced the initiation of a Phase I trial of one anticancer antibody product developed pursuant to a licensing agreement with our partner Kirin Brewery Co., Ltd. We and our partners also have a number of UltiMAb® product candidates in preclinical development.

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

In November 2004, we announced a worldwide collaboration with BMS to develop and commercialize MDX-010, an antibody product targeting the CTLA-4 receptor, that was developed by us using our UltiMAB Human Antibody Development System. The BMS collaboration also includes MDX-1379, an investigational gp100 melanoma peptide vaccine, which will be developed for potential use in combination with MDX-010 in melanoma. MDX-010 in combination with the MDX-1379 tumor vaccine is currently in Phase III clinical development for the treatment of metastatic melanoma under a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, and has been granted Fast Track status by the FDA for the treatment of high risk Stage II, Stage III and Stage IV melanoma. We received an initial cash payment from BMS of \$50.0 million, of which \$25.0 million was for the purchase of our common stock at a small premium to the market price at the time we entered into the collaboration. We and BMS have agreed to jointly continue the investigation and the development of MDX-010 in additional tumor types and have jointly committed to an initial multi-year budget of approximately \$192.0 million to fund such development. 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% of the development costs 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 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 an additional \$205.0 million pursuant to the collaboration if all regulatory milestones are met, and up to \$275.0 million in sales-related milestones. We will have an option to co-promote and share profits with BMS in the U.S. based on a 45:55 percentage split. BMS will receive an exclusive license to MDX-010 outside of the U.S. and pay us royalties on commercial sales.

In September 2004, we entered into a series of agreements with Pfizer, Inc. 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. Under this amendment, 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. 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. Under these licenses, we have the potential to receive milestones and royalty payments based upon commercial sales of any Pfizer anti-CTLA-4 antibody product. In contrast, we have no future payment obligations to Pfizer in connection with any anti-CTLA-4 product we may develop. 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 \$110.0 million, of which \$30.0 million was for the purchase of our common stock at a small premium to market price at the time we entered into the collaboration.

As of March 1, 2005, we have more than 50 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to enable other companies to use our proprietary technology in their development of new therapeutic products. These companies include industry leaders such as Abbott Laboratories, Amgen, Centocor, Eli Lilly, Human Genome Sciences, MedImmune, Inc., Novartis, Novo Nordisk A/S and Schering AG.

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.

**Products in Development**

The following table summarizes potential therapeutic indications and development stages for 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 and Phase II Product Candidates in Clinical Development***

<b>PRODUCT</b>	<b>INDICATION</b>	<b>CLINICAL STATUS</b>	<b>PARTNER</b>
MDX-010 + MDX-1379	Melanoma	Phase III	Co-developing with BMS*
MDX-010	Melanoma, Prostate, Breast, Renal Cell Cancer and Others	Phase II	Co-developing with BMS*
MDX-060	Lymphoma	Phase II	Wholly-owned
MDX-070	Prostate cancer	Phase II	Wholly-owned
CNTO 148	Inflammatory diseases	Phase II	Centocor ♦
CNTO 1275	Inflammatory diseases	Phase II	Centocor ♦
HuMax-CD4	T-cell lymphomas	Phase II	Genmab
AMG 714	Rheumatoid arthritis	Phase II	Genmab (under agreement with Amgen)
Amgen Antibody-1	Undisclosed disease	Phase II	Amgen ♦
Pfizer CP-675,206	Melanoma and Others	Phase II	Pfizer ♣

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

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PRODUCT	INDICATION	CLINICAL STATUS	PARTNER
MDX-214	Cancer	Phase I/II	Wholly-owned
MDX-018	Inflammatory disease	Phase I/II	Co-developing with Genmab
HuMax-EGFr	Head and neck cancer	Phase I/II	Genmab
HuMax-CD20	Lymphoma	Phase I/II	Genmab

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

◆ We expect to receive milestone payments, as these product candidates move through clinical trials, and royalties on product sales, should commercialization occur.

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

♣ We expect to receive milestone payments and royalty payments on product sales, should commercialization occur.

*Phase I and Selected Preclinical Product Candidates*

PRODUCT	INDICATION	CLINICAL STATUS	PARTNER
MDX-1307	Cancer	Phase I	Wholly-owned
MDX-066	<i>C. difficile</i>	Phase I	Co-developing with MBL
CNTO 95	Cancer	Phase I	Centocor ♦
Novartis Antibody-1	Autoimmune disease	Phase I	Novartis Pharma ♦
Novartis Antibody-2	Autoimmune disease	Phase I	Novartis Pharma ♦
Amgen Antibody-2	Undisclosed disease	Phase I	Amgen ♦
Amgen Antibody-3	Undisclosed disease	Phase I	Amgen ♦
FG-3019	Idiopathic pulmonary fibrosis; Diabetic nephropathy	Phase I	FibroGen ♦
HGS-TR2J	Cancer	Phase I	Kirin Brewery Co., Ltd.§
Lilly Antibody	Undisclosed disease	Phase I	Eli Lilly ♦
MDX-1100	Inflammation	Preclinical	Wholly-owned
MDX-1103	Lupus	Preclinical	MedImmune*
MDX-1333	Lupus	Preclinical	MedImmune*
MDX-1303	Anthrax infection	Preclinical	Co-developing with PharmAthene

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

**MDX-010 (Anti-CTLA-4 Antibody)\*** *Melanoma; Prostate Cancer; Breast Cancer; Renal Cell Cancer and Others.* MDX-010 is a fully human antibody that targets an immune receptor known as CTLA-4. This receptor, which is a protein 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 melanoma and prostate cancer and have expanded clinical studies into other indications such as breast cancer, renal cell cancer and HIV. We have also expanded the MDX-010 clinical program to include combination studies with chemotherapy, immunotherapy and vaccines. Effective January 2005, we are collaborating with BMS to develop and potentially commercialize MDX-010 for melanoma and additional disease indications. BMS is responsible for all development outside the U.S. and Europe. For a more detailed description of our collaboration with BMS, see the section herein entitled *Our Human Antibody Partnering Business BMS.*

We are in the process of a possible initial public offering of a portion of the common stock of our wholly-owned subsidiary Celldex Therapeutics, Inc., or Celldex. As part of this transaction, in April 2004, we assigned our rights to this product candidate, including the associated IND, to Celldex. In the event this offering is completed, we will not be entitled to license fees or milestone payments with respect to this product. We may be entitled to receive royalty payments on any commercial sales.

♦ We expect to receive milestone payments, as these product candidates move through clinical trials, and royalties on product sales, should commercialization occur.

§ We expect to receive royalties on product sales, should commercialization occur.

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





We or BMS are currently conducting the following human clinical trials for this product under our collaboration:

*Melanoma:* We are conducting a number of clinical studies investigating MDX-010 for the treatment of melanoma. Under a SPA agreement with the FDA, a Phase III trial of MDX-010 in combination with MDX-1379 (a melanoma peptide vaccine based on gp100) commenced enrollment in September 2004. Approximately 750 patients with previously treated Stage III and Stage IV metastatic melanoma are expected to be enrolled in 75-100 centers worldwide. The patients are randomized to receive one of three regimens on a 3:1:1 basis, with 450 patients receiving a MDX-010/MDX-1379 combination, 150 patients receiving MDX-1379 alone and 150 patients receiving MDX-010 alone. All patients receiving MDX-010 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 expected initial Biologics License Application, or BLA, submission. Secondary endpoints of disease progression and survival data will continue to be collected from patients being followed in the Phase III trial. Treatment assignment will be blinded, with oversight by an independent Data Monitoring Committee, or DMC.

We initiated the Phase III clinical trial based on data from a Phase II clinical trial in which 41 patients with metastatic melanoma were treated with one of two dose regimens of MDX-010 in combination with MDX-1379. As of January 5, 2005, of the 14 patients treated in the high-dose treatment cohort, two patients experienced complete responses ongoing for over 28 months, and one patient experienced a partial response ongoing for over 32 months. Of the 27 patients treated in the low-dose treatment cohort, three patients experienced partial responses, two of which have had ongoing responses of approximately two years. Median survival after diagnosis of metastatic melanoma is six to nine months.

In June 2004, the FDA granted orphan drug designation to MDX-010 for the treatment of high risk Stage II, Stage III and Stage IV melanoma, and in October 2004, granted Fast Track status to the development program for MDX-010 in combination with MDX-1379 for this indication. Orphan drug designation is granted to products that treat rare diseases or conditions that affect fewer than 200,000 people in the U.S. and provides eligibility for a special seven-year period of market exclusivity after marketing approval, potential tax credits for research, grant funding for research and development, possibly reduced filing fees for marketing applications, and assistance with the review of clinical trial protocols. Under the FDA Modernization Act of 1997, designation as a Fast Track product means that the FDA has determined that a new drug or biologic is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of such product.

*Multi-dose Studies:* As part of our joint MDX-010 clinical development program with BMS, multiple Phase II studies of MDX-010 in melanoma are underway. These studies are designed to evaluate tumor and immune responses in patients treated with MDX-010 at higher doses.

*Prostate Cancer:* An ongoing Phase II prostate cancer trial is designed to study MDX-010 as a single agent and in combination with Taxotere® (docetaxel) and is expected to enroll up to 40 chemotherapy naïve patients with hormone refractory prostate cancer, or HRPC.

*Breast Cancer:* An ongoing multi-center, open-label Phase II breast cancer trial is expected to enroll up to 33 patients with metastatic breast cancer. The study is intended to evaluate tumor and immune responses.

*Renal Cell Cancer:* A Phase II renal cell cancer clinical trial is underway. The trial is designed to study MDX-010 as a single agent and is expected to enroll up to 103 patients with renal cell cancer.

*Other Cancers:* MDX-010 is under investigation for a variety of cancer indications and exploratory clinical studies are also underway for MDX-010 in colorectal cancer, non-Hodgkin's lymphoma and ovarian cancer.

*HIV Viremia:* A multi-center, open-label Phase I clinical trial is underway to enroll up to 18 patients with HIV who have an extensive treatment history but whose virus is no longer suppressed by highly active antiretroviral therapy, or HAART. In the trial, MDX-010 has been found to have a favorable safety profile and to be well-tolerated in patients infected with HIV. This trial was expanded in 2004 to evaluate safety, tolerability and clinical efficacy.

*Additional Combination Studies:* As part of our joint MDX-010 clinical development program with BMS, separate clinical trials of MDX-010 in combination with various agents are currently underway. In addition to the Phase III trial of MDX-010 in combination with the MDX-1379 melanoma vaccine, there are Phase II clinical trials of MDX-010 in combination with IL-2 and in combination with DTIC dacarbazine chemotherapy for melanoma. There is also a Phase I clinical trial of MDX-010 in previously vaccinated metastatic melanoma and ovarian cancer patients and a separate Phase I clinical trial of MDX-010 in combination with Cell Genesys' GVAX® prostate cancer vaccine.

*Adverse Events:* Generally, our clinical trials, including our MDX-010 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. The most common events experienced in trials of MDX-010, which were anticipated and consistent with an immune-based mechanism of action due to MDX-010 mediated CTLA-4 blockade, now termed Autoimmune Breakthrough Events (ABEs), were diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes. Other than a very small number of fatalities, which may or may not be attributable to our product candidates, almost all ABEs resolved with treatment.

**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-positive cancers. Through its ability to target CD30 expressing tumor cells, we believe that MDX-060 may facilitate the elimination of such cells by the human immune system.

In December 2004, we announced findings from an ongoing Phase I and II clinical trial of MDX-060 in 56 patients with relapsed or refractory HD, ALCL or other CD30-positive lymphomas which indicated that MDX-060 demonstrated clinical activity, including two complete responses and four partial responses. In addition, stable disease was observed in 18 patients. All patients had failed multiple prior treatments and most had failed bone marrow transplantation. One episode of a possible serious drug-related adverse event (elevated liver transaminase levels, grade III) was reported in a patient with a history of Graft versus Host Disease, which resolved with steroid treatment. No maximum tolerated dose has been identified. The Phase II trial has been expanded to further explore the activity profile of MDX-060. In October 2004, the FDA granted orphan drug designation to MDX-060 for the treatment of Hodgkin's disease.

**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. In June 2004, we initiated a multi-dose, dose-escalation Phase II clinical study of MDX-070 in patients with hormone refractory prostate cancer, following Phase I clinical trial findings that MDX-070 was well-tolerated.

**CTNO 148 (Anti-TNF  $\alpha$  Antibody) ♦ *Inflammatory Diseases.*** In September 2002, Centocor reported that it was developing CTNO 148, a high affinity, fully human antibody for inflammatory diseases, including Crohn's disease, rheumatoid arthritis and uveitis. According to publicly available information, CTNO-148, also known as golimumab, is in full development (Phase II).

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♦ We expect to receive milestone payments, as these product candidates move through clinical trials, and royalties on product sales, should commercialization occur.



**CNTO 1275 (Anti-IL-12 Antibody) ♦ *Inflammatory Diseases.*** In September 2002, Centocor reported that it was developing CNTO 1275, a high affinity, fully human antibody for the treatment of inflammatory diseases such as moderate to severe psoriasis and multiple sclerosis. According to publicly

**HuMax-CD4 (Anti-CD4 Antibody) *T-cell Lymphomas.*** Genmab is developing HuMax-CD4 (also known as zanolimumab), 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. Genmab has reported that preclinical and clinical studies suggest that an antibody that targets CD4 may be useful for the treatment of cutaneous T-cell lymphomas, or CTCL. In February 2005, Genmab announced updated Phase II duration of response data in CTCL.

In March 2004, Genmab announced that HuMax-CD4 had received Fast Track status by the FDA for patients with CTCL. In April, 2004, HuMax-CD4 was designated an orphan drug for the treatment of CTCL by the European Agency for the Evaluation of Medicinal Products and, in August 2004, by the FDA. Also, in August 2004, Genmab announced the initiation of a Phase II study of HuMax-CD4 in refractory or relapsed non-cutaneous T-cell lymphoma.

**AMG 714 (Anti-IL-15 Antibody) *Rheumatoid Arthritis.*** AMG 714, formerly known as HuMax-IL15, is a fully human antibody being developed under an agreement between Genmab and Amgen against Interleukin-15 (IL-15), an immune system signaling molecule that appears early in the cascade of events that ultimately lead to inflammatory disease. According to Amgen, interim data from Phase II clinical trials for rheumatoid arthritis are suggestive of a clinical effect in this condition. The Phase II trials are expected to be completed in 2005.

**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.

**Pfizer CP-675,206 (Anti-CTLA-4 Antibody) ♣ *Melanoma.*** Pfizer is developing CP-675,206, a fully human antibody for the treatment of melanoma. Enrollment is currently underway for a Phase II clinical trial. This product candidate was not generated using our UltiMAB technology.

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

**MDX-214 (Anti-EGFr/CD89 Antibody) *Cancer.*** MDX-214 is 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 believed to have the ability to direct CD89 positive effector cells to EGFr-overexpressing tumor cells, potentially facilitating the interaction of the immune system with the cancer. A Phase I/II clinical trial is underway for the treatment of cancers that overexpress EGFr. The study is expected to enroll up to 48 patients with refractory or relapsed EGFr-expressing cancers, including cancers of the head and neck, breast, colon, prostate, lung and ovary.

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♦ We expect to receive milestone payments, as these product candidates move through clinical trials, and royalties on product sales, should commercialization occur.

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

♣ We expect to receive milestone payments and royalty payments on product sales, should commercialization occur.



**MDX-018 (Anti-inflammatory 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. Neither of the serious adverse events reported (one event of syncope and one event of acute myocardial infarction) was determined by the investigator to be related to the antibody.

**HuMax-EGFr (Anti-EGFr Antibody) *Head, Neck and Other Cancers.*** According to Genmab, HuMax-EGFr, a fully human antibody targeting EGFr, a receptor molecule that has been found in excess on many tumor cells, is under development for the treatment of carcinoma of the head and neck. In December 2004, Genmab reported partial and stable disease data for a Phase I/II clinical trial for the treatment of head and neck cancer with HuMax-EGFr.

**HuMax-CD20 (Anti-CD20 Antibody) *Lymphoma.*** Genmab is developing HuMax-CD20, a fully human antibody targeting CD20, a molecule found on B cells. 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 2004, Genmab reported interim complete and partial response data in patients with NHL. Also in December 2004, Genmab announced that this product candidate has been granted Fast Track designation by the FDA for the treatment of CLL and that the FDA had accepted an Investigational New Drug Application, or IND, for a Phase I/II dose escalation trial for HuMax-CD20 in patients with active rheumatoid arthritis who have failed one treatment with one or more disease modifying anti-rheumatic drugs.

#### ***Phase I and Selected 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-1307 (Anti-Mannose Receptor/hCG- $\beta$  Antibody) *Colorectal, Pancreatic and/or Bladder Cancers.*** MDX-1307 (also known as  $\beta$ HCG-VAC) is 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. In February 2004, the FDA accepted our IND application to initiate a dose-escalation, multi-dose Phase I study. This ongoing study 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 us were awarded a two-year \$500,000 grant from the Avon Foundation and the National Cancer Institute to initiate a Phase I clinical trial with MDX-1307/ $\beta$ HCG-VAC for the treatment of breast cancer. We have submitted the protocol for this study to the FDA and expect to begin enrolling patients in 2005.

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

We are in the process of a possible initial public offering of a portion of the common stock of Celldex. As part of this transaction, in April 2004, we assigned our rights to this product candidate, including the associated IND, to Celldex. In the event this offering is completed, we will not be entitled to license fees or milestone payments with respect to this product. We may be entitled to receive royalty payments on any product sales, should commercialization occur.





**MDX-066 (Anti-Toxin A Antibody)** *Clostridium difficile* Associated Diarrhea. MDX-066 (also known as CDA-1) is a fully human antibody that we are co-developing with the Massachusetts Biologic Laboratories of the University of Massachusetts Medical School, or MBL. MDX-066 is designed to target Toxin A, a toxin produced by the bacterium *Clostridium difficile*, which is associated with a serious and sometimes deadly form of diarrhea called *Clostridium difficile* associated diarrhea, or CDAD. Preclinical studies suggest that MDX-066 may neutralize the effects of Toxin A, the toxin associated with CDAD. We and MBL have initiated a dose-escalation Phase I trial which is expected to enroll up to 30 healthy volunteers. The participants will be monitored for any adverse side effects, and their blood will be tested to measure the concentration of the antibody in their systems.

**CNTO 95 (Anti-integrin receptors Antibody)** ♦ *Cancer*. In December 2003, we announced that Centocor had commenced a dose escalation Phase I trial of CTNO 95, a high affinity, fully human antibody targeting the integrin receptors ( $\alpha v \beta 3$  and  $\alpha v \beta 5$ ) 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.

**FG-3019 (Anti-CTGF)** ♦ *Idiopathic Pulmonary Fibrosis and Diabetic Nephropathy*. FibroGen has reported that it has completed a Phase I clinical trial of a fully human antibody therapeutic in patients with idiopathic pulmonary fibrosis and expects to initiate a Phase II clinical trial in 2005. The product candidate is FibroGen's lead anti-CTGF (connective tissue growth factor) therapeutic antibody, also known as FG-3019. According to publicly available sources, FG-3019 is also in a Phase Ib clinical trial in type 1 and type 2 diabetic patients with early-stage kidney disease.

**MDX-1100 (Anti-IP-10 Antibody)** *Inflammatory Diseases*. We are developing MDX-1100, a fully human antibody product candidate 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. We expect to file an IND application with the FDA in the first half of 2005 for a Phase I trial of MDX-1100 in patients with inflammatory bowel disease. We acquired full rights to MDX-1100 as part of our acquisition of Ability Biomedical Corporation in August 2004.

**MDX-1333 and MDX-1103 (Anti-Type 1 IFN Antibodies)\*** *Systemic Lupus Erythematosus*. MDX-1333 and MDX-1103 are 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. MDX-1333 is an antibody that we believe blocks the receptor of Type 1 IFN, and MDX-1103 is an antibody that we believe blocks multiple Type 1 IFN subtypes. 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. We understand that MedImmune expects to file an IND with respect to these antibodies before the end of 2006.

**MDX-1303 (Anti-Anthrax Antibody)** *Bacillus anthracis* Infection. MDX-1303, also known as Valortim, is a fully human antibody in preclinical development 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

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♦ We expect to receive milestone payments, as these product candidates move through clinical trials, and royalties on product sales, should commercialization occur.

\* We expect to receive milestone payments as these products move toward product approval, and royalties on product sales outside the U.S., should commercialization occur.



protective antigen. In preclinical studies, MDX-1303 both protected against infection, and, when administered some time after exposure, it induced recovery and survival in animals exposed to lethal doses of inhalation anthrax spores. An IND application could be submitted as early as 2005 to commence a Phase I dose escalation clinical trial evaluating the safety, tolerability and pharmacokinetics of MDX-1303 in healthy adults. In 2004, we 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.

**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, and Eli Lilly's antibody for an undisclosed indication. No additional information has been made public regarding any of these Phase I clinical trials.

In April 2003, we and Diatos SA entered into an agreement in which Diatos licensed from us the exclusive European rights to develop and commercialize a potential new cancer treatment, Super-Leu-Dox. This product consists of doxorubicin conjugated to a proprietary prodrug peptide. Preclinical studies have suggested that when prodrug molecules reach the vicinity of a tumor, the peptide is cleaved off by enzymes that are released by the cancer cells, freeing the cytotoxic compounds. The unconjugated compound is believed to then act as an anti-cancer agent, exerting its cytotoxic effects locally on the cancer cells.

#### **Our Human Antibody Partnering Business**

As of March 1, 2005, we have more than 50 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 November 2004, we announced a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. This collaboration became effective in January 2005. Under the terms of the collaboration, we and BMS have 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 MDX-010, a fully human antibody product candidate developed using our UltiMab Human Antibody Development System, that is antagonistic to cytotoxic T-lymphocyte antigen 4 (CTLA-4). MDX-010 is currently under investigation for the treatment of a broad range of cancers and other diseases. The collaboration also includes the grant by us to BMS of a sub-license to MDX-1379, a gp100 melanoma peptide vaccine licensed by us from the U.S. Public Health Service, for use with MDX-010 for the treatment of metastatic melanoma. The FDA has granted orphan drug designation for MDX-010 for the treatment of Stage IIc, Stage III and Stage IV melanoma, and we and BMS are currently conducting a Phase III clinical trial with MDX-010 and MDX-1379 combination therapy in Stage III and Stage IV metastatic melanoma patients, under a SPA agreement with the FDA, at multiple sites within the U.S. 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 MDX-010 as a potential treatment for a broad range of cancers. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the U.S. and Europe, with the remaining 35% to be paid by us. 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 costs that relate solely to regulatory approval in Europe and other parts of the world.

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

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

Unless terminated earlier, the BMS collaboration will continue for as long as development and/or commercialization of any collaborative 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.

#### ***MedImmune***

In November 2004, we entered into a collaboration with MedImmune to develop antibodies targeting interferon-alpha and the Type I interferon receptor 1. The collaboration will initially focus on two fully human antibodies, MDX-1103 and MDX-1333, that are currently in preclinical development by us for the treatment of autoimmune diseases, such as systemic lupus erythematosus, SLE, or lupus. We understand that MedImmune expects to file INDs on these two antibodies with the FDA before the end of 2006.

Under the terms of the collaboration with MedImmune, we received an upfront payment of \$15.0 million and will receive potential milestone payments for product candidates placed into clinical development. MedImmune will be fully responsible for all development costs up to the point of initiating pivotal trials of any product candidates. At that point, we have a choice for each potential product candidate. We can elect to enter into a profit sharing arrangement in the U.S. If we choose profit sharing, we will pay our proportionate share of the future development costs and reimburse MedImmune for a proportionate share of MedImmune's previous development costs plus interest. If we elect to enter into the profit sharing arrangement, we will also have the option to enter into a co-promotion relationship with MedImmune in the U.S. In the alternative, we can elect to forego any further funding for the product candidates and MedImmune will be fully responsible for all costs of development and commercialization. In that case, we will be entitled to milestone payments and substantial royalties on any sales in the U.S.

Regardless of what we elect to do with respect to the U.S. market, in the rest of the world we are entitled to milestone payments and royalties on any product sales.

#### ***Our 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, 2005, we had agreements with more than 25 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 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, 2005, we had more than 20 licensing partnerships with partners including industry leaders such as Amgen, Centocor, Pfizer, Eli Lilly, Human Genome Sciences, Abbott Laboratories, Novartis, Novo Nordisk 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 and 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.

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, or together, the Pfizer Licenses, of certain patents and patent applications 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, 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. In addition, 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 royalty payments based upon commercial sales of any Pfizer anti-CTLA-4 antibody product. 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 MDX-010 and Pfizer's CP-675,206, which was not generated using our UltiMab technology.

### **Kirin and Other Technology Licenses**

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 which combines the traits of our HuMab-Mouse with Kirin's TC Mouse. Under the collaboration and license agreement, we are exchanging cross-licenses with Kirin with respect to the KM-Mouse and other antibody-generating mice. In addition, certain of the cross-licenses granted under the collaboration and license agreement are subject to license, milestone and royalty payments by one party to the other. We are aware of one anti-TRAIL-R2 antibody (HGS-TR2J), currently in Phase I clinical trials, which is being developed by HGS pursuant to a license with Kirin. We expect to receive royalties on sales of this product, should commercialization occur.

Through December 31, 2004, we had not made any milestone payments to Kirin, although approximately \$1.9 million has been accrued as of December 31, 2004 representing a payment due Kirin as a result of our collaboration with Pfizer, and had made licensing and other payments of approximately \$0.5 million. Based on a total of two 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 2006, we may be required to make milestone payments to Kirin aggregating up to approximately \$8.5 million with respect to such products, or a maximum of approximately \$4.25 million per product. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

- whether or not a decision is made to request a license from Kirin;
- the type of license requested (research or commercial);
- the success and timing of development efforts and clinical trials of product candidates covered by any such licenses;
- the type of product developed (payment obligations differ depending on whether a product is an *ex vivo* therapeutic, *in vivo* therapeutic, research reagent or diagnostic); and

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

Whether we may be obligated to make milestone 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 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.

In addition to our collaboration with Kirin, we have 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 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, 2004, we had made milestone payments of approximately \$0.3 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of five products we are developing for which milestones are potentially due and that (i) are now in clinical trials, or (ii) which we anticipate may enter clinical trials before the end of 2006, we may be obligated to make future milestone payments aggregating up to approximately \$22.5 million with respect to such products. In general, potential milestone payments for our antibody products may or may not be triggered under these licenses, and may vary in size, depending on a number of variables, almost all of which are currently uncertain. Typically, the events that trigger these payments per product include:

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

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

#### Significant Partner Revenue

Revenue from partners representing 10% or more of total revenues for the years ended December 31, 2002, 2003 and 2004 is as follows:

Partner	2002	2003	2004
Genmab	37 %	48 %	26 %
Pfizer			20 %
Amgen	3 %	15 %	8 %
Lilly	11 %	7 %	6 %
IDM	36 %		





Further information regarding revenues from partners is included in Notes 10 through 12 to the Consolidated Financial Statements.

## Strategic Investments

### *Genmab*

In February 1999, we and a group of unrelated third party investors formed Genmab, a Danish biotechnology company, to develop and commercialize a portfolio of fully human antibodies derived from our HuMAb-Mouse technology. Initially, the investor group invested approximately DKK 35.4 million or \$5.3 million (based on the then current exchange rate of \$1.00 = DKK 6.73), and received approximately 44% of Genmab's share capital. At the same time, we contributed a license to our human antibody technology for producing antibodies to particular targets in exchange for comparable consideration of approximately 44% of Genmab's share capital. During Genmab's initial 12 months of operation, the investor group invested an additional DKK 49.0 million or \$7.0 million (based on the then current exchange rate of \$1.00 = DKK 6.99) for additional equity in Genmab. In connection therewith, we expanded our license to provide Genmab with broader rights to our human antibody technology in exchange for further equity, thereby maintaining our level of ownership in Genmab's share capital. Specifically, in exchange for equity, we granted Genmab 16 fully paid-up commercial licenses for antibody products. In addition, in May 2000, Genmab completed a private placement in which it received approximately DKK 321.0 million or \$38.4 million (based on the then current exchange rate of \$1.00 = DKK 8.35) from the original investor group and additional new investors. In connection therewith, we made an additional cash investment of \$18.0 million in order to maintain our approximate 44% ownership interest in Genmab. In August 2000, we received additional equity in connection with the Genomics Agreement (as described below) valued at \$2.0 million (based upon the recently completed private placement), representing payment for the first year which increased our equity interest in Genmab to approximately 45%.

In August 2000, we entered into a binding memorandum of understanding, or the Genomics Agreement, with Genmab, 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. Under the terms of the Genomics Agreement, Genmab may make available our human antibody technology (a) for large multi-target (five or more targets) partnerships to any Europe-based company except for: (i) certain Medarex partners, including Novartis, Merck KGaA, Schering, Aventis Behring, Immuno-Design Molecules S/A, or IDM, and Scil Biomedicals GmbH; and (ii) any European based pharmaceutical company with worldwide revenues in excess of \$1 billion in 1999, provided, however, that Genmab may make available our human antibody technology to Sanofi/Synthelabo and Boehringer Ingelheim, and (b) for non-large multi-target (less than five targets) partnerships, to any company worldwide. We also have the right to participate in Genmab's large multi-target (five or more targets) partnerships, thereby sharing in certain costs and commercial benefits. We retain all rights to make available our technology to companies headquartered outside of Europe and to all companies for non-large multi-target (less than five targets) partnerships in Europe. Certain license fees, milestones and royalties due to us under our previously existing agreement with Genmab were reduced. The Genomics Agreement also provides that, under certain circumstances, we must negotiate in good faith to manufacture antibodies for Genmab's partnerships. Finally, the Genomics Agreement grants Genmab certain rights to access technologies acquired by us from each of Biosite Incorporated and Kirin, respectively.

The Genomics Agreement has an initial term of five years with a right exercisable by Genmab to extend the term for an additional two years. For each year of the agreement and during the term of any extension, we will receive \$2.0 million per year from Genmab. At Genmab's option, these amounts may be paid in either cash or capital stock. During each of the years ended December 31, 2002, 2003 and 2004, the

Company recognized \$2.0 million of revenue from this agreement. The initial term of this agreement expires in August 2005.

In October 2000, Genmab became a publicly listed company on the Copenhagen Stock Exchange. As a result of raising the equivalent of \$187.0 million (based on the then current exchange rate) 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. As of December 31, 2004, our ownership interest in Genmab was approximately 24.7%. We currently account for our investment in Genmab under the equity method of accounting.

#### *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. Under the agreement, IDM acquired worldwide rights to the use of our MDX-210 anti-HER-2 product in connection with cell therapy. IDM also acquired the right to receive royalty payments from third party sales of MDX-210 in Europe, outside the field of cell therapy. Additionally, IDM acquired certain rights in all fields to additional products which we are not actively developing at this time.

As a result of this transaction, we recorded a gain from the transfer of this technology of approximately \$40.5 million (based upon an independent valuation) as non-cash contract revenue over a two year period ending in September 2002 for financial reporting purposes (see Note 12 to the Consolidated Financial Statements). In October 2000, we participated in a private placement of equity interests in IDM and purchased additional equity of approximately \$5.2 million. Our current equity position in IDM is approximately 8%. In the event that we exercise certain warrants held by us to purchase convertible or redeemable bonds of IDM and such bonds are converted or redeemed, our equity position in IDM would be approximately 23%, based on the shares of IDM currently outstanding. These warrants are exercisable between September 2002 and September 2010, and such bonds may be converted or redeemed within six months of such exercise.

#### *Celldex*

We are in the process of a possible initial public offering of a portion of the common stock of our wholly-owned subsidiary Celldex Therapeutics, Inc. As part of this transaction, we have assigned or licensed to Celldex certain intellectual property related to our vaccine technology, including the rights to MDX-1307, one of our product candidates for the treatment of cancer, as well as the IND associated with this product which became effective in February 2004. If the offering is completed, we anticipate that we will continue to hold approximately 70% of the outstanding shares of common stock of Celldex. We cannot assure you that this transaction will be consummated.

In January 2005, Celldex entered into an asset purchase agreement to acquire substantially all of the assets of Alteris Therapeutics, Inc., a Pennsylvania based private biotechnology company. Through its strategic acquisition of the Alteris assets, Celldex will acquire the following assets:

- An exclusive worldwide non-royalty bearing, fully paid-up license to the patents covering a validated proprietary cancer antigen EGFRvIII for use in vaccine and immunization approaches to prevent, inhibit and treat tumor formation and progression;
- The exclusive rights to commercialize ALT-110, a therapeutic cancer vaccine based on the EGFRvIII cancer antigen that is currently being studied by a number of academic institutions in an investigator-initiated Phase II clinical trial for brain cancer and an investigator-initiated Phase I clinical trial for various other cancers; and

- An exclusive worldwide fee and royalty bearing license to the patent applications covering the Rapid Identification of Alternative Splicing system, or RIAS, a target discovery platform technology.

The acquisition of the Alteris assets is subject to the completion of Celldex's initial public offering and certain other standard closing conditions. A majority of the Alteris stockholders have agreed to vote in favor of the acquisition, subject to their fiduciary obligations.

## **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 cause 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 effectively 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 offspring of the mice. Mice can, therefore, be 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, as high as  $10^{12}$ .

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 we believe 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 toxin

technology for creating antibody toxin conjugates, some of which we acquired from Corixa Corporation in 2002. Our toxin program includes small molecules known as duocarmycins, 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 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 between the time of the selection of the initial antibody and the time the final version of the antibody is placed into production.
- *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 immunization 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 that recognize more antigen structures. 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 the antibodies.
- *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 increased 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 and process science/formulation. 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 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 225 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 all respects in accordance with current good manufacturing practices, or cGMP, regulatory requirements for the manufacturing 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 our partners in connection with our human antibody technology in the near-term. We are currently negotiating with third-party manufacturers to establish clinical and commercial supply contracts necessary for our future production requirements. In September 2003, we entered into a clinical supply agreement with Lonza Group Ltd. with respect to MDX-010 and MDX-060, and, together with our partner BMS, we are pursuing ongoing discussions with respect to terms of a commercial supply agreement for MDX-010. We do not currently have the capability to manufacture our products under development in large commercial quantities and have no experience in commercial-scale manufacturing.

### **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.

### **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.

Currently, we hold a total of 60 issued patents in the U.S., and over 140 issued patents in foreign countries with respect to our HuMAb-Mouse technology and products, our bispecific molecule technology and products, and to our other technology and products.

Of these, 16 of our issued patents and allowed patent applications in the U.S. and 26 of our issued patents in foreign countries, including European countries, Japan, Korea, New Zealand and Australia, among others, relate to various aspects of our HuMAb-Mouse technology and products. These patents, almost all of which are in the same patent family, claim the transgene, the transgenic mouse, methods of obtaining high affinity antibodies, and compositions of matter for high affinity antibodies, among others. These patents have expiration dates beginning in 2008. We also have more than 150 related pending U.S. and foreign patent applications directed to various aspects of our HuMAb-Mouse technology and products. These include patent applications describing several of our particular human antibody product candidates, such as our anti-PSMA, anti-CTLA-4 and anti-CD30 product candidates.

Additionally, we hold exclusive and non-exclusive licenses to various pertinent technologies relating to our HuMAb-Mouse technology. 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 our anti-CTLA-4 antibody product and have licenses from BMS and Pfizer concerning other intellectual property related to our anti-CTLA-4 product. 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 our anti-CD30 antibody product. We have been assigned patent rights from Northwest Biotherapeutics, Inc. relating to aspects of our anti-PSMA antibody product and have a non-exclusive license from Millennium Pharmaceuticals, Inc. relating to aspects of our anti-PSMA antibody product. We have been assigned patent rights relating to our anti-interferon alpha receptor antibody product by Nufarm, B.V., Medisup International N.V., Pharma Pacific Pty. Ltd and Laboratoire Européen de Biotechnologie. We have acquired patent rights relating to our anti-IP-10 antibody product through our acquisition of Ability Biomedical. In addition, we have acquired patent rights from Corixa relating to tumor-activated prodrugs and Ultra-Potent Toxins.

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®, KM-Mouse®, UltiMAB Human Antibody Development System®, 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, also 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 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, 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 the clinical endpoint, 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 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. We and BMS are developing MDX-010 in combination with MDX-1379 under an SPA for the treatment of certain severe types of melanoma. 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 the design of a clinical trial 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, and there can be no assurance that the data collected will be in compliance with GCP requirements, will demonstrate that the product is safe or effective, or, in the case of a biologic product, pure and potent as well, or will provide sufficient data to support FDA approval of the product. 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 clinical subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional (in most cases, hospital) 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. Any adverse event, either before or after marketing authorization, can result in product liability claims against the company.

During the course of, and 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 FDA Center for Drug Evaluation and Research, or CDER, has responsibility for the review and approval of drugs, and also has responsibility for the review and approval of certain therapeutic biologics such as antibodies, cytokines, growth factors, enzymes, interferons and certain proteins. The FDA Center for Biologics Evaluation and Research, or CBER, has responsibility for other biologics, including vaccines. Based on this distribution of

responsibility, we expect that most of our products will be reviewed by CDER. 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 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. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products.

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. The NDA or BLA review fee alone can exceed \$0.67 million, although certain limited deferrals, waivers and reductions may be available.

Under applicable laws and FDA regulations, 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. If the FDA refuses to file an application, the FDA will retain 25% of the user fee as a penalty. 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.

*Treatment IND Status.* Treatment INDs are used to make new drugs and biologic products available to desperately ill patients as early in the drug development process as possible, before general marketing is approved and begins. The FDA may allow an investigational drug to be used under a treatment IND if there is preliminary evidence of the drug's efficacy and the drug is intended to treat a serious or life-threatening disease for which no comparable or satisfactory alternative therapy exists. We or our collaborative partners may be able to recover some of the costs of production, manufacture, research, development and handling prior to market approval if patients are allowed to be charged for the product used in such studies. There are specific conditions that must be met before a sponsor may charge for an investigational product, including notifying the FDA in writing in advance. The FDA may notify the sponsor that it is not authorized to charge for the product.

*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. MDX-010 in combination with MDX-1379 has been granted Fast Track status for the treatment of high risk Stage II, Stage III and Stage IV melanoma. Genmab's HuMax-CD4 has been granted Fast Track status for the treatment of CTCL. Certain other products employing our human antibody technology might also qualify for this accelerated regulatory procedure. However, we cannot make assurances that the FDA will agree, and, even if the FDA agrees that these products qualify for accelerated approval procedures, the FDA may deny approval of our drugs or may require that additional studies be required before approval. The FDA would also likely require us to perform post-approval, or Phase IV, studies as a condition of such early 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 FDA grant a drug orphan designation prior to approval. Products designated as orphan drugs are eligible for special grant funding for research and development, 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 FDA approval of applications by others for the same drug and the designated orphan disease or condition. FDA may approve a subsequent application from another person if FDA determines that the application is for a different drug or different use, or if 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 from receiving approval for the same or a similar drug 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 Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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, 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, or OBRA '93, 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-licensing 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 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. 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 and yeast display technology is being used by companies such as Cambridge Antibody Technology Group plc, or CAT, Dyax Corp., Genetastix Corporation and MorphoSys AG to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, MedImmune, Amgen, Biogen Idec, Inc., Novartis, Genentech, Inc., Protein Design Labs, Inc., Abbott Laboratories and Wyeth 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 Systems Incorporated, Johnson & Johnson, Wyeth, Amgen, Abbott, UCB Pharma, Biogen Idec, Abgenix, CAT, MorphoSys AG, Tanox, Inc., Genentech, Human Genome Sciences, Millennium and Protein Design Labs are addressing diseases and disease indications that are being targeted by us and certain of our partners. For example, Pfizer is developing CP-675,206, an antibody to CTLA-4, in potential competition with our product candidate, MDX-010. Several of these 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 European Union 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. In addition, the application of recombinant DNA technology to develop potential products consisting of proteins (such as growth factors, hormones, enzymes, receptor fragments and fusion proteins, or cytokines) that do not occur normally in the body, or occur only in small amounts, has been underway for some time. Included in this group are interleukins such as IL-2 and IL-11, interferons alpha, beta and gamma, colony stimulating factors such as G-CSF and GM-CSF, clotting factors, growth hormones, erythropoietin, DNase, tPA, glucocerebrosidase, PDGF, and a number of other biological response modifiers. Continuing development of new chemical entities and other drugs by large pharmaceutical companies also carries with it the potential for 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 licensing partners. Marketing and sales rights with respect to MDX-010 are subject to the terms of our collaboration with BMS. We believe that a small sales force could successfully introduce and detail certain of our potential products that have concentrated marketplaces. Other products, however, may require a larger sales force. Currently, we have no sales force. We may develop our own internal sales force for these products if they proceed to commercialization.

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

### **Employees**

As of December 31, 2004, we employed 435 regular, full and part-time employees, of whom approximately 363 are engaged in research and development activities. There are 72 employees involved in business development, legal, finance and other administrative functions. None of our employees is covered by a collective bargaining agreement. We have entered into employment contracts with certain of our executive officers. Our success will depend in large part upon our ability to attract and retain employees. We face competition for employees from other companies, research and academic institutions, government agencies and other organizations. We believe we maintain good relations with our employees.

### **Available Information**

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

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy our reports, proxy statements and other information at the SEC's public reference room at Room 1024, 450 Fifth Street N.W., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. Our SEC filings are also available at the SEC's web site at [www.sec.gov](http://www.sec.gov). In

addition, you can read and copy our SEC filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street N.W., Washington, D.C. 20006.

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

#### **FORWARD LOOKING INFORMATION AND RISK FACTORS THAT MAY AFFECT FUTURE RESULTS**

This Annual Report contains forward-looking statements within the meaning of Sections 27A and 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations, beliefs, intentions, or strategies regarding the future. Statements preceded by, followed by or that otherwise include the words believes, expects, anticipates, intends, estimates, plans, forecasts, is likely to, projected, similar expressions or future conditional verbs such as should, would, may, and could are generally forward-looking in nature and not historical facts. Forward-looking statements include, without limitation, statements in this section, and in the sections entitled Management's Discussion and Analysis of Financial Condition and Results of Operations, Business and elsewhere in this Annual Report regarding, among other things, uncertainties relating to our technology; history of operating losses and anticipation of future losses; uncertainty of product development; need for additional capital and uncertainty of change; uncertainty of patent and proprietary rights; management of growth, and risks of acquiring new technologies; uncertainties related to clinical trials; government regulation and uncertainty of obtaining regulatory approval; dependence on 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.

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

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Active product candidates employing our human antibody technology have not moved beyond clinical development. Based on public disclosures, regulatory applications, including INDs, have been submitted to the FDA or comparable foreign authorities, for 22 product candidates derived from our UltiMAb platform. To date, neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA or comparable foreign authorities and/or commercialized. In addition, we are not aware of any commercialized fully human monoclonal antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond clinical development or demonstrate clinical safety and effectiveness.

Our human antibody technology may not generate antibodies against all the antigens to which it is exposed in an efficient and timely manner, if at all. If our human antibody technology fails to generate



antibody product candidates, or if we or our partners do not succeed in the development of products employing our antibody technology, those product candidates may not be approved or commercialized and our business, financial condition and results of operations may be materially harmed.

**Successful development of our products is uncertain. To date, no revenues have been generated from the commercial sale of our products and our products may not generate revenues in the future.**

Our development of current and future product candidates is subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

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

In certain instances, we have experienced delays in our product development and clinical testing as a result of slower than anticipated patient recruitment. In a number of instances, we have terminated the development of certain products in the early stages of human clinical testing due to a lack of effectiveness. In addition, we determined not to continue the development of one late-stage product candidate due to both a lack of effectiveness and unforeseen safety issues that arose in clinical testing. This product did not employ our core fully human antibody technology.

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

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

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

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

We have incurred large operating losses and we anticipate that these losses will continue for the foreseeable future. In particular, as of December 31, 2004, we had an accumulated deficit of approximately \$599.4 million. Our net loss was \$186.5 million for the year ended December 31, 2004. Our losses have resulted principally from:

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- research and development costs relating to the development of our technology and antibody product candidates;
- costs associated with the establishment of our laboratory and manufacturing facilities and manufacturing of products; and
- general and administrative costs relating to our operations.

We intend to continue to make significant investments in:

- research and development;
- preclinical testing and clinical trials;
- establishing new collaborations; and
- new technologies.

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

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

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

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

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

- the timing of the commencement, completion or termination of partnership agreements;
- the introduction of new products and services by us, our partners or our competitors;
- delays in, or termination of, preclinical testing and clinical trials;
- changes in regulatory requirements for clinical trials;
- costs and expenses associated with preclinical testing and clinical trials;
- the timing of regulatory approvals, if any;
- sales and marketing expenses; and
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business operations and facilities.

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

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



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

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

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

We believe our current sources of liquidity will be sufficient to meet our near term operating, debt service and capital requirements for at least the next 24 months. To the extent our 2.25% convertible senior notes due in 2011 are converted into shares of our common stock on or before their maturity date, we will have use of that portion of the principal amount of the notes to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We may be unable to raise sufficient funds to complete development of any of our product candidates, to continue operations or to repay our debt obligations at maturity. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

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

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

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

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

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

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

- the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices, or cGMPs, for use in clinical trials;
- the need or desire to modify our manufacturing processes;
- slower than expected rates of patient recruitment;
- the inability to adequately observe patients after treatment;
- changes in regulatory requirements for clinical trials;
- the lack of effectiveness during the clinical trials;
- unforeseen safety issues;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or clinical holds requiring suspension or termination of the trials.

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



unforeseen safety issues that arose in clinical testing. This product did not employ our core fully human antibody technology.

Generally, our clinical trials, including our melanoma trials, are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. The most common adverse events associated with our trials of MDX-010 have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related ABEs, such as diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. Other than a very small number of fatalities, which may or may not be attributable to our product candidate, most ABEs resolved with treatment. We cannot assure you that additional safety issues will not arise with respect to our products in the future.

To date, we have experienced slower than expected rates of patient recruitment in certain of our clinical trials. As a result, in certain instances, we have experienced delays in our product development and clinical testing. In addition, data obtained from clinical trials of our products to date have been insufficient to demonstrate safety and efficacy under applicable FDA guidelines. As a result, these data will not support an application for regulatory approval without further clinical trials. Clinical trials that we conduct or that third-parties conduct on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for any of our product candidates. We expect to commence new clinical trials from time to time in the course of our business as our product development work continues. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of that product candidate as well as other product candidates. Any change in, or termination of, our clinical trials could materially harm our business, financial condition and results of operations.

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

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

In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. For example, the FDA has moved several product categories previously regulated by the agency's Center for Biologics Evaluation and Research, or CBER, to the agency's Center for Drug Evaluation and Research, or CDER. These product categories include antibodies as well as cytokines, growth factors, enzymes, interferons and certain proteins. FDA has also recently announced a planned reorganization within CDER to create a new consolidated office for the review of oncology therapies. Oncology therapies are currently reviewed by different offices within CDER. The effect that these reorganizations at the FDA will have on clinical trials and product approval outcomes or timing is uncertain, but could cause delays or other currently unforeseeable effects.



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

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

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

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

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

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

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

Third-party payors control health care costs by limiting both coverage and the level of reimbursement for new health care products. In the future, the U.S. government may institute price controls and further limits on Medicare and Medicaid spending. Internationally, medical reimbursement systems vary with differing degrees of regulation. Pricing controls and reimbursement limitations could affect the payments we receive from sales of products generated using our human antibody technology. These variations could harm our ability and the ability of our partners to sell products generated using our human antibody technology in commercially acceptable quantities at profitable prices.

**We may experience pressure to lower the prices of any prescription pharmaceutical products we are able to obtain approval for because of new and/or proposed federal legislation.**

Federal legislation, enacted in December 2003, has added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program

for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations may increase pressures to lower prices. While the new law specifically prohibits the U.S. government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the U.S. government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating *de facto* price controls on prescription drugs. In addition, the new law contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include some sorts of limitations on prescription drug prices. The new legislation also modified the methodology used for reimbursement of physician administered and certain other drugs already covered under Medicare Part B. This new methodology would likely apply to certain of our products if and when commercialized. Experience with new reimbursement methodology is limited, and could be subject to change in the future. Our results of operations could be materially harmed by the different features of the Medicare prescription drug coverage legislation, by the potential effect of such legislation on amounts that private insurers will pay for our products and by other healthcare reforms that may be enacted or adopted in the future.

**We may face increased competition from products imported from Canada or other countries.**

Any products we are able to commercialize may be subject to competition from lower priced versions of such products and competing products from Canada, Mexico, and other countries where there are government price controls or other market dynamics that make the products lower priced. The ability of patients and other customers to obtain these lower priced imports has grown significantly as a result of the Internet, an expansion of pharmacies in Canada and elsewhere targeted to American purchasers, the increase in U.S.-based businesses affiliated with Canadian pharmacies marketing to American purchasers, and other factors. Many of these foreign imports are illegal under current law. However, the volume of imports is now significant due to the limited enforcement resources of the FDA and the U.S. Customs Service, and the pressure in the current political environment to permit the imports as a mechanism for expanding access to lower priced medicines.

In addition, in December 2003, federal legislation was enacted to change U.S. import laws and expand the ability to import lower priced versions of our and competing products from Canada, where there are government price controls. These changes to the import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The previous Secretary of Health and Human Services determined that there was not a basis to make such a certification at this time. However, it is possible that a subsequent Secretary could make the certification in the future. In addition, legislative proposals have been made to implement the changes to the import laws without any certification, and to broaden permissible imports in other ways. Even if the changes to the import laws do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the Customs Service, and other government agencies. For example, state and local governments have suggested that they may import drugs from Canada for employees covered by state health plans or others, and some have already put such plans in place.

The importation of foreign products could adversely affect our profitability. This potential impact could become more significant in the future, and the impact could be even greater if there is a further change in the law or if state or local governments take further steps to import products from abroad.

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

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

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

We may also encounter problems with the following:

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

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. We are currently pursuing late-stage clinical and commercial supply agreements with cGMP-compliant third-party manufacturers with available capacity to meet our internal production timetables. We have entered into clinical supply agreements with Lonza Group Ltd. with respect to MDX-010 and MDX-060, and, together with our partner BMS, we are pursuing ongoing discussions with respect to terms of a commercial supply agreement for MDX-010. We do not currently have the capability to manufacture our products under development in large commercial quantities and have no experience in commercial-scale manufacturing. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin producing antibodies under cGMP regulations. We cannot make assurances that we will be able to contract with such companies for clinical and/or commercial supply on acceptable terms or in a timely manner, if at all. Moreover, even if we are able to enter into clinical and/or commercial supply manufacturing arrangements with cGMP-compliant third-party manufacturers, we cannot assure you that such manufacturers will be able to produce products that are substantially equivalent to the product candidates that we have produced in our own facilities and used in our clinical trials. If such companies are not able to produce products that are substantially equivalent to our product candidates, the progress of our clinical trials and/or commercialization of our products may be delayed and our business, financial condition and results of operations may be materially harmed.

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

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

We depend, in part, on our partners to support our business, including the development of products generated through the use of our antibody technology. In particular, under the terms of our collaboration and co-promotion agreement with BMS, we have granted a license to commercialize our lead product candidate, MDX-010, to BMS for the treatment of a broad range of cancers. We have also granted to BMS a sub-license to MDX-1379 for use in combination with MDX-010 for the treatment of metastatic melanoma. The successful development and commercialization of MDX-010 is dependent, in large part, on the actions of BMS, which are outside of our control. The failure of BMS to act in accordance with its obligations under the collaboration and co-promotion agreement may cause us to incur substantial additional costs in order to develop and commercialize MDX-010, which could have a material adverse effect on our business.

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

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

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

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

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

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

Our licensing partners generally have the right to terminate our partnerships at any time. Our ability to continue our current partnerships and to enter into additional partnerships is dependent in large part on our ability to successfully demonstrate that our UltiMAB technology is an attractive method of developing fully human antibody therapeutic products. Existing or potential partners may pursue alternative technologies, including those of our competitors, or enter into other transactions that could make a collaboration with us less attractive to them. For example, if an existing partner purchases or is purchased by a company that is one of our competitors, that company could be less willing to continue its collaboration with us. In addition, a company that has a strategy of purchasing companies rather than entering into partnership arrangements might have less incentive to enter into a collaboration agreement with us. Moreover, disputes may arise with respect to the ownership of rights to any technology or products



developed with any current or future partner. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays or termination in the research, development or commercialization of product candidates. If we are not able to establish additional partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely:

- limit the number of product candidates that we will be able to develop and commercialize;
- significantly increase our need for capital; and/or
- place additional strain on management's time.

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

**Due to the size of our equity interest in Genmab, we must include a portion of its income and losses in our financial statements.**

Due to the size of our equity interest in Genmab, we are currently required to account for our interest in Genmab under the equity method of accounting, which provides that we must include a portion of Genmab's income and losses equal to our percentage equity interest in Genmab in our consolidated financial statements. For the years ended December 31, 2002, 2003 and 2004, our share of Genmab's losses were approximately \$19.6 million (excluding the \$31.0 million impairment charge discussed below), \$15.0 million and \$19.8 million, respectively. As such, the current value of our equity interest in Genmab as determined by the equity method of accounting is \$1.6 million, which we expect to be reduced to zero in the first quarter of 2005 and, accordingly, recognition of our share of Genmab's net losses will be suspended.

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

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

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

deem these investments to be further impaired at the end of any future reporting period, we may incur additional impairment charges on these investments.

In addition, we have investments in several of our partners whose securities are not publicly traded, such as IDM. The value of our investments in these companies are inherently more difficult to estimate than our investments in publicly traded companies. We estimate the value of these investments by using information acquired from industry trends, the management of these companies, financial statements, and other external sources. Specifically, our determination of any potential impairment of the value of privately held securities includes an analysis of the following for each company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financing and potential strategic alternatives. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is considered to be other than temporary. For the years ended December 31, 2002, 2003 and 2004, we recorded impairment charges of approximately \$2.4 million, \$1.4 million and \$7.1 million, respectively, on our investments in privately-held companies. Approximately \$7.0 million of the 2004 impairment charge related to IDM. Future adverse changes in market conditions or adverse changes in operating results of these companies may also require an impairment charge in the future.

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

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

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

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

Our success depends in part on our ability to:

- apply for, obtain, protect and enforce patents;
- protect trade secrets;
- operate without infringing upon the proprietary rights of others; and
- in-license certain technologies.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the

development of our business. While a number of patents have been issued in the U.S. and Europe relating to our human antibody technology, we may not be able to obtain patent protection in other countries. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued or enforceable. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide sufficient protection against competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S.

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

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

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

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

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

Our patents covering the HuMAb-Mouse technology include patents that cover particular human antibodies. These patents do not cover all human antibodies.

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

Moreover, other parties could have blocking patent rights to products made using HuMAb-Mouse technology, such as antibodies, and their production and uses, for instance because of a proprietary position covering the antibody's target. For example, we are aware of certain U.S. and European patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets and bispecific products, and the manufacture and use of such products. We are also aware of certain U.S. and foreign patents and patent applications held by third parties relating to anti-CD4 antibodies, such as HuMax-CD4, anti-CD30 antibodies, such as MDX-060, anti-EGFR antibodies, such as HuMax-EGFR, anti-PSMA antibodies, such



as MDX-070, anti-Type 1 IFN antibodies, such as MDX-1103, and antibody-antigen conjugates, such as MDX-1307/bHCG-VAC, as well as other antibody products under development by us.

We are also aware of a U.S. patent owned by Genentech, relating to the production of recombinant antibodies in host cells. We currently produce certain of our products and our partners' products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in this patent, then we may need to obtain a license, should one be available. We have a license to this patent from Genentech for our anti-CTLA-4 product candidate (MDX-010) but currently do not have licenses for any of our other antibody product candidates. If we desire a license for any of our other antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to make recombinant antibodies using Genentech's techniques. In addition to the Genentech patent, we are also aware of certain U.S. patents held by third parties relating to antibody expression in particular types of host cells, including CHO cells, which may be relevant to our current or future manufacturing techniques.

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

In general, our patent protection may not prevent others from developing competitive products using our technology or other technologies. Similarly, others may obtain patents that could limit our ability and the ability of our partners to use, import, manufacture, market or sell products or impair our competitive position and the competitive position of our partners.

We do not have exclusive access to the patents underlying the HuMAb-Mouse. In March 1997, prior to our acquisition of GenPharm, GenPharm entered into a cross-license and settlement agreement with Abgenix, Cell Genesys, Inc., Xenotech, L.P. and Japan Tobacco, Inc., pursuant to which Abgenix and these entities paid us a total of approximately \$38.6 million in exchange for a non-exclusive license to certain patents, patent applications, third-party licenses and inventions pertaining to the development and use of certain transgenic rodents, including mice, that produce fully human antibodies that are integral to our products and business. These patents, licenses and inventions form the basis of our HuMAb-Mouse technology. Our business may suffer from the competition of these entities, as well as if any of these entities breach the cross-license and settlement agreement.

We are not the exclusive owner of the technology underlying the KM-Mouse. Effective September 4, 2002, we entered into a collaboration and license agreement with Kirin, which provides for us to exchange certain cross-licenses for each other's technology for the development and commercialization of human antibody products made using the HuMAb-Mouse, the KM-Mouse and certain other antibody-generating mice. Kirin has certain rights to distribute and use such mice throughout the world. Our business may suffer as a consequence of competition from Kirin or if the collaboration and license agreement were breached or terminated for any reason.

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

The administration of drugs to humans, in clinical trials or after commercialization, may expose us to product liability claims. Consumers, healthcare producers or persons selling products based on our technology may be able to bring claims against us based on the use of our products in clinical trials and the sale of products based on our technology. Product liability claims may be expensive to defend and may result in large judgments against us. We have obtained limited product liability coverage for our clinical trials, under which coverage limits are \$10 million per occurrence and \$10 million in the aggregate. Although we believe these coverage limits are adequate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. We intend to increase our coverage limits as we progress into additional late-stage clinical trials and to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for products in development. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms.

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

Generally, our clinical trials, including our melanoma trials, are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. The most common adverse events associated with our melanoma trials have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related autoimmune adverse events, such as diarrhea, rash, reduced pituitary function, colitis and increased liver enzymes, ranging from mild in most cases to severe in a very small number of instances. Almost all of these adverse events responded to medical therapy. In a very small number of instances, fatalities have occurred during the course of these trials such fatalities may or may not be attributable to our product. Any of these events could result in a product liability claim. Any such claims against us, regardless of their merit, could result in significant awards against us, which could materially harm our business, financial condition and results of operations.

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

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

We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapeutics. Some of these companies have commenced clinical trials of antibody products or have successfully commercialized antibody products. Many of these companies are addressing the same diseases and disease indications as we and our partners. Also, we compete with companies that offer antibody generation services to other companies that have

disease related target antigens. These competitors have specific expertise or technology related to monoclonal antibody development. We compete directly with Abgenix, with respect to the generation of fully human antibodies from transgenic mice. In addition, we have entered into agreements with each of Kirin and Genmab, respectively, that grant these companies licenses to our proprietary transgenic mouse technology platform, enabling them to compete with us in offering antibody generation and development services in certain markets. We have also entered into license agreements with Pfizer which enable it to compete with us in the generation and development of antibodies to CTLA-4. Xenerex Biosciences and XTL Biopharmaceutical, Ltd. have developed technology that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies in functionally modified mice. Numerous additional companies are developing therapeutic products comprising human antibody components. Furthermore, several companies are developing, or have developed, technologies that do not involve immunization of animals for creating antibodies comprising human antibody sequences. For example, phage and yeast display technology is being used by companies, such as Cambridge Antibody Technology Group plc, Dyax Corp., Genetastix Corporation and MorphoSys AG to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, MedImmune, Amgen, Biogen Idec Inc., Novartis, Genentech, Protein Design Labs, Inc., Wyeth, Abbott Laboratories and Corixa have generated therapeutic products that are currently in development or on the market and that are derived from recombinant DNA that comprise human antibody components.

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

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

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

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

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

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

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

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

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

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

- delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;
- warning letters;
- fines;
- import and/or export restrictions;
- product recalls or seizures;
- injunctions;



- total or partial suspension of production;
- civil penalties;
- withdrawals of previously approved marketing applications or licenses;
- recommendations by the FDA or other regulatory authorities against governmental contracts; and
- criminal prosecutions.

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

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

Following completion of clinical trials, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of a BLA, or a New Drug Application, or NDA, in order to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to a BLA or NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study or reporting requirements or other restrictions on product distribution, or may deny the application. The timing of final FDA review and action varies greatly, but can take years in some cases and often involves the input of an FDA advisory committee of outside experts. Product sales in the U.S. may commence only when a BLA or NDA is approved.

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

Product candidates that appear promising in the early phases of development, such as in early human clinical trials, may fail to reach the market for a number of reasons, such as the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results; the product candidate was not effective in treating the specified disease or condition; the product candidate had harmful side effects on humans or presented unacceptable safety risks; the governing regulatory authorities (such as the FDA) denied approval to the product candidate altogether or denied a commercially important indicated use; the product candidate was not economical for us to manufacture; and/or the product candidate was not cost effective in light of alternative therapies. We cannot guarantee that we will ever be able to produce commercially successful products.

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

We will depend on our own manufacturing facilities and on those of our partners and other third parties to manufacture products generated through the use of our human antibody technology. Before commercializing a new drug, manufacturers must demonstrate compliance with the applicable current good manufacturing practices, or cGMP, requirements which include quality control and quality assurance

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

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

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

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to FDA's current good manufacturing practice requirements. Application holders must obtain FDA approval for product, manufacturing, and labeling changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veteran's Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

There is no such abbreviated approval process under current law for biological products approved under the Public Health Service Act through a BLA, such as monoclonal antibodies, cytokines, growth factors, enzymes, interferons and certain other proteins. However, various proposals have been made to establish an abbreviated approval process to permit approval of generic or follow-on versions of these types of biological products. The proposals include proposals for legislation, and proposals for FDA to extend its existing authority to this area. For example, some have proposed that FDA allow a generic or follow-on copy of certain therapeutic biologics to be approved under the Public Health Service Act or under an existing mechanism known as a 505(b)(2) application. A 505(b)(2) application is a form of a New Drug Application, or NDA, where the applicant does not have a right to reference some of the data being relied upon for approval. Under current regulations, 505(b)(2) applications can be used where the applicant is relying in part on published literature or on findings of safety or effectiveness in another company's NDA.

505(b)(2) has not been used to date for therapeutic biologic products. In addition, the use of 505(b)(2) applications even for conventional chemical drug products is the subject of an ongoing legal challenge. It is thus not clear what the permitted use of a 505(b)(2) application might be in the future for biologics products, or whether any other proposals on generic or follow-on biologics will be adopted. However, if the law is changed or if FDA somehow extends its existing authority in new ways, and third parties are permitted to obtain approvals of versions of our products through an abbreviated approval mechanism, and without conducting full clinical studies of their own, it could adversely effect our business. Such products would be significantly less costly than ours to bring to market, and could lead to the existence of multiple lower priced competitive products. This would substantially limit our ability to obtain a return on the investments we have made in those products.

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

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

**Our stock price may be volatile.**

There has been significant volatility in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- fluctuations in our operating results;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- published reports by securities analysts;
- progress with clinical trials;
- governmental regulation;
- developments in patent or other proprietary rights;
- developments in our relationship with collaborative partners;



- public concern as to the safety and effectiveness of our products; and
- general market conditions.

During the two-year period ended December 31, 2004, the sale prices of our common stock ranged between \$2.69 and \$11.55. The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these or other factors, including the sale or attempted sale of a large amount of our common stock into the market. Broad market fluctuations may also adversely affect the market price of our common stock.

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

As of February 28, 2005, we had 14,394,964 shares of common stock reserved for issuance pursuant to options and other stock based awards which had been granted under our stock option plans having a weighted average exercise price of \$7.88 per share and we had reserved 886,313 shares of common stock for issuance pursuant to future grants of options under our stock option plans. We have filed registration statements on Form S-8 under the Securities Act covering all of these shares. Shares issued pursuant to these plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

In addition, as of that date, there were 102,915 shares reserved for issuance pursuant to a deferred compensation plan. The shares reserved for the deferred compensation plan will be issued in various amounts over various periods of time during the next three years. We have filed a registration statement on Form S-8 under the Securities Act covering those shares. Shares issued pursuant to this plan, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

As of February 28, 2005, we had reserved 1,000,978 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, 2005, we had 10,936,935 shares of common stock reserved for the issuance pursuant to the conversion of the \$150.0 million aggregate principal amount of our outstanding 2.25% Convertible Senior Notes due May 15, 2011. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or redemption by us at a conversion rate of 72.9129 shares per each \$1,000 principal amount of the notes (\$13.72 per share), subject to adjustment.

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

As of February 28, 2005, we had 110,529,979 shares of common stock outstanding, of which 9,374,318 are restricted securities as that term is defined in Rule 144 under the Securities Act. Under certain circumstances, these restricted securities may be sold without registration pursuant to such rule. We are unable to predict the effect that sales made under Rule 144 or pursuant to any registration may have on the market price of our common stock. The sale of a significant number of additional securities, or even the possibility thereof, may lower the market price of our common stock.

We have filed a registration statement on Form S-3 under the Securities Act relating to 3,791,346 shares of common stock that may be offered by one of our shareholders. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitations of Rule 144.

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

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

We have also filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of up to 7,214,345 shares of our common stock which were issued upon the conversion of our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010 in connection with the provisional redemption of such notes in January 2005. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144. We also have filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of up to 3,272,091 shares of our common stock which were issued on the conversion of all of our \$21.986 million 4.25% Convertible Senior Notes due August 15, 2010, in connection with the provisional redemption of such notes in January 2005. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144. In connection therewith, we have agreed to use our best efforts to keep these registration statements continuously effective until the earliest of (i) the sale of all outstanding registrable securities registered under the registration statements; (ii) the expiration of the period referred to in Rule 144(k) of the Securities Act with respect to the notes held by non-affiliates of us; (iii) all the registrable securities have ceased to be outstanding (whether as a result of repurchase or otherwise); and (iv) two years after the respective effective dates of these registration statements.

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

We have filed a registration statement on Form S-4 under the Securities Act to register shares of our common stock having a maximum aggregate offering price of \$12.0 million. Such shares are freely tradable without restriction or further registration under the Securities Act. On August 5, 2004 we issued 731,823 shares of such common stock, valued at approximately \$4.3 million to satisfy a portion of the purchase price in connection with the acquisition of Ability Biomedical Corporation. This registration statement on Form S-4 under the Securities Act remains available for the sale of up to \$7.7 million of our common stock.

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

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our outstanding 2.25% Convertible Senior Notes due May 11, 2011. As of February 28, 2005, \$150.0 million aggregate principal amount of these notes was outstanding. In each instance, we may pay the repurchase price in cash or, at our option, in common stock. These change of control events

include, without limitation, (i) the acquisition by any third party of at least 50% of our common stock; or (ii) our merger or consolidation with or into any other person, any merger or consolidation of another person into us or our sale or other disposal of all or substantially all of our assets, except in certain limited circumstances provided in the indentures relating to the notes. Such repurchase rights may be triggered at a time at which we do not have sufficient funds available to pay the repurchase price in cash or determine that payment in cash is otherwise inadvisable. In such event, the issuance of a significant number of additional shares of common stock in payment of the repurchase price may lower the market price of our common stock.

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

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

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

- a classified board of directors;
- a requirement that special meetings of shareholders be called only by our board of directors, chairman of the board, chief executive officer or president;
- advance notice requirements for shareholder proposals and nominations;
- limitations on the ability of shareholders to amend, alter or repeal our by-laws; and
- the authority of the board of directors to issue, without shareholder approval, preferred stock with such terms as the board of directors may determine.

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

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

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

**Legislative and regulatory actions, NASDAQ rules and potential new accounting pronouncements may impact our future financial position or results of operations.**

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ National Market rules, are creating uncertainty with respect to, among other things, the enforcement of these new standards and the potential effect thereof for companies such as ours. Investments required to comply with changes in SEC, NASDAQ and accounting rules may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future.

**Item 2. Properties**

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

**Leased/Owned Properties**

Location	Leased/Owned	Square Feet	Use	Lease Expiration Date
Annandale, New Jersey	Leased	45,000	Laboratory, Office	2008
Bloomsbury, New Jersey	Owned	165,000	Laboratory, Office	N/A
Milpitas, California	Owned	60,000	Laboratory, Office	N/A
Sunnyvale, California	Leased	37,000	Laboratory, Office	2009
Princeton, New Jersey	Leased	20,000	Corporate Headquarters, Office	2006

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 our current legal proceedings, individually or in the aggregate, will have a material adverse effect on our operations or financial condition.

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

There were no matters submitted to a vote of security holders during the last quarter of the year ended December 31, 2004, through the solicitation of proxies or otherwise.

**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 Price</b>	
	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2003</b>		
First Quarter	\$ 4.36	\$ 2.69
Second Quarter	\$ 7.35	\$ 3.15
Third Quarter	\$ 7.67	\$ 4.48
Fourth Quarter	\$ 7.56	\$ 5.78
<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

The number of shares of our common stock outstanding as of February 28, 2005 was 110,529,979. As of February 28, 2005, there were approximately 600 record holders of our common stock. As of March 22, 2004, the record date for our last Annual Meeting of Shareholders held on May 19, 2004, there were approximately 600 record holders of common stock (which includes individual holders) and approximately 32,447 beneficial shareholders of 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 herein will be reported in our definitive Proxy Statement for the Annual Meeting of Shareholders which we expect will be filed on or before April 29, 2005, and is incorporated herein by reference.

## Item 6. Selected Consolidated Financial Data

	For the Year Ended December 31,				
	2000	2001	2002	2003	2004
	(Dollars in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenues:					
Sales	\$ 264	\$ 191	\$ 176	\$ 25	\$
Contract and license revenues	19,619	37,140	24,552	5,833	9,119
Sales, contract and license revenues from Genmab	2,574	4,973	14,751	5,316	3,355
Total revenues	22,457	42,304	39,479	11,174	12,474
Costs and expenses:					
Cost of sales	1,189	642	8,327	3	
Research and development	33,942	38,626	82,626	95,459	122,007
General and administrative	18,142	19,344	22,852	21,727	24,314
Write-off of facility costs			11,294		
Acquisition of in-process technology			16,312	6,500	5,455
Total costs and expenses	53,273	58,612	141,411	123,689	151,776
Operating loss	(30,816 )	(16,308 )	(101,932 )	(112,515 )	(139,302 )
Equity in net loss of affiliate	(353 )	(7,334 )	(50,625 )	(14,997 )	(19,791 )
Interest and dividend income	21,158	24,728	18,495	12,342	7,145
Impairment loss on investments in partners			(11,886 )	(1,400 )	(7,309 )
Additional (payments) receipts related to asset acquisition			(2,425 )	(31 )	16
Interest expense	(3 )	(4,615 )	(9,065 )	(11,777 )	(12,845 )
Debt conversion expense					(10,151 )
Net loss on extinguishment of debt					(4,241 )
Gain on disposition of Genmab stock		1,442			
Loss before provision (benefit) for income taxes	(10,014 )	(2,087 )	(157,438 )	(128,378 )	(186,478 )
Provision (benefit) for income taxes	(13,075 )	600	103	69	31
Income (loss) before cumulative effect of change in accounting principle	3,061	(2,687 )	(157,541 )	(128,447 )	(186,509 )
Cumulative effect of change in accounting principle				(830 )	
Net income (loss)	\$ 3,061	\$ (2,687 )	\$ (157,541 )	\$ (129,277 )	\$ (186,509 )
Basic and diluted net income (loss) per share(1):					
Income (loss) before cumulative effect of change in accounting principle	\$ 0.04	\$ (0.04 )	\$ (2.09 )	\$ (1.64 )	\$ (2.29 )
Cumulative effect of change in accounting principle				(0.01 )	
Net income (loss)	\$ 0.04	\$ (0.04 )	\$ (2.09 )	\$ (1.65 )	\$ (2.29 )
Weighted average common shares outstanding(1)					
basic	71,532	73,937	75,231	78,314	81,494
diluted	73,232	73,937	75,231	78,314	81,494

	December 31,				
	2000	2001	2002	2003	2004
	(Dollars in thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$ 343,603	\$ 466,952	\$ 350,046	\$ 358,458	\$ 374,507
Working capital	329,807	447,326	339,480	350,437	341,110
Total assets	558,107	720,427	549,051	557,726	549,345
Long term obligations		175,000	175,000	300,000	296,986
Cash dividends declared per common share					
Accumulated deficit	(123,375 )	(126,062 )	(283,603 )	(412,880 )	(599,389 )
Total shareholders' equity	485,289	482,562	352,143	234,011	107,389

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

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

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

**Overview**

We are a biopharmaceutical company focused on the discovery, development and 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, 22 antibody products generated from our UltiMAB Human Antibody Development System are in human clinical trials. These antibodies are designed to treat a wide range of diseases, such as cancer, rheumatoid arthritis and other inflammatory, autoimmune and infectious diseases. The most advanced of these products is MDX-010 (currently in Phase III, Phase II and Phase I clinical trials), which we are developing jointly with Bristol-Myers Squibb Company, or BMS, for the treatment of metastatic melanoma and other cancers. Four of these antibody products are fully owned by Medarex and its affiliates: MDX-060 for lymphomas (Phase II clinical trial), MDX-070 for prostate cancer (Phase II clinical trial), MDX-214 for cancer (Phase I/II clinical trial) and MDX-1307 for genitourinary and breast cancers (Phase I clinical trial). We are also developing MDX-066 (Phase I clinical trial) jointly with The Massachusetts Biologic Laboratories for the treatment of *Clostridium difficile* associated diarrhea. Another antibody, MDX-018 (Phase I/II clinical trial), is being jointly developed with Genmab A/S for autoimmune disease, and three are being developed separately by Genmab: HuMax-CD4 (Phase II clinical trials) for T-cell lymphomas, HuMax-EGFr (Phase I/II clinical trial) for head and neck cancer and HuMax-CD20 (Phase I/II clinical trial) for lymphomas. Genmab and Amgen, Inc. are developing AMG 714 (Phase II clinical trial) for rheumatoid arthritis. Additionally, other licensing partners, including Novartis Pharma AG, Eli Lilly and Company, and Centocor, Inc. (a subsidiary of Johnson & Johnson), are developing a total of ten antibody products, for inflammatory and/or autoimmune diseases and cancer, that are currently in early clinical trials. Human Genome Sciences, Inc. has also announced the initiation of a Phase I trial of one anticancer antibody product developed pursuant to a licensing agreement with our partner Kirin Brewery Co., Ltd. We and our partners also have a number of UltiMAB® product candidates in preclinical development. The preceding information regarding the clinical status of antibody products is based on our and our partners' public disclosure and other publicly available information.

Our revenue is principally 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, 2004, we had an accumulated deficit of approximately \$599.4 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.
- We receive research fees from the licensing of our proprietary technologies for research and development performed by our customers and partners. Revenue from these research fees is recognized generally over the term of the respective license period beginning only after both the license period has begun and the technology has been delivered.



- We receive fees for product development services (including manufacturing) we perform for our customers and partners. These fees are recognized ratably over the entire period during which the services are performed.
- Revenue from milestone payments is recognized when each milestone is achieved and when collectibility of such milestone payment is assured. Milestone payments are triggered either by the results of our research efforts or by the efforts of our partners and include such events as submission of an Investigational New Drug Application, or IND, commencement of Phase I, II or III clinical trials, submission of a Biologic License Application, or BLA, and approval of a product. Milestone payments are substantially at risk at the inception of an agreement. Upon achievement of a milestone event, we have no future performance obligations relating to that event.
- Revenue arrangements that include multiple deliverables, are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.

#### ***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 represented approximately 1.5% of total marketable securities as of December 31, 2003 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 separate line items in our consolidated balance sheet entitled Investments in IDM and Investments in, and advances to, other partners and were approximately \$51.7 million as of December 31, 2004. 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, the 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 is 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, 2002, 2003 and 2004*

#### *Contract and License Revenues*

Contract and license revenues totaled \$24.6 million, \$5.8 million and \$9.1 million for the years ended December 31, 2002, 2003 and 2004, respectively. Contract and license revenues for 2003 decreased by \$18.7 million or 76% as compared to 2002. This decrease relates principally to a decrease in revenue from Immuno-Design Molecules, S.A., or IDM, of \$14.3 million as a result of the completion of the recognition of revenue associated with the transfer of technology to IDM in July 2000, as well as a decrease in revenue of \$3.4 million from Eli Lilly and Company. 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, Inc. which was executed in September 2004 and approximately \$0.6 million of revenue from the National Institutes of Health 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.

#### *Sales, Contract and License Revenues from Genmab*

Sales, contract and license revenues from Genmab A/S were \$14.8 million, \$5.3 million and \$3.4 million for the years ended December 31, 2002, 2003 and 2004, respectively. Sales, contract and license revenues from Genmab for 2003 decreased by \$9.4 million or 64% as compared to 2002. In 2002 there were sales of MDX-CD4 and MDX-015 totaling \$11.4 million in order to support Genmab's clinical trials. There were no sales of such material to Genmab in 2003 or 2004. The 2003 decrease was offset, in part, by increased contract and license revenues related principally to an increased number of research licenses and antibody exclusive licenses requested by and granted to Genmab. Sales, contract and license revenues from Genmab for 2004 decreased by \$2.0 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.

#### *Cost of Sales*

Cost of sales were \$8.3 million, \$3 thousand and \$0 for the years ended December 31, 2002, 2003 and 2004, respectively. Cost of sales in 2003 decreased by \$8.3 million, as compared to 2002. The decrease is the result of no sales of MDX-CD4 and MDX-015 to Genmab in 2003 as discussed above.

#### *Research and Development Expenses*

Research and development expenses for our products in development were \$82.6 million, \$95.5 million and \$122.0 million for the years ended December 31, 2002, 2003 and 2004, respectively. Research and development expenses in 2003 increased by \$12.8 million, or 16% as compared to 2002 and research and development expenses in 2004 increased by \$26.5 million, or 28% as compared to 2003. Historically, due to the relatively small number of our products in clinical trials, we have not accounted for our research and development expenses on a project-by-project basis and, therefore, we do not provide a breakdown of such historical information in that format. We have, historically, tracked our costs in the categories discussed below, namely, research and product development and by the types of costs as outlined below.

Our research costs consist of costs associated with the breeding, care and continued development of our HuMAb-Mouse and KM-Mouse, as well as costs associated with research and testing of our product candidates prior to reaching the preclinical stage. Such research costs primarily include personnel costs,

facilities (including depreciation), research supplies, funding of outside research and license and technology access fees.

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

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

	Year Ended December 31,		
	2002	2003	2004
Research	\$ 34,659	\$ 37,495	\$ 53,284
Product Development	47,967	57,964	68,723
Total	\$ 82,626	\$ 95,459	\$ 122,007

### Research Costs

Research costs in 2003 increased by \$2.8 million, or 8% as compared to 2002. Research costs in 2004 increased by \$15.8 million, or 42% as compared to 2003. The increases in research costs primarily relate to the following.

- Personnel costs in 2003 were \$12.7 million, an increase of \$2.6 million or 25% as compared to 2002. 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. 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 payments were made in 2002 and 2003. The total consideration of \$8.5 million is being paid to Gilead in eight equal quarterly installments. The first two of these payments were made in 2004. As of December 31, 2004, approximately \$6.4 million (six installments) remained due to Gilead under this obligation (see further discussion under the section herein entitled *Other Liquidity Matters* ).
- Facility costs in 2003 were \$7.5 million, an increase of \$2.3 million or 44% as compared to 2002. Facility costs in 2004 were \$8.7 million, an increase of \$1.2 million or 15% as compared to 2003. The increase in facility costs primarily relates to the substantial investments made in our research facilities in recent years. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for 2003, as compared to 2002, and for 2004, as compared to 2003. We expect to incur increased facility costs as a result of continued capital expansion, renovations and replacements.
- License and technology access fees in 2003 were \$3.1 million, a decrease of \$4.1 million or 58% as compared to 2002. License and technology access fees in 2004 were \$6.9 million, an increase of \$3.8 million or 125% as compared to 2003. These costs represent fees paid to certain partners and research organizations in connection with certain of our collaboration and license agreements. 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.



***Product Development Costs***

Product development costs in 2003 increased by \$10.0 million, or 21% as compared to 2002. Product development costs increased by \$10.8 million in 2004, or 19% as compared to 2003. The increases in product development costs primarily relate to the following:

- Contract manufacturing costs in 2003 were \$0.7 million, an increase of \$0.7 million or 100% as compared to 2002. 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 MDX-010 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 2003 were \$20.6 million, an increase of \$2.5 million or 14% as compared to 2002. 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 MDX-010. 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 products through clinical trials.
- Facility costs in 2003 were \$12.6 million, an increase of \$1.8 million or 16% as compared to 2002. Facility costs in 2004 were \$13.1 million, an increase of \$0.5 million or 4% as compared to 2003. The increase in facility costs primarily relates to the substantial investments made in our product development facilities in recent years. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for each of 2003 and 2004, as compared to prior year periods. We expect to continue to incur increased facility costs as a result of continued capital expansion, renovations and replacements.
- Supply costs in 2003 were \$5.7 million, a decrease of \$4.3 million or 44% as compared to 2002. In 2002 we manufactured larger quantities of material for Phase I and Phase II clinical trials for ourselves and our partners resulting in a significant increase in supply costs. Supply costs in 2004 were \$4.6 million, a decrease of \$1.1 million or 19% as compared to 2003. 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 and small equipment 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 2003 were \$4.7 million, an increase of \$3.1 million or 190% as compared to 2002 primarily as a result of an increase in the number of ongoing clinical trials particularly for MDX-010 and MDX-060. Clinical research fees in 2004 were also \$4.7 million, representing the conclusion of certain Phase II clinical trials for MDX-010 offset by the initiation of the Phase III clinical trial for MDX-010 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.

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

Clinical Phase	Estimated Completion Period
Phase I	1-2 Years
Phase II	1-2 Years
Phase III	2-4 Years

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

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

We continue to explore new collaborative arrangements that may affect future spending for research and development. As part of our partnering strategy, a significant portion of the research and development expenses incurred in connection with products using our technology is expected to be borne by our partners. We believe this allows us to participate in the research and development of substantially more potential product candidates than we could develop on our own if we bore the entire cost of development. 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 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 \$22.9 million, \$21.7 million and \$24.3 million for the years ended December 31, 2002, 2003 and 2004, respectively. General and administrative expenses decreased by \$1.1 million in 2003, or 5% as compared to 2002. The 2003 decrease was generally attributable to a reduction in legal fees of \$2.3 million primarily as a result of the completion of the negotiation and execution of our collaboration and license agreement with Kirin in 2002, and decreased consulting fees of \$0.6 million, partially offset by higher personnel costs of \$1.5 million. 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 in 2004. General and administrative expenses are expected to increase in the future as our products are developed and we expand our business activities.

***Write-off of Facility Costs***

Write-off of facility costs in 2002 relates to a determination we made to delay indefinitely the planned construction of a large scale manufacturing facility at our Bloomsbury, New Jersey, location and to pursue late-stage clinical and commercial supply agreements with third party manufacturers with available capacity to meet our current internal production timetables. As a result of this decision, we recorded a charge of \$11.3 million in 2002, representing the write-off of design, engineering and other pre-construction costs. We believe that our existing facility in Annandale, New Jersey, is adequate for the production of materials for clinical trials of our products and for providing support we offer 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 MDX-010 and MDX-060, and, together with our partner BMS, we are pursuing ongoing discussions with respect to terms of a commercial supply agreement for MDX-010.

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

Acquisition of in-process technology for the year ended December 31, 2002, related to our acquisition of certain assets (including certain preclinical product candidates and programs related to the research and development of therapeutic products for the treatment of autoimmune disorders, cancer and infectious diseases) of Corixa Corporation in May 2002. The total cost of the acquisition (including transaction costs), discussed more fully under the section herein entitled Liquidity and Capital Resources, was \$21.4 million. Based upon an independent third-party valuation, in 2002, \$16.3 million of the cost of the acquisition was charged to operations as acquisition of in-process technology.

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, whose license agreement we acquired as part of the May 2002 asset acquisition. 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.

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.

***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, 2002, 2003 and 2004. Genmab is an affiliated company and is accounted for using the equity method of accounting (see Note 12 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. We expect that during the first quarter of 2005 the remaining basis of our investment in Genmab will be reduced to zero and, accordingly, recognition of our share of Genmab's net losses will be suspended.

Equity in net loss of affiliate was \$50.6 million, \$15.0 million and \$19.8 million for the years ended December 31, 2002, 2003 and 2004, respectively. Equity in net loss of affiliate in 2003 decreased by \$35.6 million or 70% as compared to 2002. Included in equity in net loss of affiliate for 2002 is in an impairment



loss on our investment in Genmab of \$31.0 million resulting from an approximate 60% decrease in the market value of Genmab's stock following Genmab's September 24, 2002, press release in which it announced that its HuMax-CD4 product, a fully human antibody that targets CD4 receptors on cells known as T-cells was found not to be effective in combination with methotrexate in a Phase II study of 155 patients with active rheumatoid arthritis. We recorded the \$31.0 million impairment charge in the third quarter of 2002 as a result of the decrease in the market price of the Genmab stock, which was deemed to be other than temporary at the time. If we deem our investment in Genmab to be further impaired at the end of any future period, we may incur an additional impairment charge on this investment. Excluding the impact of the impairment in 2002, equity in net loss of affiliate would have decreased by \$4.6 million or 23% as compared to 2002. This decrease was the result of a decrease in Genmab's net loss for 2003, primarily as a result of the recognition of \$10.5 million of milestone revenue by Genmab during 2003.

On July 6, 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 additional equity raised 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. 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 the 2004 private placement, and therefore a reduction of our share of Genmab's net loss for the second half of 2004.

#### ***Interest and Dividend Income***

Interest and dividend income consists primarily of interest earned from our cash, cash equivalents and marketable securities. Interest and dividend income was \$18.5 million, \$12.3 million and \$7.1 million for the years ended December 31, 2002, 2003 and 2004, respectively. Interest and dividend income in 2003 decreased by \$6.2 million, or 33% as compared to 2002. The decrease reflects lower returns on our investment portfolio and a reduction in the size of our average cash balances invested, which, on average, were also lower during the period. Interest and dividend income in 2004 decreased by \$5.2 million, or 42% 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***

In the course of our business we may make investments in companies (both public and private) as part of strategic collaborations. We recorded impairment charges of \$9.5 million, \$0 and \$0.2 million for the years ended December 31, 2002, 2003 and 2004, respectively related to investments in certain of our partners (other than Genmab) whose securities are publicly traded. The 2002 impairment charge was the result of certain investments trading below their original cost basis for more than six months. 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 inherently more difficult to estimate than investments in publicly traded companies. We recorded impairment charges of \$2.4 million, \$1.4 million and \$7.1 million for the years ended December 31, 2002, 2003 and 2004, respectively, related to investments in certain of our partners whose securities are not publicly traded. 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.

***Additional Payments (Receipts) Related to Asset Acquisitions***

Additional payments (receipts) related to asset acquisition of \$2.4 million, \$31 thousand and (\$16) thousand for the years ended December 31, 2002, 2003 and 2004, respectively, represent net additional purchase payments (receipts) to Northwest Biotherapeutics, Millennium Pharmaceuticals and Corixa in 2002, to Northwest Biotherapeutics in 2003 and to Gilead, Pharma Pacific and Ability Biomedical shareholders in 2004. Pursuant to the terms of our agreements with these companies, under certain circumstances we were required to pay (or to receive) an amount equal to the difference between the proceeds received by these companies from the sale of any shares of our common stock delivered as payment of any installment of the purchase price of the assets and the total amount of the purchase price installment due under the agreements.

***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 \$9.1 million, \$11.8 million and \$12.8 million for the years ended December 31, 2002, 2003 and 2004, respectively. Interest expense in 2003 increased by \$2.7 million, or 30% as compared to 2002 reflecting the addition of approximately five months of accrued interest on our 4.25% notes. 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 of 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. We expect interest expense to decrease in the future as a result of the redemption, repurchase and cancellation of the 4.50% Notes and the January 2005 conversion of our 4.25% notes (see further explanation under the section entitled *Other Liquidity Matters* ).

***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, 2002 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. 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 \$0.1 million, \$0.1 million and \$31 thousand for the years ended December 31, 2002, 2003 and 2004, respectively, relates primarily to the New Jersey alternative minimum tax assessment which became effective in 2002.

#### ***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 2002, 2003, and 2004, we received net proceeds of \$301.1 million from sales of our equity and debt securities.

At December 31, 2003 and 2004, we had \$358.5 million and \$374.5 million, respectively, in cash, cash equivalents and marketable securities. We primarily invest our cash equivalents and marketable securities in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

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

Cash used in operating activities was \$64.0 million, \$89.3 million and \$6.0 million for the years ended December 31, 2002, 2003 and 2004, respectively. This reflects an increase of \$25.3 million in 2003 as compared to 2002 and a decrease of \$83.3 million in 2004 as compared to 2003.

The 2003 increase was primarily due to higher research and development expenses (approximately \$12.8 million) related to the development of our product pipeline, a decrease in interest and dividend income (approximately \$6.2 million) due to lower interest rates as well as lower average cash balances and an increase in interest expense (approximately \$2.7 million) representing the addition of approximately five months of interest on our 4.25% notes which were issued in July 2003. 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, 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, but at a reduced rate. To a lesser extent, we expect our general and administrative costs to increase as we expand our administrative and business development activities. Furthermore, we expect our investment income to decrease as we fund our future operations and capital expenditures from our cash reserves. We anticipate that our operating expenditures may be partially offset by revenues from partners for license fees, milestone payments, and development and manufacturing services.

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

Net cash provided by investing activities was \$93.9 million in 2002. Net cash used in investing activities was \$22.6 million in 2003 and \$33.8 million in 2004, respectively. Cash was provided by and used in investing activities primarily as follows:

- Capital expenditures of \$43.7 million, \$8.9 million and \$9.1 million in 2002, 2003 and 2004, respectively. Capital spending in 2002 reflects an investment in building improvements related to the expansion of our Milpitas, California, facility as well as leasehold improvements and the purchase of machinery, equipment and furniture and fixtures for our Sunnyvale, California, facility, which we leased in July 2002. The capital expenditures in 2003 and 2004 reflect an investment in laboratory automation as well as the addition of machinery and equipment.
- Net sales of marketable securities were \$136.7 million and \$3.2 million in 2002 and 2003, respectively. The net sales of marketable securities in 2002 were primarily to fund operations and capital expenditures. 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*.

We expect 2005 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 \$0.6 million, \$123.0 million and \$31.6 million in 2002, 2003 and 2004, respectively. In 2002, cash provided by financing activities consisted primarily of proceeds received from the issuance of stock under our employee stock purchase plan of \$0.5 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 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 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 has been classified as segregated securities in the current assets section of our December 31, 2004, consolidated balance sheet.

On January 14, 2005, we completed the provisional redemption of all of our 4.25% notes which was previously announced in December 2004. Holders of all of the outstanding 4.25% notes (\$146.986 million) converted their notes into a total of 21,875,353 shares of our common stock prior to the redemption date. In connection with the redemption, we paid approximately \$12.5 million in cash 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, 2004, we had federal net operating loss (NOL) carryforwards of approximately \$426.6 million. These NOL carryforwards will expire in the years 2005-2024 (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 carryforward credits before utilization. At December 31, 2004 the amount of NOL subject to the limitation was \$43.8 million and the amount not subject to limitation was \$382.8 million.

In connection with our merger with Essex Medical Products in 1987, we are committed to pay to Essex Chemical Corporation, or Essex, 20% of our net after-tax income until a total of \$1.0 million has been paid, contingent upon the occurrence of certain events. As the result of our net income in 2000 we accrued \$0.7 million payable to Essex, which remains accrued at December 31, 2004. At our option, this obligation may be satisfied by the payment of shares of our common stock having a fair market value equal to the amount owed, provided such shares are registered for sale with the Securities and Exchange Commission.

Our wholly-owned subsidiary Celldex Therapeutics, Inc. has filed a registration statement with the Securities and Exchange Commission related to a proposed initial public offering of a portion of its common stock. As part of this transaction, we have assigned or licensed to Celldex certain intellectual property related to our vaccine technology, including the rights to MDX-1307, one of our product candidates for the treatment of cancer, as well as the IND associated with this product which became effective in February 2004. If the initial public offering is completed, we anticipate that we will continue to hold approximately 70% of the outstanding shares of common stock of Celldex. We cannot assure you that this transaction will be consummated.

In July 2004, we entered into an amendment to a collaboration and license agreement with Gilead, 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 payment was made on January 3, 2005 in cash. The five remaining payments will be made on a quarterly basis, commencing on April 1, 2005 and ending on April 3, 2006. If we decide to make a quarterly installment payment in shares of our common stock, the number of shares of common stock subject to issuance for any installment will be determined by dividing (x) \$1.063 million (less any cash paid in connection with the installment) by (y) the average of the closing sales prices of our common stock for

each of the trading days during the five-trading-day period ending on (and including) the trading day that is two trading days immediately prior to the applicable date of issuance as publicly reported by NASDAQ. In the event that, during the 60-day period following the applicable date of issuance of such common stock, Gilead sells all of the shares of our common stock delivered as part of an installment payment under the Gilead License and the proceeds of such sale are less than \$1.063 million (less any cash paid in connection with such installment), we must pay the difference to Gilead in cash. If such sale proceeds exceed \$1.063 million (less any cash paid in connection with such installment), Gilead must pay us 50% of any such excess in cash. In the event that, during any such 60-day period, Gilead does not sell all of the shares of our common stock comprising the installment, there will be no such adjustment. In August 2004, we paid Gilead approximately \$0.1 million representing the difference between the proceeds received by Gilead upon the sale of the 185,622 shares of common stock and the initial payment of \$1.063 million.

In August 2004, we completed the acquisition of all of the outstanding capital stock not already owned by us of Ability Biomedical. 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. During the 60-day period following an issuance of shares of our common stock to the Ability Biomedical shareholders in connection with the acquisition, certain of such shareholders sold all of the shares 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, we received approximately \$0.1 million representing 50% of the difference between the actual proceeds received and the amount due under the share purchase agreement.

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 \$3.68 million in cash and/or common stock subject to fluctuations in currency exchange rates. In lieu of such additional payment, we also have the option to revert to the original joint collaboration agreement with the former shareholders of Ability Biomedical whereby each party would be responsible for 50% of the costs associated with the anti-IP-10 antibody.

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 and the per share price represented a premium to market price at the time we entered into the collaboration.

In November 2004, we announced a collaboration and co-promotion agreement and a related securities purchase agreement with BMS. This collaboration became effective in January 2005. Under the terms of the collaboration, we and BMS have 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 MDX-010, a fully human antibody product developed using our UltiMAb Human Antibody Development System, that is antagonistic to CTLA-4. MDX-010 is currently under investigation for the treatment of a broad range of cancers and other diseases. The collaboration also includes the grant by us to BMS of a sub-license to MDX-1379, a gp100 peptide vaccine licensed by us from the U.S. Public Health Service, for use with MDX-010 for the treatment of metastatic melanoma. We and BMS are currently conducting a Phase III clinical trial with MDX-010 and MDX-1379 combination therapy in Stage III and Stage IV metastatic melanoma patients at multiple sites within the U.S.

As part of the collaboration, we and BMS have committed to an initial multi-year budget of approximately \$192.0 million to fund the development of MDX-010 as a potential treatment for a broad range of cancers. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the U.S. and Europe, with the remaining 35% to be paid by us. We and BMS will share equally the costs of any clinical trials of 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 premium to the market price on the date we entered into the collaboration. BMS has agreed to a two-year lock-up period with respect to any sales of such stock. We have no future obligation to register such stock.

### **Contractual Obligations**

Our material contractual obligations under lease, debt and research funding agreements for the next five years, and thereafter, as of December 31, 2004, are as follows:

	Payments Due by Period				Total
	Less Than 1 Year (in thousands)	1-3 Years	4-5 Years	After 5 Years	
<b>Contractual Obligations(1)</b>					
Convertible notes(2)	\$	\$	\$	\$ 296,986	\$ 296,986
Research funding	3,542	6,185	2,435	93	12,255
Operating leases and other	3,250	5,059	2,831		11,140
<b>Total contractual cash obligations</b>	<b>\$ 6,792</b>	<b>\$ 11,244</b>	<b>\$ 5,266</b>	<b>\$ 297,079</b>	<b>\$ 320,381</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, (d) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above and (e) any obligations related to the collaboration with BMS which became effective in January 2005.

(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. In January 2005, we completed the 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. The aggregate amount of convertible notes outstanding in this table does not reflect the redemption of the 4.25% notes.

***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 are exchanging cross-licenses with Kirin with respect to the KM-Mouse and other antibody-generating mice. In addition, certain of the cross-licenses granted under the Collaboration and License Agreement are subject to license, milestone and royalty payments by one party to the other.

Through December 31, 2004, we have not made any milestone payments to Kirin although approximately \$1.9 million has been accrued as of December 31, 2004 representing a payment due Kirin as a result of our collaboration with Pfizer. Based on a total of two products we are developing which use or, we believe may use, Kirin technology that (i) are currently in clinical trials, or (ii) we anticipate may enter clinical trials through the end of 2005, we may be required to make milestone payments to Kirin aggregating up to approximately \$8.5 million with respect to such products, or a maximum of approximately \$4.25 million per product. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

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

We have also entered into a number of other agreements that contain licenses of third-party technology which may be used together with our own platform technologies for the generation, development and/or manufacture of our antibody products. In addition, we have entered into other third-party agreements that contain licenses associated with antibody products that target specific antigens. Many of these agreements contain milestone payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization

events occur. Not all of our products currently under development trigger such milestone payments. Through December 31, 2004, we had made milestone payments of approximately \$0.3 million under these agreements. In addition, under the agreements we currently have in place (other than with Kirin), based on a total of five products we are developing for which milestones are potentially due and that (i) are now in clinical trials, or (ii) which we anticipate may enter clinical trials before the end of 2006, we may be obligated to make future milestone payments aggregating up to approximately \$22.5 million with respect to such products. In general, potential milestone payments for our antibody products may or may not be triggered under these licenses, and may vary in size, depending on a number of variables, almost all of which are currently uncertain. Typically, the events that trigger these payments per product include:

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

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

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

Our current sources of liquidity are our cash, cash equivalents and marketable securities, interest and dividends earned on such cash, cash equivalents and marketable securities, contract and licensing revenue and sales of our products for research. We believe that such sources of liquidity will be sufficient to meet our operating, debt service, and capital requirements for at least the next 24 months. To the extent our 2.25% notes are converted into shares of our common stock on or before their maturity date, we will have use of that portion of the principal amount of the notes to fund our on-going operations. In any event, we may require additional financing within this time frame and may raise funds through public or private financings, line of credit arrangements, collaborative relationships and/or other methods. The use of cash on hand or other financial alternatives will depend on several factors including, but not limited to, the future success of our products in clinical development, the prevailing interest rate environment, and access to the capital markets. We cannot assure you that we will be able to raise such additional funds. We may be unable to raise sufficient funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

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

In December 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends Statement No. 95, *Statement of Cash Flows*. Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Historically, in accordance with SFAS 123 and SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, we 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 will be required to adopt Statement No. 123(R) no later than the quarter beginning July 1, 2005. We are currently in the process of evaluating the option valuation methods and adoption transition alternatives available under Statement 123(R). Although we have not yet determined the impact of Statement 123(R), it may be significant to our consolidated results of operations.

**Item 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.

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

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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, 2003 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, 2004. 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 did not audit the financial statements of Genmab A/S, a corporation in which Medarex has a 25% interest, which represents 2.0% and 0.3% of total assets as of December 31, 2003 and 2004, respectively, and equity in net loss of affiliate which constitutes 32% in 2002, 12% in 2003 and 10% in 2004 of pre-tax loss. Those statements were audited by other auditors whose report has been furnished to us and our opinion, insofar as it relates to the amounts included for Genmab A/S, is based solely on the report of other auditors.

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, 2003 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, 2004 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, 2004, 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 15, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey  
March 15, 2005

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

	<b>December 31,</b>	
	<b>2003</b>	<b>2004</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 72,998	\$ 64,843
Marketable securities	285,460	309,664
Segregated securities	5,617	12,301
Prepaid expenses and other current assets	6,244	6,708
Total current assets	370,319	393,516
Property, buildings and equipment:		
Land	6,624	6,795
Buildings and leasehold improvements	74,764	77,995
Machinery and equipment	37,006	43,077
Furniture and fixtures	4,081	4,290
Construction in progress	4,384	2,821
	126,859	134,978
Less accumulated depreciation and amortization	(31,494 )	(45,098 )
	95,365	89,880
Investment in Genmab	10,976	1,657
Investment in IDM	48,199	41,206
Investments in, and advances to, other partners	11,182	10,482
Segregated securities	11,579	1,700
Other assets	10,106	10,904
Total assets	\$ 557,726	\$ 549,345
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Trade accounts payable	\$ 2,197	\$ 4,998
Accrued liabilities	13,878	32,148
Deferred contract revenue - current	3,807	15,260
Total current liabilities	19,882	52,406
Deferred contract revenue - long-term	661	86,691
Other long-term liabilities	3,172	5,873
4.25% Convertible senior notes due August 15, 2010	125,000	146,986
2.25% Convertible senior notes due May 15, 2011		150,000
4.50% Convertible subordinated notes due July 1, 2006	175,000	
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, \$1.00 par value, 2,000,000 shares authorized; none issued and outstanding		
Common stock, \$.01 par value; 200,000,000 shares authorized; 79,501,080 shares issued and 79,007,564 outstanding at December 31, 2003 and 85,865,333 shares issued and 85,673,693 shares outstanding at December 31, 2004	795	859
Capital in excess of par value	639,784	699,380
Treasury stock, at cost 493,516 shares in 2003 and 191,640 shares in 2004	(1,242 )	(482 )
Deferred compensation	994	372
Accumulated other comprehensive income	6,560	6,649
Accumulated deficit	(412,880 )	(599,389 )
Total shareholders' equity	234,011	107,389
Total liabilities and shareholders' equity	\$ 557,726	\$ 549,345

See notes to these consolidated financial statements.

**MEDAREX, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

	<b>For the Year Ended</b>		
	<b>December 31,</b>		
	<b>2002</b>	<b>2003</b>	<b>2004</b>
Sales	\$ 176	\$ 25	\$
Contract and license revenues	24,552	5,833	9,119
Sales, contract and license revenues from Genmab	14,751	5,316	3,355
Total revenues	39,479	11,174	12,474
Costs and expenses:			
Cost of sales	8,327	3	
Research and development	82,626	95,459	122,007
General and administrative	22,852	21,727	24,314
Write-off of facility costs	11,294		
Acquisition of in-process technology	16,312	6,500	5,455
Total costs and expenses	141,411	123,689	151,776
Operating loss	(101,932 )	(112,515 )	(139,302 )
Equity in net loss of affiliate	(50,625 )	(14,997 )	(19,791 )
Interest and dividend income	18,495	12,342	7,145
Impairment loss on investments in partners	(11,886 )	(1,400 )	(7,309 )
Additional (payments) receipts related to asset acquisitions	(2,425 )	(31 )	16
Interest expense	(9,065 )	(11,777 )	(12,845 )
Debt conversion expense			(10,151 )
Net loss on extinguishment of debt			(4,241 )
Pre tax loss	(157,438 )	(128,378 )	(186,478 )
Provision for income taxes	103	69	31
Loss before cumulative effect of change in accounting principle	(157,541 )	(128,447 )	(186,509 )
Cumulative effect of change in accounting principle		(830 )	
Net loss	\$ (157,541 )	\$ (129,277 )	\$ (186,509 )
Basic and diluted net loss per share:			
Loss before cumulative effect of change in accounting principle	\$ (2.09 )	\$ (1.64 )	\$ (2.29 )
Cumulative effect of change in accounting principle		(0.01 )	
Net loss	\$ (2.09 )	\$ (1.65 )	\$ (2.29 )
Weighted average number of common shares outstanding			
basic and diluted	75,231	78,314	81,494

See notes to these consolidated financial statements.

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

	Common stock		Capital	Treasury Stock		Deferred	Accumulated other comprehensive	Accumulated	Total
	Number of shares	Amount	in excess of par value	Number of shares	Amount	Compensation	income (loss) deficit	deficit	shareholders equity
Balance at December 31, 2001	74,005,466	\$ 740	\$ 608,226	(1,129,226 )	\$ (2,840)	\$ 2,188	\$ 310	\$ (126,062)	\$ 482,562
Issuance of common stock for exercise of options and grant of restricted shares	160,800	2	859			(27 )			834
Withdrawal from executive deferred compensation plan			11	333,834	839	(850 )			
Issuance of common stock for asset acquisition and license agreements, net	3,412,128	34	20,691						20,725
Issuance of common stock under the employee stock purchase plan	146,982	1	492						493
Net loss								(157,541 )	(157,541 )
Other comprehensive income (loss)									
foreign currency translation adjustment							(1,262 )		(1,262 )
unrealized gain on securities							6,332		6,332
Comprehensive loss									(152,471 )
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 )



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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

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>2002</b>	<b>2003</b>	<b>2004</b>
<b>Operating activities:</b>			
Net loss	\$ (157,541 )	\$ (129,277 )	\$ (186,509 )
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Cumulative effect of change in accounting principle		830	
Depreciation	7,859	10,650	12,020
Amortization	3,084	4,613	8,914
Loss on sale of equipment			105
Stock options and awards to employees	631	773	1,203
Stock options and warrants to non-employees	(8 )		
Non cash revenue IDM	(14,332 )		
Non cash revenue Genmab		(834 )	(1,166 )
Licenses fees paid with stock	1,500		2,560
Write-off of facility costs	11,294		
Write-off of in-process technology	14,157	6,100	5,455
Equity in net loss of Genmab	50,625	14,997	19,791
Impairment loss on investments in partners	11,886	1,400	7,309
Gain on exchange of convertible debt			(325 )
Loss on redemption convertible debt			4,566
Gain on sale of partners stock		(1,530 )	(1,664 )
Deferred income taxes	250		
<b>Changes in operating assets and liabilities</b>			
Other current assets	11,393	3,799	(458 )
Trade accounts payable	(453 )	(489 )	2,801
Accrued liabilities	(985 )	214	20,769
Deferred contract revenue	(3,329 )	(497 )	98,649
Net cash used in operating activities	(63,969 )	(89,251 )	(5,980 )
<b>Investing activities:</b>			
Purchase of property and equipment	(43,691 )	(8,890 )	(9,074 )
Proceeds from sale of land and equipment	906		600
Increase in investments and advances to affiliates and partners		(1,000 )	(581 )
Decrease (increase) in segregated cash		(15,896 )	3,195
Purchase of marketable securities	(2,500 )	(121,191 )	(270,500 )
Sales and maturities of marketable securities	139,205	124,407	242,573
Net cash provided by (used in) investing activities	93,920	(22,570 )	(33,787 )
<b>Financing activities:</b>			
Cash received from sales of securities and exercise of stock options, net	680	2,091	31,850
Proceeds from sale of convertible subordinated notes, net		121,239	145,217
Repurchase of 4.50% convertible notes			(144,585 )
Deferred offering costs Celldex			(692 )
Debt exchange costs			(100 )
Principal payments under debt obligations	(88 )	(323 )	(78 )
Net cash provided by financing activities	592	123,007	31,612
Net increase (decrease) in cash and cash equivalents	30,543	11,186	(8,155 )
Cash and cash equivalents at beginning of period	31,269	61,812	72,998
Cash and cash equivalents at end of period	\$ 61,812	\$ 72,998	\$ 64,843
<b>Non-cash investing and financing activities:</b>			
Issuance of common stock for intangible assets	\$ 20,725	\$ 7,100	\$
<b>Supplemental disclosures of cash flow information</b>			
<b>Cash paid during period for:</b>			
Income taxes	\$ 25	\$ 108	\$ 3
Interest	\$ 7,985	\$ 11,841	\$ 10,789

See notes to these consolidated financial statements.



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

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**(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 has six wholly-owned subsidiaries: Medarex Europe B.V.; Houston Biotechnology Incorporated ( HBI ); GenPharm International, Inc. ( GenPharm ); Medarex Belgium, S.A.; Medarex Canada; and Celldex Therapeutics, Inc. ( Celldex ) As of December 31, 2004, the Company has significant investments in Genmab A/S ( Genmab ) (see Note 11) and Immuno-Designed Molecules S.A. ( IDM ) (see Note 12). The Company's operations constitute one business segment. All significant intercompany balances and transactions have been eliminated in consolidation.

Celldex has filed a registration statement with the Securities and Exchange Commission related to a proposed initial public offering of a portion of its common stock. The Company has assigned or licensed to Celldex certain intellectual property related to the Company's vaccine technology, including the rights to MDX-1307, one of the Company's product candidates for the treatment of cancer, as well as the Investigational New Drug Application, or IND, associated with this product which became effective in February 2004. If the initial public offering is completed, the Company anticipates that it would continue to hold approximately 70% of the outstanding shares of common stock of Celldex.

**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.

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**MEDAREX, INC. AND SUBSIDIARIES**  
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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, the management of these 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 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 \$9.5 million, \$0 and \$0.2 million related to investments in partners whose securities are publicly traded for the years ended December 31, 2002, 2003 and 2004, respectively. In addition, the Company recorded investment impairment charges of \$2.4 million, \$1.4 million and \$7.1 million in partners whose securities are privately held for the years ended December 31, 2002, 2003 and 2004, respectively.

***Segregated Securities***

Segregated securities primarily represent U.S. treasury security strips which collateralize interest payments related to the Company's 4.25% convertible senior notes due August 15, 2010.

***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, 2003 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

**MEDAREX, INC. AND SUBSIDIARIES**  
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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 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, 2004, the accumulated unrealized foreign exchange translation gain included in other comprehensive income was approximately \$5.5 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.
- 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

**MEDAREX, INC. AND SUBSIDIARIES**  
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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.

***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.

***Stock-Based Compensation***

At December 31, 2004, the Company has twelve stock option plans, which are described more fully in Note 8. The Company accounts for those plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. The following table illustrates the effect on net loss per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	<b>Year ended December 31</b>		
	<b>2002</b>	<b>2003</b>	<b>2004</b>
Net loss, as reported	\$ (157,541 )	\$ (129,277 )	\$ (186,509 )
Add: Non-cash employee compensation	631	773	1,203
Deduct: Total stock-based employee compensation expense determined under fair value method	(11,876 )	(11,303 )	(14,797 )
Pro forma net loss	\$ (168,786 )	\$ (139,807 )	\$ (200,103 )
Loss per share:			
Basic and diluted, as reported	\$ (2.09 )	\$ (1.65 )	\$ (2.29 )
Basic and diluted, pro forma	\$ (2.24 )	\$ (1.79 )	\$ (2.46 )

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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:

	2002	2003	2004	
Expected dividend yield	0	% 0	% 0	%
Expected stock price volatility	76.7	% 64.0	% 55.0	%
Risk-free interest rate	3.5	% 2.75	% 3.60	%
Expected life of options	5 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.

***Reclassifications***

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

***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 from the assumed exercise of outstanding stock options, which are included under the treasury stock method. Potentially dilutive securities have been excluded from the computation of diluted net loss per share for all years presented, as their effect is antidilutive.

***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 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.



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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 nor would it have had a material impact on a pro forma basis in 2002 assuming an adoption of SFAS No. 143 at such time.

***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*, Medarex 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. Medarex will be required to adopt Statement No. 123(R) no later than the quarter beginning July 1, 2005. Medarex is currently in the process of evaluating the option valuation methods and adoption transition alternatives available under Statement 123(R). Although the Company has not yet determined the impact of Statement 123(R), it may be significant to its consolidated results of operations.

**3. Available for Sale Investments**

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

	2003			2004			Estimated Fair Value	Estimated Fair Value
	Cost	Unrealized Gain	Unrealized Loss	Cost	Unrealized Gain	Unrealized Loss		
Money market funds (included in cash and cash equivalents)	\$ 64,459	\$	\$	\$ 64,459	\$ 57,984	\$ 1	\$ (2 )	\$ 57,983
U.S. Treasury Obligations	18,175	27	(109 )	18,093	32,746	2	(201 )	32,547
U.S. Corporate Debt Securities	264,029	761	(1,687 )	263,103	275,131	23	(1,267 )	273,887
Equity Securities	1,509	2,755		4,264	674	2,556		3,230
	\$ 348,172	\$ 3,543	\$ (1,796 )	\$ 349,919	\$ 366,535	\$ 2,582	\$ (1,470 )	\$ 367,647

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The Company's available for sale investments have the following maturities at December 31, 2004:

Due in one year or less	\$ 268,371
Due after one year, less than five years	99,276
Due after five years	

For the years ended December 31, 2002, 2003 and 2004, realized gains totaled \$1.8 million, \$2.1 million and \$2.3 million, respectively, and realized losses totaled \$0, \$0.1 million and \$0, 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, 2004, is summarized as follows:

	Fair Value	Unrealized Loss
Less than one year	\$ 290,323	\$ (1,305 )
Greater than one year	21,279	(165 )
	\$ 311,602	\$ (1,470 )

Unrealized losses in the portfolio relate to various debt securities including U.S. treasury obligations, asset backed securities and corporate bonds. For these securities, the unrealized losses were primarily due to increases in interest rates. The gross unrealized losses in the portfolio of investments represent less than one percent of the total fair value of the portfolio. 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.

#### **4. Balance Sheet Detail**

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

	2003	2004
Interest and dividends receivable	\$ 2,422	\$ 2,198
Employee receivables	512	488
Prepaid insurance	1,745	2,011
Receivables from partners	190	915
Other	1,375	1,096
	\$ 6,244	\$ 6,708

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Other assets consist of the following as of December 31:

	2003	2004
Deferred debt issuance costs, net	\$ 6,502	\$ 7,477
Patents, net	3,276	1,995
Acquired workforce, net	328	454
Deferred offering costs Celldex		978
	\$ 10,106	\$ 10,904

Accrued liabilities consist of the following as of December 31:

	2003	2004
Accrued convertible debt redemption expense	\$	\$ 10,151
Accrued construction and equipment costs	817	330
Accrued interest	2,317	2,793
Accrued compensation	5,746	5,902
Accrued contract manufacturing		1,984
Accrued license and royalty fees		6,313
Accrued professional fees	980	1,280
Due to Essex Chemical Corp.	667	667
Accrued clinical trial expenses	699	928
Other	2,652	1,800
	\$ 13,878	\$ 32,148

## 5. Taxes

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

	Year ended December 31		
	2002	2003	2004
Federal			
Current	\$	\$	\$
Deferred			
Total federal			
State			
Current	103	34	21
Deferred			
Total state	103	34	21
Foreign			
Current		35	10
Deferred			
Total foreign		35	10
Total	\$ 103	\$ 69	\$ 31

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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 which became effective in 2002.

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		
	2002	2003	2004
Computed at statutory rate	\$ (53,529 )	\$ (43,649 )	\$ (63,403 )
State income taxes, net of federal tax effect	68	(7,733 )	(10,832 )
In-process technology			1,836
Loss of foreign subsidiary	56	24	64
Foreign withholding taxes		23	7
Research and development credit carryforward benefit		(2,876 )	(2,922 )
Other		74	54
Other change in deferred tax valuation reserve	53,508	54,206	75,227
	\$ 103	\$ 69	\$ 31

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

	2003	2004
Deferred tax assets:		
Net operating loss carryforwards	\$ 113,718	\$ 165,789
Accrued compensation	271	1,196
Research and development capitalized for tax purposes	4,217	4,217
Deferred revenue	1,293	116
Research credits	8,449	10,505
Impairment loss on investments	15,463	25,615
License fees capitalized for tax purposes	1,049	6,117
In-process technology capitalized for tax purposes	9,533	9,671
Accrued debt make-whole payment		4,059
Accrued royalty		814
Cumulative effect asset retirement obligation	332	332
Other	919	856
	155,244	229,287
Deferred tax asset valuation allowance	(154,225 )	(229,287 )
	1,019	
Net deferred tax liabilities:		
Unrealized gain	157	
Fixed assets and amortization	862	
	1,019	
Net deferred tax assets	\$	\$

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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At December 31, 2004, approximately \$18.0 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, 2004, the Company had federal NOL carryforwards of approximately \$426.6 million. The NOL carryforwards expire in 2006 (\$0.9 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) and 2024 (\$131.6 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, 2004, the amount of NOL subject to the limitation was \$43.8 million and the amount not subject to limitation was \$382.8 million.

The Company had federal research tax credit carryforwards at December 31, 2004 of approximately \$9.6 million which expire between 2005 and 2024. 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, 2004, the Company had state NOL carryforwards of approximately \$258.3 million. These NOL carryforwards will expire in varying amounts between 2006 and 2013.

**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 received net proceeds from the public offering of approximately \$169.1 million.

The Company was obligated to pay interest on the 4.50% Notes on January 1 and July 1 of each year. Interest paid per \$1,000 principal amount of 4.50% Notes for the period from issue date to January 1, 2002 was approximately \$23,125. Interest payable per \$1,000 principal amount of notes for each subsequent interest period was \$22.50. Interest is 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, 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-

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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. The costs of issuance of the 4.25% Notes of approximately \$3.8 million have been deferred and are being amortized over the term of the 4.25% Notes. The amortization of these costs are reflected in interest expense.

The 4.25% Notes are senior unsecured obligations and rank equal in right of payment with the Company's existing and future unsecured and unsubordinated indebtedness. The 4.25% Notes are effectively subordinated to any future secured indebtedness to the extent of the value of the assets securing such indebtedness. The indenture under which the 4.25% Notes were issued does not restrict the Company from incurring additional senior or other indebtedness and other liabilities, including secured indebtedness.

Prior to August 15, 2006, the Company may redeem some or all of the 4.25% Notes at any time at a redemption price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest to the redemption date and the "make-whole" payment described below, if the closing price of the Company's common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days ending on the trading day before the date of mailing of the provisional redemption notice. Upon any such provisional redemption, the Company will make an additional "make-whole" payment equal to \$130.10 per \$1,000 principal amount of the 4.25% Notes redeemed, less the amount of any interest actually paid and any interest accrued and unpaid on these notes before the provisional redemption date. The Company may make such additional payment, at its option, in cash or shares or a combination thereof. Payments made in shares of the Company's common stock will be valued at 95% of the average of the closing sale prices of the Company's common stock for

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the five consecutive trading days ending on the third trading day immediately prior to the provisional redemption date.

In December 2004, the Company announced that it was calling for the redemption on January 14, 2004 of all of its outstanding 4.25% Notes. The total principal amount of the 4.25% Notes called for redemption was \$146.986 million (see Note 21). In connection with the redemption, the Company accrued approximately \$12.5 million as of December 31, 2004, representing the make-whole payment of \$10.2 million as well as accrued interest of \$2.3 million.

***2.25% Convertible Senior Notes***

On May 3, 2004, the Company completed a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended, 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.

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).

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.

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**8. Stock Options**

The Company has twelve Stock Option Plans (the "Plans"). The purchase price of stock options under the Plans 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, 2004, a total of 1,062,333 shares were available for future grants under the Plans.

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 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 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, 2002, 2003 and 2004 is as follows:

	2002		2003		2004	
	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price
Outstanding at beginning of year	6,765,191	\$ 17.21	9,935,072	\$ 13.64	11,629,594	\$ 8.32
Granted	3,663,900	7.25	5,018,019	6.43	3,141,325	5.80
Exercised	(163,300 )	5.64	(451,897 )	2.52	(201,450 )	(3.88 )
Canceled	(330,719 )	20.42	(2,871,600 )	24.25	(324,282 )	(7.53 )
Outstanding at end of year	9,935,072	13.64	11,629,594	8.32	14,245,187	7.84
Exercisable at end of year	6,271,172	17.38	5,093,394	10.04	7,372,351	9.21
Weighted average fair value of options granted during the year		\$ 4.69		\$ 3.63		\$ 2.99



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Stock options outstanding at December 31, 2004 are summarized as follows:

Range of Exercise Price	Outstanding Options at December 31, 2004	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable Options at December 31, 2004	Weighted Average Exercise Price
\$ 1.47 to \$ 5.61	5,186,285	7.28	\$ 4.55	1,994,529	\$ 3.03
\$ 5.70 to \$ 6.37	3,659,516	7.96	\$ 6.34	2,658,236	\$ 6.31
\$ 6.46 to \$12.50	3,596,112	8.78	\$ 6.99	1,134,239	\$ 7.14
\$12.90 to \$53.41	1,803,274	6.41	\$ 22.09	1,585,347	\$ 23.32
	14,245,187			7,372,351	

## 9. Deferred Compensation Plans

### *Executive Deferred Compensation Plan*

Effective March 31, 1999, the Company instituted an executive deferred compensation plan to permit certain individuals to defer the gain on the exercise of stock options to a specified future period. In June 1999, six individuals deferred the gain on the exercise of options to purchase 1,205,000 shares of the Company's common stock. The Company's executive deferred compensation plan does not permit diversification and must be settled by the delivery of 1,181,042 shares of the Company's stock over various periods of time ranging from 12 to 60 months, which began in May 2002. Accordingly, changes in the fair value of the amount owed to the individuals are not recognized.

As of January 1, 2002, one individual had withdrawn early from this plan reducing the balance in treasury stock by 75,774 shares and reducing the deferred compensation by \$0.2 million. During 2002, another individual elected to withdrawal early from this plan reducing the balance in treasury stock by 37,841 shares and reducing deferred compensation by \$0.1 million. In addition, the remaining four individuals who had previously elected to have shares distributed received distributions further reducing the balance in treasury stock by 295,993 shares and deferred compensation by \$0.7 million. During 2003 and 2004, there were further distributions from this plan reducing the balance in treasury stock by 301,876 shares each year and reducing deferred compensation by \$0.8 million and \$0.8 million, respectively.

As of December 31, 2004, a total of 157,800 shares of common stock remain to be distributed.

### *Deferred Compensation Programs*

The Company maintains two deferred compensation programs under its 2001 Stock Option Plan. Under the deferred compensation programs, each of the Company's executive officers elected to have a portion of their 2003 and 2004 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 by the Company and 25% of the match vested as of

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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 \$0.1 million and \$0.3 million for the years ended December 31, 2003 and 2004, 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 supercedes the binding letter of intent. Pursuant to the letter of intent, the Company and Kirin developed the KM-Mouse®, a unique crossbred mouse which combines the traits of the Company's HuMAB-Mouse® with Kirin's TC Mouse. Under the Collaboration and License Agreement, the Company and Kirin are exchanging cross-licenses with respect to the KM-Mouse and other antibody-generating mice. In addition, each of the cross-licenses granted under the Collaboration and License Agreement are subject to certain license, milestone and royalty payments by each party to the other.

Through December 31, 2004, the Company has not made any milestone payments to Kirin although approximately \$1.9 million has been accrued as of December 31, 2004 representing a payment due Kirin as a result of the Company's collaboration with Pfizer. Based on a total of two 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 2006, the Company may be required to make milestone payments to Kirin aggregating up to approximately \$8.5 million with respect to such products, or a maximum of approximately \$4.25 million per product. 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.

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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.

*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). EITF 00-21 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. In applying the guidance, revenue arrangements with multiple deliverables can only be considered as separate units of accounting if: a) the delivered item has value to the customer on a standalone basis, b) there is objective and reliable evidence of the fair value of the undelivered items and c) if the right of return exists, delivery of the undelivered items is considered probable and substantially in the control of the vendor. If these criteria are not met, the revenue elements must be considered a single unit of accounting for purposes of revenue recognition.

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.

*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 initially focuses on two fully human antibodies, MDX-1103 and MDX-1333, that are currently in preclinical development by the Company for the treatment of autoimmune diseases.

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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 payment was made on January 3, 2005 in cash. The five remaining payments will be made on a quarterly basis, commencing on April 1, 2005 and ending on April 3, 2006. If the Company decides to make a quarterly installment payment in shares of its common stock, the number of shares of common stock subject to issuance for any installment will be determined by dividing (x) \$1.063 million (less any cash paid in connection with the installment) by (y) the average of the closing sales prices of the Company's common stock for each of the trading days during the five-trading-day period ending on (and including) the trading day that is two trading days immediately prior to the applicable date of issuance as publicly reported by NASDAQ. In the event that, during the 60-day period following the applicable date of issuance of such common stock, Gilead sells all of the shares of the Company's common stock delivered as part of an installment payment under the Gilead License and the proceeds of such sale are less than \$1.063 million (less any cash paid in connection with such installment), the Company must pay the difference to Gilead in cash. If such sale proceeds exceed \$1.063 million (less any cash paid in connection with such installment), Gilead must pay the Company 50% of any such excess in cash. In the event that, during any such 60-day period, Gilead does not sell all of the shares of the Company's common stock comprising the installment, there will be no such adjustment. In August 2004, the Company paid Gilead approximately \$0.1 million representing the difference between the proceeds received by Gilead upon the sale of the 185,622 shares of common stock and the initial payment of \$1.063 million.

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**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. Under the terms of the Genomics Agreement, Genmab may market the Company's human antibody technology (a) for large multi-target (five or more targets) partnerships to any Europe-based company except for: (i) certain Medarex partners, including Novartis, Merck KGaA, Schering, Aventis Behring, Immuno-Design Molecules S/A, or IDM, and Scil Biomedicals GmbH; and (ii) any European based pharmaceutical company with worldwide revenues in excess of \$1 billion in 1999, provided, however, that Genmab may market the Company's human antibody technology to Sanofi/Synthelabo and Boehringer Ingelheim, and (b) for non-large multi-target (less than five targets) partnerships, to any company worldwide. The Company also has the right to participate in Genmab's large multi-target (five or more targets) partnerships, thereby sharing in certain costs and commercial benefits. The Company retains all rights to market its technology to companies headquartered outside of Europe and to all companies for non-large multi-target (less than five targets) partnerships in Europe. Certain license fees, milestones and royalties due to the Company under its previously existing agreement with Genmab were reduced. The Genomics Agreement also provides that, under certain circumstances, the Company must negotiate in good faith to manufacture antibodies for Genmab's partnerships. Finally, the Genomics Agreement grants Genmab certain rights to access technologies acquired by the Company from Biosite Incorporated and Kirin.

The Genomics Agreement has an initial term of five years (expiring in August 2005) with a right exercisable by Genmab to extend the term for an additional two years. For each year of the agreement and during the term of any extension, the Company will receive \$2.0 million per year from Genmab. At Genmab's option, these amounts may be paid in either cash or capital stock. During each of the years ended December 31, 2002, 2003 and 2004, the Company recognized \$2.0 million of revenue from this agreement.

As of January 1, 2002, the Company owned approximately 31.6% of the outstanding stock of Genmab. In June 2002, Genmab announced that one of its corporate partners had purchased shares of Genmab stock in connection with an antibody collaboration. As a result of this transaction, the Company's ownership percentage was reduced to approximately 31.3%.

In September 2002, Genmab issued a press release in which it announced that its HuMax-CD4 product, a fully human antibody that targets the CD4 receptor on cells known as T-cells, was found not to be effective in combination with methotrexate in a Phase II study of 155 patients with active rheumatoid arthritis. Following this press release, the market value of Genmab's stock decreased by approximately 60%, and accordingly, the Company recorded an impairment charge of \$31.0 million, which was deemed to be other than temporary at the time. The impairment charge of \$31.0 million is included in equity in net loss of affiliate in the Company's consolidated statement of operations for the year ended December 31, 2002.

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

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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 additional equity raised 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 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.

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, 2002, 2003 and 2004.

As of December 31, 2004, the market value of the Company's investment in Genmab was approximately \$134.8 million.

Summary financial information for Genmab is as follows as of and for the years ended December 31, 2002, 2003 and 2004:

	2002	2003	2004
Current Assets	\$ 199,648	\$ 178,596	\$ 217,582
Non Current Assets	23,890	19,487	15,044
Current Liabilities	22,649	12,606	12,796
Non Current Liabilities	3,328	3,117	3,833
Revenue		10,500	750
Gross Profit		10,500	750
Net Loss	(62,053 )	(47,613 )	(70,787 )

## 12. Transactions with IDM

In July 2000, the Company entered into an agreement with IDM whereby the Company licensed to IDM certain of its technologies in exchange for equity units in IDM. As a result of this transaction, the Company realized a gain from the transfer of its technology of approximately \$40.5 million (based upon an independent valuation). In accordance with SAB No. 104, *Revenue Recognition in Financial Statements*, the Company recognized the \$40.5 million gain as revenue over a two-year period ending in September 2002 for financial statement reporting purposes. The Company recognized \$14.3 million, \$0 and \$0, as non-cash revenue from this transaction during the years ended December 31, 2002, 2003 and 2004, respectively. For tax reporting purposes, the entire gain on the transfer of technology was taxable to the Company at the time the transaction closed in 2000.

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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. If the Company deems its investment in IDM to be further impaired at the end of any future period, the Company may incur additional non-cash investment impairment charges on this investment.

The Company currently accounts for its interest in IDM under the cost method. The Company's equity ownership in IDM is approximately 8% as of December 31, 2004. With the closing of the agreement in September 2000, the Company was issued 7,528 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 are exercised and converted or redeemed, the Company would own an additional 3,653,282 Class B shares of IDM, which would give the Company an equity interest in IDM of approximately 23%. The warrants are 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.

One of the members of the Company's Board of Directors acts as the Company's representative on the board of directors of IDM.

### 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 March 2006 and July 2009. The Company is also obligated under certain research and license agreements. A summary of the Company's commitments as of December 31, 2004 is as follows:

	2005	2006	2007	2008	2009	2010
Operating leases	\$ 3,250	\$ 2,607	\$ 2,452	\$ 2,141	\$ 690	\$
Research funding	7,793	5,218	3,093	2,343	93	93
Total	\$ 11,043	\$ 7,825	\$ 5,545	\$ 4,484	\$ 783	\$ 93

The Company incurred rent expense of \$4.0 million in 2002, \$3.5 million in 2003 and \$3.9 million in 2004.

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 balance sheet.

The Company has entered into a number of other agreements that contain in-licenses of third-party technology (other than 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 milestone payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of the Company's products currently under development trigger such milestone payments. Through December 31, 2004, the Company had made milestone payments under these agreements of approximately \$0.3 million. In addition, under the agreements the

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Company currently has in place (other than with Kirin), based on a total of five 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 2006, the Company may be obligated to make future milestone payments aggregating up to approximately \$22.5 million with respect to such products. In general, potential milestone payments for 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.

The Company has a contingent commitment to pay \$1.0 million to Essex Chemical Corporation ( Essex ) without interest in installments equal to 20% of net after tax earnings of the Company in future years. The Company's contingent commitment, as amended, to pay up to \$1.0 million out of future earnings may be satisfied, at the Company's option, through the payment of cash or shares of the Company's common stock having a fair market value equal to the amount owed, provided that such shares are registered with the Securities and Exchange Commission. The Company accrued \$0.7 million related to this liability during 2000, which remains accrued at December 31, 2004.

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 its current legal proceedings, 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 wholly-owned subsidiaries constitute one business segment.

Revenue from partners representing 10% or more of total revenues for the years ended December 31, 2002, 2003 and 2004 is as follows:

<b>Partners</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>
Genmab	37 %	48 %	26 %
Pfizer			20 %
Amgen	3 %	15 %	8 %
Lilly	11 %	7 %	6 %
IDM	36 %		



**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2002, 2003 and 2004**  
**(Dollars in thousands, unless otherwise indicated, except share data)**

No other single partner accounted for more than 10% of the Company's total revenues for the years ended December 31, 2002, 2003 and 2004, respectively.

**15. 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 2002, 2003 and 2004, the Company made contributions to the plan totaling \$0.4 million, \$0.6 million and \$0.6 million, respectively.

**16. Asset Acquisition**

In May 2002, the Company and its newly created subsidiary Medarex Belgium, S.A. entered into an Asset Purchase Agreement with Corixa Corporation, Coulter Pharmaceutical, Inc., a wholly owned subsidiary of Corixa Corporation, and Corixa Belgium S.A., a wholly-owned subsidiary of Corixa Corporation (collectively referred to as Corixa). Under the terms of the Asset Purchase Agreement, the Company acquired certain selected assets and business operations of Corixa, including certain preclinical product candidates and programs related to the research and development of therapeutic products for the treatment of autoimmune diseases, cancer and infectious diseases. In addition, the Company retained approximately 30 Corixa employees related to such product candidates and programs.

Under the terms of the Asset Purchase Agreement, the Company acquired the assets for \$21.0 million (excluding transaction costs of \$0.4 million). A total of 3,086,075 shares of common stock with a fair value of \$19.25 million were issued to Corixa along with cash of \$1.75 million as payment for the \$21.0 million purchase price. In the event that, during any month during the six-month period following the closing of the transaction, Corixa sold all of the shares of the common stock delivered as payment for the preceding monthly installment and the proceeds of such sale were less than \$3.5 million, the Company was required to pay the difference to Corixa in cash. The Company paid Corixa approximately \$2.3 million representing the difference between the proceeds received by Corixa from the sale of the Company's common stock and the total amount due under the six monthly installments. Such amount is included as a charge to earnings in the Company's consolidated statement of operations for the year ended December 31, 2002.

The Company also purchased from Corixa certain equipment and laboratory supplies for \$2.5 million, of which approximately \$2.1 million was capitalized with the remaining \$0.4 million charged to expense.

The cost of the asset acquisition in 2002 was \$21.4 million, of which \$0.4 million represented transaction costs. This amount has been allocated as follows based upon an independent third party valuation using the income approach:

In-process technology	\$ 16,312
Patents	4,388
Acquired workforce	705
	\$ 21,405

**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2002, 2003 and 2004**  
**(Dollars in thousands, unless otherwise indicated, except share data)**

The \$16.3 million of in-process research and development, which was charged to operations in 2002, was determined not to be technologically feasible and had no alternative future uses. Patents and acquired workforce are being amortized over useful lives of five years and three years, respectively.

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 25%. The discount rate was based on the Company's estimated weighted average cost of capital taking into account the risk associated with the technologies acquired. The projected cash flows from such projects were based on estimated revenues and operating profits related to such projects considering the state of development of each of 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 including obtaining FDA and other regulatory approvals.

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 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.

**17. 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)**  
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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
	\$ 5.7

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.

#### **18. Write-off of Facility Costs**

During the second quarter of 2002, the Company made a determination to delay indefinitely the planned construction of a large-scale manufacturing facility at its Bloomsbury, New Jersey, location and, instead, to pursue late-stage clinical and commercial supply agreements with third party manufacturers with available capacity to meet the Company's current internal production timetables. As a result of this decision, the Company recorded a charge of approximately \$11.3 million in the second quarter of 2002, representing the write-off of design, engineering and other pre-construction costs. In September 2003, the Company entered into a clinical supply agreement with Lonza Group Ltd. with respect to MDX-010, and discussions are ongoing with respect to terms of a commercial supply agreement.

#### **19. 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

**MEDAREX, INC. AND SUBSIDIARIES**  
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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, 2002, 2003 and 2004, 146,982, 175,955 and 176,625 shares of common stock were issued under the ESPP resulting in net proceeds to the Company of \$0.5 million, \$1.0 million and \$1.1 million, respectively.

**20. Quarterly Financial Information Unaudited**

The following is a summary of the quarterly results of operations for the years ended December 31, 2003 and 2004:

<b>2003</b>	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>	<b>Total</b>
Sales	\$ 25	\$	\$	\$	\$ 25
Contract and license revenues	3,939	2,251	2,260	2,699	11,149
Total revenue	3,964	2,251	2,260	2,699	11,174
Cost of sales	3				3
Loss before provision for income taxes	(28,765 )	(29,111 )	(33,267 )	(37,235 )	(128,378 )
Net loss	(29,623 )	(29,125 )	(33,270 )	(37,259 )	(129,277 )
Basic and diluted net loss per share	\$ (0.38 )	\$ (0.37 )	\$ (0.43 )	\$ (0.47 )	\$ (1.65 )

<b>2004</b>	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>	<b>Total</b>
Sales	\$	\$	\$	\$	\$
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
Cost of sales					
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 )

**21. Subsequent Events**

***Bristol-Myers Squibb Collaboration***

In January 2005, the Company announced the closing of a collaboration and co-promotion agreement and a related securities purchase agreement with Bristol-Myers Squibb Company, or BMS, pursuant to which the Company and BMS have each granted the other certain intellectual property licenses and product rights on a worldwide basis in order to enable the parties to collaborate in research and development of certain therapeutic antibody-based 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 the Company to BMS of a license to commercialize MDX-010, a fully human antibody product developed using the Company's UltiMab Human Antibody Development System, that is antagonistic to cytotoxic T-lymphocyte antigen 4 (CTLA-4).

**MEDAREX, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**December 31, 2002, 2003 and 2004**  
**(Dollars in thousands, unless otherwise indicated, except share data)**

MDX-010 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 MDX-010 for the treatment of metastatic melanoma.

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 MDX-010 as a potential treatment for a broad range of cancers. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the United States and Europe, with the remaining 35% to be paid by the Company. The parties will share equally the costs of any clinical trials of 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.

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

Pursuant to these agreements, BMS made an initial cash payment to the Company of \$25.0 million. 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.

***Redemption of 4.25% Notes***

In January 2005, the Company completed the provisional redemption of all of its outstanding 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 the Company's common stock prior to the redemption date. In connection with the redemption, the Company paid approximately \$12.5 million in cash primarily representing the make-whole payment of \$10.2 million described in Note 6 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 this transaction, unamortized debt issuance costs of approximately \$3.2 million were reclassified to capital in excess of par value.

**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 sheets and the related consolidated statements of operations, shareholders' equity and cash flows 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 2003, and the results of their operations and their cash flows for each of the three years ended 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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Genmab A/S (A development stage company)  
Consolidated Statements of Operations

	Note	12 months ended December 31, 2004 DKK 000	12 months ended December 31, 2004 USD 000 (Unaudited)	12 months ended December 31, 2003 DKK 000	12 months ended December 31, 2002 DKK 000	Total since inception DKK 000
Revenues		4,101	750	68,326		72,427
Costs and expenses:						
Research and development costs	8	373,330	68,280	345,983	396,234	1,389,123
General and administrative expenses	8	72,044	13,177	64,552	86,847	302,686
Impairment loss on manufacturing facility	6				42,907	42,907
Total costs and expenses		445,374	81,457	410,535	525,988	1,734,716
<b>Operating loss</b>		<b>(441,273 )</b>	<b>(80,707 )</b>	<b>(342,209 )</b>	<b>(525,988 )</b>	<b>(1,662,289 )</b>
Interest income		38,625	7,064	36,362	70,424	265,689
Interest expenses		(1,802 )	(330 )	(2,047 )	(2,184 )	(10,280 )
Other expense, net	3	(17,597 )	(3,218 )	(2,449 )	(19,338 )	(31,867 )
<b>Loss before provision for income taxes</b>		<b>(422,047 )</b>	<b>(77,191 )</b>	<b>(310,343 )</b>	<b>(477,086 )</b>	<b>(1,438,747 )</b>
Provision (benefit) for income taxes	4			(66 )	326	265
<b>Net loss</b>		<b>(422,047 )</b>	<b>(77,191 )</b>	<b>(310,277 )</b>	<b>(477,412 )</b>	<b>(1,439,012 )</b>
<b>Basic and diluted net loss per share (in DKK/USD)</b>		<b>(15.9 )</b>	<b>(2.9 )</b>	<b>(13.6 )</b>	<b>(21.4 )</b>	
<b>Weighted average number of shares outstanding during the year basic and diluted</b>		<b>26,470,014</b>	<b>26,470,014</b>	<b>22,830,818</b>	<b>22,336,150</b>	

The accompanying notes are an integral part of these consolidated financial statements.

Genmab A/S (A development stage company)  
Consolidated Balance Sheets

	Note	December 31, 2004 DKK 000 (Unaudited)	December 31, 2004 USD 000	December 31, 2003 DKK 000
<b>ASSETS</b>				
<b>Current assets:</b>				
Cash and cash equivalents (Includes restricted cash of DKK 27,727 thousand at December 31, 2004 and DKK 11,269 at December 31, 2003)		419,566	76,737	308,916
Marketable securities	5	738,862	135,135	726,860
Other current assets		31,224	5,710	28,227
<b>Total current assets</b>		<b>1,189,652</b>	<b>217,582</b>	<b>1,064,003</b>
<b>Non-current assets:</b>				
Plant and equipment, net	6	57,353	10,489	73,160
Other securities and equity interests	9	5,726	1,047	5,726
Licenses and rights	7	10,725	1,962	33,773
Deposits and other assets, net		8,452	1,546	3,446
<b>Total non-current assets</b>		<b>82,256</b>	<b>15,044</b>	<b>116,105</b>
<b>Total Assets</b>		<b>1,271,908</b>	<b>232,626</b>	<b>1,180,108</b>

The accompanying notes are an integral part of these consolidated financial statements.



Genmab A/S (A development stage company)  
Consolidated Balance Sheets

	Note	December 31, 2004 DKK 000 (Unaudited)	December 31, 2004 USD 000	December 31, 2003 DKK 000
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>				
<b>Liabilities:</b>				
<b>Current liabilities:</b>				
Trade accounts payable		15,768	2,884	24,033
Accrued liabilities		46,150	8,441	34,009
Short-term portion of payable technology rights	10			11,495
Short-term portion of lease liabilities	16	8,044	1,471	5,569
<b>Total current liabilities</b>		<b>69,962</b>	<b>12,796</b>	<b>75,106</b>
<b>Long-term liabilities:</b>				
Long-term portion of lease liabilities	16	20,960	3,833	18,568
<b>Total Liabilities</b>		<b>90,922</b>	<b>16,629</b>	<b>93,674</b>
<b>Commitment and contingencies</b>	16			
<b>Shareholders' Equity:</b>				
Common stock, DKK1.00 par value, 29,752,363 shares authorized, issued and outstanding at December 31, 2004, and 22,980,534 at December 31, 2003 and 22,716,620 at December 31, 2002	11	29,752	5,442	22,981
Share Premium		2,596,981	474,976	2,093,750
Deficit accumulated during development stage		(1,439,012 )	(263,189 )	(1,016,965 )
Accumulated other comprehensive income		(6,735 )	(1,232 )	(13,332 )
<b>Total Shareholders' Equity</b>		<b>1,180,986</b>	<b>215,997</b>	<b>1,086,434</b>
<b>Total Liabilities and Shareholders' Equity</b>		<b>1,271,908</b>	<b>232,626</b>	<b>1,180,108</b>

The accompanying notes are an integral part of these consolidated financial statements.

Genmab A/S (A development stage company)  
**Consolidated Statements of Shareholders Equity**  
**For the year ended December 31, 2004**

	Number of shares	Share Capital DKK 000	Share Premium DKK 000	Deficit accumulated during development stage DKK 000	Unearned compensation DKK 000	Accumulated other comprehensive income Unrealized gains/ (losses) on securities DKK 000	Cumulative translation adjustments DKK 000	Shareholders equity DKK 000	Shareholders equity USD 000 (Unaudited)
<b>December 31, 2003</b>	<b>22,980,534</b>	<b>22,981</b>	<b>2,093,750</b>	<b>(1,016,965)</b>	<b>0</b>	<b>(18,099)</b>	<b>4,767</b>	<b>1,086,434</b>	<b>198,704</b>
Issuance of shares for cash	5,623,000	5,623	472,332					477,955	87,416
Expenses related to share issues			(32,342 )					(32,342 )	(5,914 )
Exercise of warrants	1,148,829	1,148	63,241					64,389	11,776
Loss for the period				(422,047 )				(422,047 )	(77,191 )
Other comprehensive income:									
Translations gains							(238 )	(238 )	(44 )
Unrealized gain on marketable securities						2,236		2,236	409
Unrealized exchange rate gain on marketable securities						4,599		4,599	841
Comprehensive loss								(415,450 )	(75,985 )
<b>December 31, 2004</b>	<b>29,752,363</b>	<b>29,752</b>	<b>2,596,981</b>	<b>(1,439,012)</b>	<b>0</b>	<b>(11,264)</b>	<b>4,529</b>	<b>1,180,986</b>	<b>215,997</b>

The accompanying notes are an integral part of these consolidated financial statements.

Genmab A/S (A development stage company)  
 Consolidated Statements of Shareholders Equity  
 For the year ended December 31, 2003

	Number of shares	Share Capital DKK 000	Share Premium DKK 000	Deficit accumulated during development stage DKK 000	Unearned compensation DKK 000	Accumulated other comprehensive income Unrealized gains/ (losses) on securities DKK 000	Cumulative translation adjustments DKK 000	Shareholders equity DKK 000
<b>December 31, 2002</b>	<b>22,716,620</b>	<b>22,717</b>	<b>2,079,994</b>	<b>(706,688 )</b>	<b>0</b>	<b>(1,262 )</b>	<b>4,408</b>	<b>1,399,169</b>
Issuance of shares by debt conversion	246,914	247	12,716					12,963
Expenses related to share issues			256					256
Exercise of warrants	17,000	17	784					801
Loss for the period				(310,277 )				(310,277 )
Other comprehensive income:								
Translations gains							359	359
Unrealized loss on marketable securities						(6,774 )		(6,774 )
Unrealized exchange rate loss on marketable securities						(10,063)		(10,063 )
Comprehensive loss								(326,755 )
<b>December 31, 2003</b>	<b>22,980,534</b>	<b>22,981</b>	<b>2,093,750</b>	<b>(1,016,965</b>	<b>0</b>	<b>(18,099)</b>	<b>4,767</b>	<b>1,086,434</b>

The accompanying notes are an integral part of these consolidated financial statements.

Genmab A/S (A development stage company)  
**Consolidated Statements of Shareholders Equity**  
**For the year ended December 31, 2002**

	Number of shares	Share Capital DKK 000	Share Premium DKK 000	Deficit accumulated during development stage DKK 000	Unearned compensation DKK 000	Accumulated other comprehensive income Unrealized gains/ (losses) on securities DKK 000	Cumulative translation adjustments DKK 000	Shareholders equity DKK 000
<b>December 31, 2001</b>	<b>21,812,020</b>	<b>21,812</b>	<b>1,931,797</b>	<b>(229,276)</b>	<b>(13,062)</b>	<b>655</b>	<b>4</b>	<b>1,711,930</b>
Issuance of shares for cash	880,100	880	157,537					158,417
Expenses related to share issues			(2,923)					(2,923)
Exercise of warrants	24,500	25	1,330					1,355
Adjustment of value of warrants granted			(7,747)		7,747			
Expense recognized for warrants granted					5,315			5,315
Loss for the period				(477,412)				(477,412)
Other comprehensive income:								
Translations gains							4,404	4,404
Unrealized loss on marketable securities						(1,063)		(1,063)
Unrealized exchange rate loss on marketable securities						(854)		(854)
Comprehensive loss								(474,925)
<b>December 31, 2002</b>	<b>22,716,620</b>	<b>22,717</b>	<b>2,079,994</b>	<b>(706,688)</b>	<b>0</b>	<b>(1,262)</b>	<b>4,408</b>	<b>1,399,169</b>

The accompanying notes are an integral part of these consolidated financial statements.

## Genmab A/S (A development stage company)

## Consolidated Statements of Shareholders Equity

For the period from inception (June 11, 1998) to December 31, 2004

	Number of shares	Share Capital DKK 000	Share Premium DKK 000	Deficit accumulated during development stage DKK 000	Unearned compensation DKK 000	Accumulated other comprehensive income Unrealized gains/(losses) on securities DKK 000	Cumulative translation adjustments DKK 000	Shareholder equity DKK 000	Shareholders equity USD 000 (Unaudited)
<b>June 11, 1998</b>	<b>125,000</b>	<b>125</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>125</b>	<b>23</b>
Issuance of shares for cash	7,518,566	7,519	1,035,654				1,043,173	190,792	
Issuance of shares for licenses	437,596	438	94,515				94,953	17,366	
Issuance of shares by debt conversion	246,914	247	12,716				12,963	2,371	
Exercise of warrants	1,193,469	1,192	66,375				67,567	12,358	
Expenses and foreign currency fluctuations related to share issues			(38,901 )				(38,901 )	(7,115 )	
Issuance of bonus shares	14,230,818	14,231	(14,231 )						
Issuance of shares at initial public offering	6,000,000	6,000	1,553,689				1,559,689	285,260	
Expenses related to initial public offering			(138,546 )				(138,546 )	(25,339 )	
Adjustment of value of warrants granted			20,040		(20,040)				
Expense recognized for warrants granted					20,040		20,040	3,665	
Transaction entered into by principal shareholder on company s behalf			5,670		(5,670 )				
Expensed portion of transaction entered into by principal shareholder on company s behalf					5,670		5,670	1,037	
Loss for the period				(1,439,012)			(1,439,012)	(263,189)	
Other comprehensive income:									
Translation gains							4,529	4,529	828
Unrealized loss on marketable securities						(3,506 )	(3,506 )	(641 )	
Unrealized exchange rate loss on marketable securities						(7,758 )	(7,758 )	(1,419 )	
Comprehensive loss							(1,445,747)	(264,421)	
<b>December 31, 2004</b>	<b>29,752,363</b>	<b>29,752</b>	<b>2,596,981</b>	<b>(1,439,012)</b>	<b>0</b>	<b>(11,264)</b>	<b>4,529</b>	<b>1,180,986</b>	<b>215,997</b>

The accompanying notes are an integral part of these consolidated financial statements.

**Genmab A/S (A development stage company)**  
**Consolidated Statements of Cash Flows**

	12 months ended December 31, 2004 DKK 000	12 months ended December 31, 2004 USD 000 (Unaudited)	12 months ended December 31, 2003 DKK 000	12 months ended December 31, 2002 DKK 000	Total since inception DKK 000
<b>Operating activities:</b>					
Net loss	(422,047 )	(77,191 )	(310,277 )	(477,412 )	(1,439,012 )
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	30,615	5,599	32,843	16,971	85,046
Amortization	23,048	4,215	30,827	30,497	141,759
Impairment loss				42,170	42,170
Non-cash interest expense reversed	432	79	5,661	8,564	33,131
Non-cash interest income and non-cash other expense reversed	12,164	2,225	(18,300 )	(9,871 )	(30,361 )
Expensed value of warrants granted				5,315	20,040
Other non-cash transactions	(1,243 )	(227 )	(402 )	(384 )	3,641
Paid technology rights	(12,228 )	(2,236 )	(13,865 )		(43,005 )
Changes in operating assets and liabilities, net of acquisition:					
Other current assets	278	51	33,179	1,379	(291 )
Trade accounts payable	(8,106 )	(1,483 )	(48,317 )	51,234	23,086
Accrued liabilities	10,101	1,848	(14,951 )	23,628	43,910
<b>Net Cash used in operating activities</b>	<b>(366,986 )</b>	<b>(67,120 )</b>	<b>(303,602 )</b>	<b>(307,909 )</b>	<b>(1,119,886 )</b>
<b>Investing activities:</b>					
Deposits on leasehold	(712 )	(129 )	1,238	(407 )	(4,158 )
Purchase of plant and equipment, net	(7,878 )	(1,441 )	(13,123 )	(86,865 )	(163,235 )
Investments in other securities and equity interests, net			1,743	(1,839 )	(30,012 )
Non-current receivables	(5,947 )	(1,088 )			(5,947 )
Purchase of marketable securities	(1,163,346 )	(212,771 )	(1,676,845 )	(5,037,176 )	(12,573,072 )
Sales of marketable securities	1,152,106	210,715	2,050,130	5,364,432	11,833,985
<b>Net cash provided by (used in) investing activities</b>	<b>(25,777 )</b>	<b>(4,714 )</b>	<b>363,143</b>	<b>238,145</b>	<b>(942,439 )</b>
<b>Financing activities:</b>					
Increase in restricted cash	(16,458 )	(3,010 )	(11,269 )		(27,727 )
Cash received from sales of stock, net	445,613	81,501	256	155,494	2,425,541
Warrants exercised	64,389	11,776	801	1,355	67,567
Paid installments on lease liabilities	(6,589 )	(1,205 )	(4,628 )		(11,217 )
<b>Net cash provided by (used in) financing activities</b>	<b>486,955</b>	<b>89,062</b>	<b>(14,840 )</b>	<b>156,849</b>	<b>2,454,164</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>94,192</b>	<b>17,228</b>	<b>44,701</b>	<b>87,085</b>	<b>391,839</b>
Cash and cash equivalents at the beginning of period	297,647	54,438	252,946	165,861	
<b>Cash and cash equivalents at the end of period</b>	<b>391,839</b>	<b>71,666</b>	<b>297,647</b>	<b>252,946</b>	<b>391,839</b>
Supplemental schedule of non-cash contributions:					
Acquisitions of licenses and rights					57,532
Liabilities assumed	(19,744 )	(3,611 )	(15,370 )	(13,395 )	(106,041 )
Assets acquired	19,744	3,611	15,370	13,395	143,461
Shares issued for licenses and rights contributed					(94,952 )

The accompanying notes are an integral part of these consolidated financial statements.



**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements**

**1. Accounting Policies**

**Basis of Presentation**

The financial statements of Genmab A/S (the company) are reported in Danish Kroner (DKK) and are prepared in accordance with Generally Accepted Accounting Principles in The United States (US GAAP). The accounting policies are unchanged from prior years.

**Currencies**

The company's financial statements are published in Danish Kroner. Solely for the convenience of the reader, the financial statements contain a conversion of certain DKK amounts into US Dollars (USD) at specified rates. This conversion has been made at the exchange rate in effect at the balance sheet date. These converted amounts should not be construed as representations that the DKK amounts actually represent such USD amounts or could be converted into USD at the rates indicated or at any other rate.

Unless otherwise indicated, translations herein of financial information into USD have been made using the Danish Central Bank spot rate on December 31, 2004, which was USD 1.00 = DKK 5.4676.

**Consolidated Financial Statements**

The consolidated financial statements comprise the parent company, Genmab A/S, and subsidiaries in which Genmab A/S controls more than 50% of the voting rights or otherwise has a controlling interest. The consolidated financial statements (Genmab Consolidated) consist of Genmab A/S, Genmab B.V., Genmab, Inc. and Genmab, Ltd., and they are prepared based on the parent company's and subsidiaries' financial statements by aggregation of similar financial statement items.

The financial statements used for the consolidation have been prepared using the accounting policies of the group. For the consolidation, intercompany income and expenses, intercompany accounts and gains and losses on transactions between the consolidated entities are eliminated. In the consolidated financial statements, the book value of the equity interests in the consolidated subsidiaries is eliminated with the parent company's share of the subsidiaries' equity and incorporated in the shareholders' equity.

**Foreign Currency Transactions**

The company holds certain cash and cash equivalents as well as short-term investments denominated in foreign currencies, which are remeasured into DKK at the exchange rate prevailing at the balance sheet date. Receivables, debt and other items in other foreign currencies, which are not settled at the balance sheet date, are remeasured at the exchange rate prevailing at the balance sheet date. During the year, transactions in foreign currencies are translated at the exchange rates prevailing on the date of transaction. The resulting realized gains and losses are reported as other income in the statement of operations.

**Foreign Currency Translations**

When translating financial statements of foreign subsidiaries that prepare financial statements in currencies other than the Danish Kroner, the income statements are translated at the average exchange rate for the year, while all items in the balance sheets are translated using the exchange rate prevailing at the balance sheet date. Translation adjustments are included in accumulated other comprehensive income in shareholders' equity.



**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (Continued)**

**Revenues**

Revenues comprise milestone payments and other income from research and development agreements. Revenue is recognized when it is probable that future economic benefits will flow to the company and these benefits can be measured reliably. Further, revenue recognition requires that all significant risks and rewards of ownership of the goods or services included in the transaction have been transferred to the buyer.

As of January 1, 2003, the Group adopted EITF 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21), which addresses how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. EITF 00-21 requires revenue arrangements with multiple deliverables to be divided into separate units of accounting if the deliverables in the arrangement meet certain criteria. Arrangement consideration must then be allocated among the separate units of accounting based on their relative fair values. EITF 00-21 also supersedes certain guidance set forth in SAB 101. In 2003, we also adopted SAB 104, Revenue Recognition (SAB 104), which revises or rescinds certain interpretive guidance regarding SAB 101 that was in conflict with the provisions of EITF 00-21.

**Research and Development Costs**

Research and development costs include salaries and related compensation expenses, license fees, production costs, amortization of licenses and rights, and depreciation of plant and equipment, to the extent such costs are related to the group's research and development activities. Costs are expensed in the period to which they relate.

**General and Administrative Expenses**

General and administrative expenses consist primarily of salaries and related compensation expenses, office facilities, travel and other expenses relating to general management, financial, administrative and business development activities, including depreciation of plant and equipment, to the extent such costs are related to the group's general and administrative activities. Costs are expensed in the period to which they relate.

**Interest Income and Expenses**

Interest income includes interest received as well as imputed interest on zero coupon securities. Interest expenses include interest paid as well as imputed interest on payable technology rights.

**Other Expense, Net**

Other income, net includes realized gains and losses on marketable securities as well as realized exchange rate adjustments. Unrealized gains and losses on marketable securities are recorded as accumulated other comprehensive income in shareholders' equity.

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**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (Continued)**

**Stock-Based Compensation**

The company applies the intrinsic value method when accounting for stock-based compensation of employees and, in addition, discloses the pro forma effects on net loss and net loss per share had the estimated fair value of the warrants granted to employees been expensed. For fixed awards granted to employees, the intrinsic value of the award is recognized as an expense using a straight-line method over the vesting period. The estimated fair value of warrants granted to non-employees is expensed when the service is performed.

If the company had elected to recognize compensation expense based on the fair value of the warrants granted at the grant date, net loss and net loss per share would have been increased to the pro forma amounts indicated in the table below.

	12 months ended December 31, 2004 DKK 000	12 months ended December 31, 2004 USD 000 (Unaudited)	12 months ended December 31, 2003 DKK 000	12 months ended December 31, 2002 DKK 000	Total since inception DKK 000
Net loss, as reported	(422,047 )	(77,191 )	(310,277 )	(477,412 )	(1,439,012 )
Total stock-based employee compensation expense determined under fair value based method for all awards	(45,315 )	(8,288 )	(43,004 )	(33,625 )	(139,799 )
Stock-based employee compensation expense included in reported net loss				4,668	7,451
Pro forma net loss	(467,362 )	(85,479 )	(353,281 )	(506,369 )	(1,571,360 )
Net loss per share, basic and diluted (in DKK/USD)	(15.9 )	(2.9 )	(13.6 )	(21.4 )	
Pro forma net loss per share, basic and diluted (in DKK/USD)	(17.7 )	(3.2 )	(15.5 )	(22.7 )	

The fair value of each warrant grant is estimated on the date of the grant using the Black Scholes pricing model with the following assumptions.

	2004	2003
Expected dividend yield	0	% 0
Expected stock price volatility	44	% 54
Risk-free interest rate	3.25	% 3.73
Expected life of warrants preceding warrant scheme	4 years	4 years
Expected life of warrants current warrant scheme	6 years	

The expected stock price volatility has been determined as the historical volatility of the company's stock price for the latest 12 months prior to the balance sheet date.

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (Continued)**

**Stock-Based Compensation (Continued)**

The risk-free interest rate is determined as the interest rate on central government securities (bullet issues) with a maturity of 5 years.

**Income Taxes**

Income taxes are accounted for using the liability method which requires the recognition of deferred tax assets or liabilities for temporary differences between the financial reporting and tax bases of the company's assets and liabilities and for tax loss carry-forwards at current statutory rates in effect for the years in which the differences are expected to reverse. Deferred tax assets are evaluated and reduced to the amount expected to be realized. Deferred tax liabilities and assets are stated at the current tax rate of 30%.

**Net Loss per Share**

Basic net loss per share is calculated by dividing net loss for the year by the weighted average number of ordinary shares outstanding during the period.

Diluted net loss per share is computed using the weighted average number of ordinary shares and dilutive share equivalents outstanding during the period. Since Genmab recorded a loss during the periods presented, the diluted net loss per share is the same as basic, as any potentially dilutive securities would reduce the net loss per share from continuing operations.

The weighted average number of common shares outstanding used to calculate diluted net loss per share was 26,470,014, 22,830,818 and 22,336,150 for the years ended December 31, 2004, 2003 and 2002, respectively. The amount of potentially dilutive warrants excluded from the diluted net loss per share calculation, since they were anti-dilutive, is as follows:

Year ended December 31, 2004	4,031,046
Year ended December 31, 2003	4,455,450
Year ended December 31, 2002	4,236,575

**Cash and Cash Equivalents**

Time deposits and notes with a maturity of three months or less at the date of deposit/investment are considered to be cash equivalents. Certain cash deposits are restricted for use as they are pledged as collateral for the Group's lease obligations.

**Marketable Securities**

Marketable securities consist of investments in securities with a maturity of greater than three months at the time of purchase. The company invests its cash in deposits with major financial institutions, money market funds, corporate bonds and DKK denominated notes issued by the Danish Government and USD denominated notes issued by the US Government. The investments can be readily purchased and sold using established markets. When sold, the cost of marketable securities is recorded based on the first-in-first-out principle including imputed interest on zero coupon-securities.

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (Continued)**

**Marketable Securities (Continued)**

The company's investments are characterized as available-for-sale marketable securities and carried at their market value, with unrealized gains and losses (including unrealized exchange rate gains and losses) reported as part of accumulated other comprehensive income.

**Plant and Equipment**

Plant and equipment are recorded at cost and include office equipment, furniture, fixtures and leasehold improvements. Depreciation is computed using the straight-line method over the estimated useful lives which range from three to five years.

Leasehold improvements are amortized using the straight-line method over the useful life of the asset or the related lease term, whichever is shorter.

Items costing less than DKK 10,800 are expensed in the year of acquisition. Depreciation as well as profit and loss in connection with the replacement of tangible fixed assets, are expensed as research and development costs or general and administrative expenses, as appropriate.

Costs associated with the design and building of laboratory facilities are capitalized until completion. Upon completion, costs will be depreciated over the facility's expected useful life.

**Leasing**

Lease contracts, which in all material respects transfer the significant risks and rewards associated with the ownership of the asset to the lessee, are classified as finance leases and recognized in the balance sheet at the inception of the lease term at the lower of the fair value of the asset or the net present value of the future minimum lease payments. A liability equaling the asset is recognized in the balance sheet. Each lease payment is separated between a finance charge, recorded as interest expense, and a reduction of the outstanding liability. Assets under finance leases are depreciated in the same manner as owned assets and are subject to regular reviews for impairment.

Lease contracts, where the lessor retains the significant risks and rewards associated with the ownership of the asset, are classified as operating leases. Lease payments under operating leases are recognized in the statement of operations ratably over the lease term.

**Other Securities and Equity Interests**

Other securities and equity interests, acquired for long-term strategic holding, are considered non-current assets. These investments are accounted for in accordance with SFAS 115, Accounting for Certain Investments in Debt and Equity Securities.

Other securities and equity interests are measured at fair value at the balance sheet date. The fair value for listed shares is the listed market price and, for interests in non-listed companies, the fair value is the net sales price. If the net sales price cannot be reliably determined for interests in non-listed companies, the assets are measured at cost. Realized and unrealized gains and losses are recognized in the income statement as financial items.

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (Continued)**

**Licenses and Rights**

Licenses and rights, which include technology licenses and licenses to targets, are recorded at cost, including the net present value for any remaining payments. The net present value of the remaining payments is included as a liability in the balance sheet and allocated to short-term and long-term payable technology rights. The licenses are amortized using the straight-line method over an estimated useful life of five years.

**Impairment of Long-lived Assets**

In addition to amortizing licenses and rights and depreciating plant and equipment, management periodically reviews long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If factors indicate that an asset should be evaluated for possible impairment, management compares the estimated undiscounted future cash flows from the asset or group of related assets to its carrying amount. If the carrying amount of the asset is greater than the undiscounted future cash flows, an impairment loss would be recognized. An impairment loss would be computed as the excess of the carrying amount of the asset over the estimated fair value of the asset (calculated based on discounting estimated future cash flows).

**Use of Estimates**

The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States. In preparing these financial statements, management is required to make estimates and assumptions that affect amounts reported in the financial statements and accompanying notes. As a result, actual results could differ from reported results.

**Segment Information**

The group is managed and operated as one business unit in order to create and develop human antibodies for the treatment of life-threatening and debilitating diseases. The entire group is managed by a single management team reporting to the Chief Executive Officer. No separate lines of business or separate business entities have been identified with respect to any of the product candidates or geographical markets.

**New Accounting Pronouncements**

In January 2003, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB 51 . FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest, or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, the FASB issued FIN 46R, a revision to FIN 46. FIN 46R requires that all public entities must apply FIN 46 to all legal entities in existence prior to January 31, 2003, to the first reporting period ended after March 15, 2004. For all new legal entities formed after January 31, 2003, the provisions of the Interpretation must be adopted immediately upon formation. The adoption of FIN 46 did not have an impact on the company's financial position, cash flows or results of operation.

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**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (Continued)**

**New Accounting Pronouncements (Continued)**

In May 2003, the FASB issued Statement of Financial Accounting Standard No. 150 (SFAS 150), *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, which established standards for how an issuer of financial instruments should classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or in some circumstances, as an asset). If there is a conditional or unconditional duty of responsibility of the issuer to transfer assets or to issue equity shares to satisfy the instrument. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have an effect on the company's financial position, cash flows or results of operations.

In May 2003, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 01-08, *Determining Whether an Arrangement Contains a Lease*. This Issue provides guidance as to whether a contract contains a lease that should be accounted for under FASB Statement No. 13. The EITF requires that companies review all agreements concerning plant, property and equipment to determine whether it contains a lease because the contract a) explicitly or implicitly specifies the plant, property and equipment to be used to satisfy the contract, b) provides the counterparty with the right to operate, access or direct others to operate the plant, property and equipment with at least a minor amount of the output, and c) facts and circumstances indicate that it is remote that one or more parties other than the purchaser will take more than a minor amount of the output that will be produced or generated during the term of the arrangement. The consensus in this Issue should be applied to a) arrangements agreed to or committed to, if earlier, after the beginning of an entity's next reporting period beginning after May 28, 2003, b) arrangements modified after the beginning of an entity's next reporting period beginning after May 28, 2003, and c) arrangements acquired in business combinations initiated after the beginning of an entity's next reporting period beginning after May 28, 2003. The adoption of this EITF did not have an impact on the company's financial position, cash flows or results of operations.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123(R) (SFAS 123R), *Share-Based Payment*, which is effective for public companies in periods beginning after June 15, 2005. This statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123R eliminates the ability to account for share-based compensation transactions using APB 25, and generally requires instead that such transactions be accounted for using a fair-value based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. We are currently evaluating option valuation methodologies and assumptions in light of SFAS 123R related to employee stock options. Current estimates of option values using the Black-Scholes method (as disclosed) may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 153 (SFAS 153), *Exchanges of Non-monetary Assets*, which is effective for non-monetary asset exchanges occurring in fiscal periods beginning after December 2004. This statement amends the guidance in

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**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (Continued)**

**New Accounting Pronouncements (Continued)**

APB Opinion No. 29, Accounting for Non-monetary Transactions, to eliminate the exception for non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. We do not expect the adoption of SFAS 153 to have an effect on the company's financial position, cash flows or results of operations.

**2. Organization and Business**

Genmab is a biotechnology company that creates and develops human antibodies for the treatment of life-threatening and debilitating diseases. Genmab has numerous products in development to treat various cancers, infectious diseases, and autoimmune and inflammatory conditions. We intend to continue expanding our portfolio with new therapeutic products. Genmab has established multiple partnerships with other biotechnology and pharmaceutical companies to gain access to disease targets and develop novel human antibodies. Its activities have consisted primarily of pre-clinical and clinical development of therapeutic antibody products.

The company was founded in 1999 by GenPharm International, Inc, a wholly-owned subsidiary of Medarex, Inc., through the purchase of a shell company that was formed in June 1998, but had not conducted any business activities.

The company has three wholly-owned subsidiaries: Genmab B.V. which was incorporated in The Netherlands in 2000 and focuses on the discovery and development of antibodies; Genmab, Inc. which started in July 2001 and is mainly focused on conducting clinical trials in the US and Canada on behalf of the Genmab group; and Genmab Ltd., an empty shell company that was formed in the United Kingdom in 2001. This entity is currently not active. Genmab A/S also holds equity interests in two strategic partners.

In 2003, Genmab recognized its first revenue since inception, DKK 68 million in milestone payments from our partner, Amgen. However, since the company has only recognized limited revenue, it is still considered a development stage company in accordance with SFAS No. 7,

Accounting and Reporting by Development Stage Enterprises. There are no assurances of significant future revenues from its research and development activities as there is a high degree of risk and uncertainty. The ability of the company to successfully develop, manufacture and market its proprietary products is dependent upon many factors. These factors could include, but are not limited to, the need for additional financing, the reliance on collaborative arrangements for research and development, marketing and product commercialization and the ability to develop or obtain manufacturing, sales and marketing capabilities. Additional factors could include maintaining patents and proprietary technologies, technological change and risk of obsolescence, development of products, competition, government regulations and regulatory approval, and product liability exposure. As a result of the aforementioned factors and related uncertainties, there can be no assurance of the company's future success.

Genmab A/S (A development stage company)  
Notes to the Consolidated Financial Statements (Continued)

## 3. Other Expense, net

	12 months ended December 31, 2004 DKK 000	12 months ended December 31, 2004 USD 000 (Unaudited)	12 months ended December 31, 2003 DKK 000	12 months ended December 31, 2002 DKK 000	Total since inception DKK 000
Realized gains on securities	12,853	2,351	13,996	13,369	44,897
Exchange rate gains	17,103	3,128	33,349	16,581	112,572
Realized loss on securities	(21,512 )	(3,934 )	(1,660 )	(14,059 )	(36,726 )
Impairment loss on other securities and equity interests			(4,525 )	(5,858 )	(24,610 )
Exchange rate losses	(26,041 )	(4,763 )	(43,609 )	(29,371 )	(128,000 )
	<b>(17,597 )</b>	<b>(3,218 )</b>	<b>(2,449 )</b>	<b>(19,338 )</b>	<b>(31,867 )</b>

## 4. Income Taxes

The provision for income taxes for the twelve-month period ended December 31, 2004, 2003 and 2002 is DKK 0, DKK 0, and DKK 200 thousand, respectively. In 2003, the company recognized DKK 66 thousand as refunded taxes expensed and paid in prior years. The tax expense for 2002 includes calculated tax for 2002 of DKK 200 thousand and DKK 126 thousand related to prior years. A reconciliation of the provision for income taxes and the amount computed by applying the applicable tax rate of 30% to income before tax is as follows:

	12 months ended December 31, 2004 DKK 000	12 months ended December 31, 2004 USD 000 (Unaudited)	12 months ended December 31, 2003 DKK 000	12 months ended December 31, 2002 DKK 000
Income taxes at statutory rate	(126,614 )	(23,157 )	(93,103 )	(143,126 )
Permanent differences	172	31	1,710	2,267
Permanent differences related to expensed warrants				1,595
Change in valuation allowance to unrealized gains and losses	2,050	375	(5,051 )	575
Other changes	(4,994 )	(913 )	(45 )	(2,035 )
Change in tax rate				(89 )
Expired tax losses	3,088	565		
Adjustment to prior years' deferred tax				(2,737 )
Other changes in deferred tax valuation allowance	126,298	23,099	96,423	143,876
<b>Provision for income taxes</b>	<b>0</b>	<b>0</b>	<b>(66 )</b>	<b>326</b>

At December 31, 2004, the parent company had net tax loss carry-forwards of approximately DKK 1,379,360 thousand for income tax purposes of which DKK 189,253 thousand expires in 2005 and 2006. DKK 1,190,107 thousand can be carried forward without limitation. In addition, the parent company had deductible temporary differences of approximately DKK 41,397 thousand.



**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**4. Income Taxes (Continued)**

For local tax purposes, the subsidiaries had net tax loss carry-forwards and deductible temporary differences totaling DKK 9,443 thousand.

Significant components of the deferred tax assets are as follows:

	<b>December 31, 2004 DKK 000</b>	<b>December 31, 2004 USD 000 (Unaudited)</b>	<b>December 31, 2003 DKK 000</b>	<b>December 31, 2002 DKK 000</b>
Tax deductible losses	1,386,099	253,511	970,886	662,335
Licenses and rights	35,411	6,477	35,431	27,672
Property and equipment	2,685	491	(1,733 )	(5,509 )
Other securities and equity interests	4,525	828	4,525	
Other temporary differences	1,480	271	97	3,298
Accumulated temporary differences	1,430,200	261,578	1,009,206	687,796
Deferred tax asset, calculated at 30%	429,060	78,473	302,762	206,339
Valuation allowance	(429,060 )	(78,473 )	(302,762 )	(206,339 )
	0	0	0	0

For financial reporting purposes, the value of the net deferred tax asset has been reduced to zero due to uncertainties with respect to the company's and the Group's ability to generate sufficient taxable income in the future.

**5. Marketable Securities**

All marketable securities are classified as available-for-sale and are reported at fair value. The company's portfolio of marketable securities has an average duration of less than two years and no securities have more than four years remaining to maturity. The company has classified all investments as short-term since it has the intent and ability to sell and redeem them within a year.

	<b>December 31, 2004 DKK 000</b>	<b>December 31, 2004 USD 000 (Unaudited)</b>	<b>December 31, 2003 DKK 000</b>
Cost at the end of the period	749,159	137,018	744,584
Unamortized cost	885	162	293
Total amortized costs at the end of the period	750,044	137,180	744,877
Unrealized loss at the end of the period	(3,647 )	(667 )	(5,883 )
Unrealized foreign exchange loss at the end of the period	(7,535 )	(1,378 )	(12,134 )
<b>Net book value</b>	<b>738,862</b>	<b>135,135</b>	<b>726,860</b>

Genmab A/S (A development stage company)  
Notes to the Consolidated Financial Statements (Continued)

5. Marketable Securities (Continued)

Specification of Portfolio as of December 31, 2004

	Cost DKK 000	Cost USD 000 (Unaudited)	Market Value DKK 000	Market Value USD 000 (Unaudited)
Kingdom of Denmark bonds	455,187	83,252	454,520	83,130
Other Danish securities	238,057	43,539	236,637	43,280
	693,244	126,791	691,157	126,410
US Government and Federal Agency Notes	28,714	5,252	25,006	4,573
US Corporate Notes	28,086	5,137	22,699	4,152
	56,800	10,389	47,705	8,725
<b>Total securities</b>	<b>750,044</b>	<b>137,180</b>	<b>738,862</b>	<b>135,135</b>

Scheduled maturities per December 31, 2004

	Cost DKK 000	Cost USD 000 (Unaudited)	Market Value DKK 000	Market Value USD 000 (Unaudited)
Maturity within one year	151,930	27,787	144,028	26,342
Maturity from one to three years	598,114	109,393	594,834	108,793
<b>Total securities</b>	<b>750,044</b>	<b>137,180</b>	<b>738,862</b>	<b>135,135</b>

Specification of Portfolio as of December 31, 2003

	Cost DKK 000	Cost USD 000 (Unaudited)	Market Value DKK 000	Market Value USD 000 (Unaudited)
Kingdom of Denmark bonds	437,075	79,939	432,062	79,022
Other Danish securities	213,023	38,961	214,094	39,157
	650,098	118,900	646,156	118,179
US Government and Federal Agency Notes	54,184	9,910	46,412	8,489
US Corporate Notes	40,302	7,371	34,292	6,272
	94,486	17,281	80,704	14,761
<b>Total securities</b>	<b>744,584</b>	<b>136,181</b>	<b>726,860</b>	<b>132,940</b>

Genmab A/S (A development stage company)  
Notes to the Consolidated Financial Statements (Continued)

5. Marketable Securities (Continued)

Scheduled maturities per December 31, 2003

	Cost DKK 000	Cost USD 000 (Unaudited)	Market Value DKK 000	Market Value USD 000 (Unaudited)
Maturity within one year	129,802	23,740	122,469	22,399
Maturity from one to four years	614,782	112,441	604,391	110,540
<b>Total securities</b>	<b>744,584</b>	<b>136,181</b>	<b>726,860</b>	<b>132,939</b>

6. Plant and Equipment, net

	December 31, 2004 DKK 000 (Unaudited)	December 31, 2004 USD 000	December 31, 2003 DKK 000
Machinery and other equipment	68,193	12,472	84,222
Fixed assets under construction	47,781	8,739	47,176
Leasehold improvements	32,684	5,978	30,195
Cost at the end of the period	148,658	27,189	161,593
Accumulated depreciation at the end of the period	(49,135 )	(8,987 )	(46,263 )
Accumulated impairment loss on fixed assets under construction at the end of the period	(42,170 )	(7,713 )	(42,170 )
<b>Net book value</b>	<b>57,353</b>	<b>10,489</b>	<b>73,160</b>
Net book value of assets under finance lease included above	28,357	5,186	23,448

7. Licenses and Rights, net

	December 31, 2004 DKK 000 (Unaudited)	December 31, 2004 USD 000	December 31, 2003 DKK 000
Cost at the end of the period	152,484	27,889	152,484
Accumulated amortization at the end of the period	(141,759 )	(25,927 )	(118,711 )
<b>Net book value</b>	<b>10,725</b>	<b>1,962</b>	<b>33,773</b>

Genmab A/S (A development stage company)  
Notes to the Consolidated Financial Statements (Continued)

## 8. Depreciation and Amortization

	12 months ended December 31, 2004 DKK 000	12 months ended December 31, 2004 USD 000 (Unaudited)	12 months ended December 31, 2003 DKK 000	12 months ended December 31, 2002 DKK 000	Total since inception DKK 000
Licenses and rights (amortized)	23,048	4,215	30,827	30,497	141,759
Property and equipment (depreciated)	30,615	5,600	32,843	16,971	85,045
	<b>53,663</b>	<b>9,815</b>	<b>63,670</b>	<b>47,468</b>	<b>226,804</b>
Depreciation and amortization was classified as follows:					
Research and development costs	47,999	8,779	56,888	42,996	208,804
General and administrative expenses	5,664	1,036	6,782	4,472	18,000
	<b>53,663</b>	<b>9,815</b>	<b>63,670</b>	<b>47,468</b>	<b>226,804</b>

## 9. Other Securities and Equity Interests

	December 31, 2004 DKK 000 (Unaudited)	December 31, 2004 USD 000	December 31, 2003 DKK 000
Cost at the end of the period	10,251	1,875	10,251
Accumulated impairment loss at the end of the period	(4,525 )	(828 )	(4,525 )
<b>Net book value</b>	<b>5,726</b>	<b>1,047</b>	<b>5,726</b>

Other securities and equity interests consist of investments in strategic partners of Genmab. As per December 31, 2004, such investments comprise equity shares in Scancell Ltd. and Paradigm Therapeutics Ltd., both privately held British biotech companies.

Until 2003, other securities and equity interests also included equity shares in Oxford GlycoSciences Plc., a publicly held British biotech company. During 2003, Oxford GlycoSciences was acquired by Celltech and our shares were sold.

As of December 31, 2004 and 2003, the company has recorded accumulated impairment losses on the investments of DKK 4,525 thousand and DKK 4,525 thousand, respectively, as a result of significant declines in the value of these investments, which are determined to be other than temporary.

## 10. Payable Technology Rights

In 2000, Genmab entered into the Genomics Agreement with Medarex, Inc. See Note 14 for additional details. Under this agreement, Genmab was required to pay USD 2 million annually for four consecutive years beginning on August 26, 2001. The company calculated the net present value of these payments using an interest rate of 5.71% per annum and capitalized this amount as licenses and rights. A

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**10. Payable Technology Rights (Continued)**

corresponding amount was recorded as a liability in the balance sheet. The company recognized imputed interest on the outstanding payment. In August 2004, the final payment under the Genomics Agreement was paid to Medarex.

**11. Share Capital**

In February 1999, Medarex and Bankforeningernes Erhvervsudviklingsforening Biomedicinsk Udvikling, BI Asset Management Fondsmæglerselskab A/S, L&#248;nmodtagernees Dyrtdisfond, A/S Dansk Erhvervsinvestering and Leif Helth Care A/S (the Bank Invest Group ) entered into an agreement in which the Bank Invest Group invested approximately DKK 35.4 million of cash in exchange for an approximate 45% equity interest in the company. Concurrently, Medarex granted Genmab a limited number of licenses to develop and commercialize a portfolio of human antibodies derived from its HuMAB-Mouse® Technology and retained an approximate 45% equity interest through its wholly owned subsidiary GenPharm International, Inc.

In May 1999 and March 2000, Medarex and the Bank Invest Group made additional contributions to the company in proportion to their existing equity interests. The Bank Invest Group invested approximately DKK 49 million of cash and Medarex granted the company an additional number of fully paid licenses along with an unlimited number of royalty bearing licenses to develop additional antibodies. After the March 2000 contributions, Medarex and the Bank Invest Group each owned approximately 45% of Genmab s outstanding common shares.

In June 2000, Genmab completed a private offering where it received approximately DKK 321 million from Medarex, the Bank Invest Group and new investors who subscribed to a total of 576,646 new shares. In August 2000, a total of 27,976 new shares were issued to Medarex in connection with the Genomics Agreement and the grant of an option of up to four antibodies obtained through an agreement with Eos Biotechnology. In August 2000, Genmab s shareholders approved a conversion of all existing classes of shares to one class of ordinary shares and a bonus share issuance of nine ordinary shares for each ordinary share. Following the issuance of the additional shares to Medarex and the bonus shares, the company had 15,812,020 outstanding ordinary shares.

In October 2000, Genmab completed an Initial Public Offering with a dual listing on the Copenhagen Stock Exchange and the Neuer Markt of the Frankfurt Stock Exchange. The global offering, which constituted 6,000,000 new shares equaling approximately 28% of the company s issued share capital after the listing, consisted of a public offering in both Denmark and Germany and a concurrent international offer to institutional investors outside the US and a private placement in the US to qualified institutional buyers under Rule 144A.

In May 2002, Genmab entered into a collaboration agreement with Roche. Following this agreement, Roche subscribed to 880,100 shares in the company in June 2002.

In December 2002, the company delisted from the Neuer Markt of the Frankfurt Stock Exchange. The primary reason for this delisting was that trading in this market was limited compared to the administration costs in connection with the listing.

In July 2003, the company issued 246,914 ordinary shares to Medarex, pursuant to the Genomics Agreement entered into in August 2000. The shares were issued through GenPharm International, Inc.

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**11. Share Capital (Continued)**

In July 2004, the company completed an international private placement with issuance of 5,623,000 new ordinary shares, raising gross proceeds to the company of DKK 478 million.

At 31 December 2004, the total number of outstanding shares was 29,752,363. Each share has a nominal value of DKK 1 and one vote.

**12. Warrants**

**Warrant Scheme**

Since inception, Genmab A/S has established warrant schemes, which have the primary objective of giving those who help build the company an opportunity to share in the value of the business that they are helping to create. The warrant schemes are meant to provide an incentive for all Group employees, members of the board of directors and members of the executive management as well as certain external consultants with a long-term relationship with us.

All employees to date have been granted warrants in connection with their employment.

Warrants are granted by our board of directors in accordance with authorizations given to it by the company's shareholders. The most recent warrant scheme was adopted by the board of directors in August 2004.

Under the terms of the recent warrant schemes, warrants are granted at an exercise price equal to the share price on the grant date. According to the company's Articles of Association, the exercise price cannot be fixed at a lower price than the market price at the grant date.

The warrant schemes contain anti-dilution provisions if changes occur in the company's share capital prior to the warrants being exercised.

**Warrants Granted From August 2004**

Under the current warrant scheme, effective from August 2004, warrants can be exercised from one year after the grant date. The warrant holder may as a general rule only exercise 25% of the warrants granted per full year of employment or affiliation with Genmab after the grant date. However, the warrant holder will be entitled to exercise all warrants granted regardless of termination of the relationship in instances where the employment or consultancy relationship is terminated without the warrant holder having given the company a good reason to do so. All warrants lapse at the tenth anniversary of the grant date.

**Warrants Granted Prior to August 2004**

Half of warrants granted under these warrant schemes can be exercised one year after the grant date with the other half exercisable two years after the grant date. The exercise period lasts for three years from the date when a warrant first becomes exercisable. If the warrants are not exercised within these periods, they lapse.

The exercise of warrants is not conditional upon continued employment or affiliation with Genmab. However, if the warrant holder exercises warrants, then upon the conclusion of employment or affiliation, the holder is obligated to offer to sell a specified percentage of shares issued back to the company. The sell

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**12. Warrants (Continued)**

back clause is not applicable in the event of termination as a result of the company's breach of the employment of affiliation contract. The sell back clause defines the percentage of shares that the holder is required to offer to sell back to the company in accordance with the following schedule:

- 75% of shares if termination occurs in the second year after grant.
- 50% of shares if termination occurs in the third year after grant.
- 25% of shares if termination occurs in the fourth year after grant.

The repurchase price to be paid for the shares by the company in these instances is the warrant holder's original exercise price. Accordingly, the warrant holder will not be able to profit on shares sold back to the company.

**Warrant Activity**

In February 1999, the company's shareholders authorized the board of directors to grant 250,000 warrants. In January 2000, the company's shareholders authorized the board of directors to grant an additional 600,000 warrants. The number of warrants authorized was increased by an additional 1,257,730 warrants in June 2000 and 2,163,533 in August 2000. In April 2003, the board of directors was authorized to grant an additional 500,000 warrants by the company's shareholders and in April 2004, this number of warrants authorized was increased by an additional 1,250,000 warrants. Accordingly, as per December 31, 2004, the board of directors has been authorized to grant a total of 6,021,263 warrants.

The following schedule specifies the warrant grants. The classification of warrant holders has been updated to reflect the current status of the individual warrant holders; i.e. if a non-employee consultant has been granted warrants and subsequently becomes employed by the company, such person will be included in the employees category. As a result, the updated totals of the individual groups may differ from information disclosed in previously issued financial statements.

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Genmab A/S (A development stage company)  
Notes to the Consolidated Financial Statements (Continued)

## 12. Warrants (Continued)

A summary of warrant activity and related information for the company's warrant compensation plans is as follows:

	12 months ended December 31, 2004	12 months ended December 31, 2003	12 months ended December 31, 2002	12 months ended December 31, 2004 Weighted average exercise price DKK	12 months ended December 31, 2004 Weighted average exercise price USD (Unaudited)	12 months ended December 31, 2003 Weighted average exercise price DKK	12 months ended December 31, 2002 Weighted average exercise price DKK
Outstanding at the beginning of the period	4,455,450	4,236,575	3,403,300	104.45	19.10	107.48	108.38
Granted	914,625	235,875	857,775	87.11	15.93	46.00	102.40
Exercised	(1,148,829 )	(17,000 )	(24,500 )	56.05	10.25	47.11	55.29
Expired	(190,200 )			253.38	46.34		
<b>Outstanding at the end of the period</b>	<b>4,031,046</b>	<b>4,455,450</b>	<b>4,236,575</b>	<b>107.29</b>	<b>19.62</b>	<b>104.45</b>	<b>107.48</b>
Warrants available for future grants at the end of the year	609,688						

Weighted average exercise price of warrants issued in 2004 and 2003:

	12 month period ended December 31, 2004 DKK	12 month period ended December 31, 2004 USD (Unaudited)	12 month period ended December 31, 2003 DKK
Warrants issued at a discount			
Warrants issued at market price	87.11	15.93	46.00
Warrants issued at a premium			

Weighted average grant date fair value of warrants granted in 2004 and 2003:

	12 month period ended December 31, 2004 DKK	12 month period ended December 31, 2004 USD (Unaudited)	12 month period ended December 31, 2003 DKK
Warrants issued at a discount			
Warrants issued at market price	54.89	10.04	20.80
Warrants issued at a premium			



**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**12. Warrants (Continued)**

**Compensation Costs Relating to Warrants**

The cost relating to warrants granted to employees is based on the intrinsic value of the outstanding warrants at each balance sheet date. Once the compensation costs have been expensed, they are not reversed, even if the intrinsic value of the warrants decreases. The total cost recognized in the statement of operations for warrants granted to employees was DKK 0 thousand for the year ended December 31, 2004 compared to DKK 0 thousand in 2003 and DKK 4,668 thousand in 2002.

The cost relating to warrants granted as compensation to non-employee consultants is based on the fair value of the outstanding warrants at each balance sheet date, and is calculated using the Black Scholes pricing model. Once the compensation costs have been expensed, they are not reversed, even if the fair value of the warrants decreases. The total compensation costs to non-employees for the year ended December 31, 2004 were DKK 0 thousand compared to DKK 0 thousand in 2003 and DKK 647 thousand in 2002.

Until 2002, the warrant program included a repurchase condition and, accordingly, the warrants were considered variable. The cost relating to warrants granted to employees was based on the intrinsic value of the outstanding warrants at each balance sheet date. Once the compensation costs had been expensed, they were not reversed, even if the intrinsic value of the warrants decreased. In 2002, employees and board members accepted a modification to the existing warrant program. The modification changed the repurchase condition and, accordingly, the outstanding warrants are no longer considered variable for accounting purposes. Therefore, the warrants to employees and the board of directors are not remeasured at each balance sheet date.

The grant of 212,500 warrants made on March 6, 2001 was subsequently re-priced by reducing the exercise price from DKK 222 to DKK 148 following the extraordinary board meeting of Genmab on July 30, 2001. According to FIN 44, this re-pricing triggers variable accounting under APB Opinion 25. This means that the ultimate charge recognized for this grant of warrants should be based on the intrinsic value at the point of exercise. Until that time, charges in each fiscal year should be based on the intrinsic value of the warrants as measured at the end of that year.

Genmad A/S (A development stage company)  
Notes to the Consolidated Financial Statements (Continued)

12. Warrants (Continued)

The issued and outstanding warrants to shareholders, board members, employees and non-employee consultants as of December 31, 2004 are summarized as follows:

Exercise price	Warrants outstanding			Warrants exercisable						
	Warrants exercisable from	Number of warrants outstanding	Weighted average remaining contractual life (in years)	Weighted average exercise price DKK	Weighted average exercise price USD (Unaudited)	Value of outstanding warrants at year end DKK (Unaudited)	Value of outstanding warrants at year end USD (Unaudited)	Number of warrants exercisable	Weighted average exercise price DKK	Weighted average exercise price USD (Unaudited)
<u>Preceding Warrant Scheme</u>										
DKK 33.70	September 26, 2003	377,395	2.28	33.70	6.16	69.35	12.68	377,395	33.70	6.16
DKK 37.00	June 25, 2004	142,775	2.99	37.00	6.77	67.85	12.41	69,763	37.00	6.77
DKK 48.90	February 11, 2001	212,250	0.13	48.90	8.94	51.31	9.38	212,250	48.90	8.94
DKK 51.50	December 4, 2004	7,250	3.43	51.50	9.42	58.70	10.74	3,625	51.50	9.42
DKK 59.00	November 11, 2004	25,000	3.36	59.00	10.79	53.90	9.86	12,500	59.00	10.79
DKK 59.70	June 26, 2001	582,751	0.56	59.70	10.92	41.93	7.67	582,751	59.70	10.92
DKK 62.50	October 10, 2004	57,600	3.28	62.50	11.43	51.59	9.44	28,800	62.50	11.43
DKK 86.00	April 1, 2005	68,750	3.75	86.00	15.73	42.28	7.73			
DKK 116.00	December 5, 2002	84,000	1.43	116.00	21.22	16.56	3.03	84,000	116.00	21.22
DKK 117.50	November 7, 2002	254,300	1.35	117.50	21.49	15.39	2.81	254,300	117.50	21.49
DKK 139.50	June 28, 2003	210,000	1.99	139.50	25.51	15.06	2.75	210,000	139.50	25.51
DKK 148.00	March 6, 2002	212,500	0.68	148.00	27.07	3.82	0.70	212,500	148.00	27.07
DKK 165.00	July 30, 2002	563,500	1.08	165.00	30.18	4.69	0.86	563,500	165.00	30.18
DKK 183.00	March 20, 2003	18,750	1.72	183.00	33.47	6.79	1.24	18,750	183.00	33.47
DKK 190.00	February 15, 2003	139,100	1.63	190.00	34.75	5.66	1.03	139,100	190.00	34.75
DKK 196.00	March 7, 2003	75,000	1.68	196.00	35.85	5.44	1.00	75,000	196.00	35.85
DKK 300.00	December 6, 2001	154,250	0.93	300.00	54.87	0.13	0.02	154,250	300.00	54.87
<u>Current Warrant Scheme</u>										
DKK 86.00	August 3, 2005	730,550	9.59	86.00	15.73	49.79	9.11			
DKK 89.50	September 22, 2005	33,575	9.73	89.50	16.37	49.10	8.98			
DKK 97.00	December 1, 2005	81,750	9.92	97.00	17.74	47.39	8.67			
<b>DKK 33.70 to DKK 300.00</b>		<b>4,031,046</b>	<b>3.10</b>	<b>107.29</b>	<b>19.62</b>	<b>33.24</b>	<b>6.08</b>	<b>2,998,484</b>	<b>115.85</b>	<b>21.19</b>

Genmab A/S (A development stage company)  
Notes to the Consolidated Financial Statements (Continued)

13. Internal Shareholders

	Number of ordinary shares owned as of December 31, 2004	Number of warrants held as of December 31, 2004
<b>Board of directors</b>		
Lisa N. Drakeman	448,540	492,500
Ernst Schweizer	234,340	74,500
Irwin Lerner	25,000	40,000
Michael Widmer		70,000
Karsten Havkrog Pedersen		35,000
Anders Gersel Pedersen		35,000
	<b>707,880</b>	<b>747,000</b>
<b>Management</b>		
Lisa N. Drakeman, see above		
Jan van de Winkel	117,500	270,000
Claus Juan M&quot;ller-San Pedro	332,415	142,500
	<b>449,915</b>	<b>412,500</b>
<b>Total</b>	<b>1,157,795</b>	<b>1,159,500</b>

14. Related Party Transactions

**Medarex Inc.**

On December 31, 2004, Medarex, Inc. owned approximately 25% of the outstanding shares of the company through its wholly owned subsidiary, GenPharm International, Inc.

During 1999 and 2000, Medarex granted 16 fully paid-up exclusive licenses to the company to use its HuMAb-Mouse and to produce human monoclonal antibodies for 16 antigens to be specified by Genmab. Furthermore, Genmab also has the right to access the TC Mouse technology on commercial terms. In addition, Medarex granted Genmab a non-exclusive license to use the HuMAb technology to produce human monoclonal antibodies for an unlimited number of antigens, subject to availability and the payment of fees, milestones and royalties. The licenses contributed to Genmab by Medarex have been recorded at their value on the date of contribution, and are supported by independent valuation studies. These licenses are amortized using the straight-line method over an estimated useful life of five years.

In 2000, the company and Medarex entered into a manufacturing agreement under which Medarex will produce antibodies to be used by the company in the clinical testing phase of product development. The company has also entered into manufacturing agreements with a number of third party suppliers, and accordingly, Medarex is not the company's sole source for antibody production capacity.

In 2000, Genmab entered into the Genomics Agreement, pursuant to which Medarex granted the company the exclusive rights to market its transgenic mouse technologies for certain multi-target (five or more targets) European genomics partnerships. Genmab's territory includes companies with European headquarters that have either developed or gained access to genomics or other novel targets. The company may also conduct business with any company it may choose for non multi-target (less than five targets)

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**14. Related Party Transactions (Continued)**

agreements. In exchange for the rights granted to Genmab by Medarex under the Genomics Agreement, the company issued 27,976 shares at a value of DKK 16,702 thousand, equal to USD 2 million to Medarex. Beginning in 2001, the Genomics Agreement states that the company will pay Medarex USD 2 million per year for four years. In 2001 and 2002, Medarex was paid in cash. However, Genmab had the option to pay these amounts in either cash or by issuance of shares. In 2003 Genmab exercised its option to pay the amount of USD 2 million that would otherwise become payable in cash, through the issuance of shares to GenPharm International, Inc. A total of 246,914 shares at a price of DKK 52.50 per share were subscribed by GenPharm by conversion of debt in the amount of DKK 12,963 thousand, pursuant to the Genomics Agreement. In 2004, the final payment of USD 2 million was made to Medarex in cash.

The company has paid Medarex for manufacturing services, licenses and the reimbursement of administrative expenses. For 2004, 2003 and 2002, the company has recorded transactions totalling DKK 7,309 thousand, DKK 15,335 thousand, and DKK 105,880 thousand, respectively, in connection with these agreements.

No significant costs have been reimbursed by Medarex during the years presented, for costs incurred on their behalf. In part of 2002, the company leased from Medarex a limited area of office space in Princeton, New Jersey, USA. This leasing transaction is not considered material. In addition to the payable technology rights recorded in 2003 and 2002, the company has recorded payables to Medarex of DKK 547 thousand as of December 31, 2004, compared to DKK 645 thousand as of December 31, 2003.

The partnering model entered into between Medarex and Genmab in the Genomics Agreement is based on collaboration, cost sharing and shared commercial rights. In a typical collaboration, the target company will contribute five or more targets to the alliance. Genmab and Medarex will jointly contribute the antibody products to the targets. For each product to be developed the target company will pay half the development costs and Genmab and Medarex together will pay equally the other half. Genmab and Medarex together may also make their full repertoire of antibody development capabilities available to the collaborations, including pre-clinical and clinical research and manufacturing capacity.

In June 2001, Genmab and Medarex entered into a collaboration agreement to develop HuMax-Inflam. Under the agreement, the parties will share the costs associated with the pre-clinical and clinical development of the product and will share the commercialization rights and royalties. In 2004, the development activities led to recognition of net cost reimbursement of DKK 4,480 thousand, which reduced our development expenses. The comparative net cost reimbursement for 2003 was DKK 5,374 thousand.

**IPC-Nordic A/S**

IPC-Nordic is considered a related party, as the company is controlled by a member of management of Genmab. During the past years, Genmab has purchased drug supply distribution services from IPC-Nordic, as the services were not available elsewhere in Denmark. The fees for the services are determined following an arms length principle and the total fees paid for such services were DKK 599 thousand in 2004 compared to DKK 1,663 thousand in 2003. As per December 31, 2004, the company had recorded payables to IPC-Nordic of DKK 16 thousand.

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**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**14. Related Party Transactions (Continued)**

**The Company's Board of Directors and its Officers**

One member of the board of directors has rendered additional services to the company during the year for which he has received consultancy fees totalling DKK 4,378 thousand.

**15. Research and Development Agreements**

**Amgen / Immunex**

In 2001, the company entered into an agreement with Immunex Corporation ( Immunex ) for the exclusive worldwide rights to Immunex's patent estate relating to antibodies towards IL15 and IL15r. Immunex retained an option, exercisable after Phase II clinical trials have been completed, to commercialize the resulting product. Upon exercise of the option, Immunex would be obligated to pay to the company license fees, milestone payments as well as be obligated to share future profits with the company. Immunex would also be responsible for all future development costs. Subsequent to signing this agreement, Immunex was acquired by Amgen, who took over the rights and obligations under this agreement. In 2003, Amgen exercised its commercialization options for both the HuMax-IL15 antibody program and the IL-15 receptor program ahead of schedule, prior to receiving Phase II clinical data for HuMax-IL15. Amgen is responsible for further development of HuMax-IL15. In connection with the exercise of the commercialization option in 2003, Amgen expanded its agreement with Genmab to include a new antibody program for a different undisclosed disease target. Under the terms of the expanded and amended agreement, if products to all three targets are successfully commercialized and certain sales levels are achieved, Genmab will be entitled to receive license fees and milestone payments. Genmab is also entitled to royalties on commercial sales instead of the profit sharing designated in the original agreement. Positive interim data from the first 110 patients treated with AMG 714 (formerly known as HuMax-IL15) in the RA Phase II trial was presented in October 2004, and it was concluded that AMG 714 was well tolerated and generated adverse events similar to that of placebo. Amgen plans to enroll a total of 180 patients in the study.

**Roche**

In 2001 the company announced a broad antibody development collaboration with Roche for the creation and development of human antibody therapeutics products towards targets identified by Roche. The company is to undertake research and development activities whereas Roche will undertake commercialization after filing of biologics license application. The company will receive certain milestone and royalty payments depending on the successful development of products. In 2002, the company announced a broad expansion of its collaboration with Roche for the creation and development of human antibody therapeutic products for life-threatening and debilitating diseases. Roche also made an equity investment totalling USD 20 million at a price of DKK 180 per share, equal to net proceeds of DKK 158 million. This expanded program involves a number of new disease targets from Roche. Genmab expects to initiate approximately fifteen new projects in the coming years across a number of therapeutic areas. In January and October 2003, Genmab announced the achievement of the first and second milestones in our expanded collaboration with Roche having reached the proof of concept stage with two different human antibodies generated by Genmab. In September 2004, Genmab announced that we had established proof of concept for two additional human antibodies and thereby reached two more milestones in our collaboration with Roche. These antibodies were each designed to target a different disease area and

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**15. Research and Development Agreements (Continued)**

represented the third and fourth antibodies in the collaboration to reach this stage. Up to now, Roche has selected a total of four Genmab antibodies as candidates for clinical development. Under the partnership agreement, we utilize our broad antibody expertise and development capabilities to create human antibodies to a wide range of disease targets identified by Roche. Genmab will receive milestone and royalty payments based on successful products. Under certain circumstances, Genmab may obtain rights to develop products based on disease targets identified by Roche.

**Other**

During 2001, the company entered into a number of additional agreements with parties such as Scancell and deCODE to develop new antibody therapeutic products. The collaborations will utilize novel disease targets discovered by the partners. The companies will focus on several therapeutic areas. The alliances are mainly multi-target alliances based on the company's Genomics Agreement with Medarex and a number of partners have already identified initial groups of disease targets using genomics or other capabilities.

In 2002, the company entered into a number of additional agreements with parties such as Bionomics, Paradigm Therapeutics and ACE BioSciences to develop new antibody therapeutic products. The collaborations will utilize novel disease targets discovered by the partners. In 2003, Genmab and ACE BioSciences identified the first target of the collaboration, and Genmab is now developing an antibody for potential treatment of fungal infection. No material costs have yet been incurred in connection with these agreements.

In 2003, the company entered into an agreement with the not-for-profit-organization Sanquin to develop a treatment against hemophilia. In addition, Genmab in-licensed the rights to a human antibody from Connex GmbH, a privately owned German company currently in administration, and INSERM, the French National Institute for Health and Medical Research. The antibody, HuMax-HepC has potential use in the treatment of Hepatitis C virus reinfection.

In 2004, Genmab licensed new membrane phosphatase from Ganymed Pharmaceuticals AG, a privately held pharmaceutical company located in Germany. The membrane phosphatase is a new cancer target that is associated with a variety of cancers, including melanoma, breast and lung cancers. Under the terms of the agreement, Ganymed will be entitled to license fees, milestones and royalties on the sale of successfully commercialized products.

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**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**16. Commitments and Contingencies**

**Leases**

The Group leases office space under operating leases, which are non-cancelable for various periods until 2010. At December 31, 2004, future minimum payments under the office leases were as follows:

	DKK 000	USD 000 (Unaudited)
2005	16,973	3,104
2006	13,460	2,462
2007	8,992	1,645
2008	8,992	1,645
2009	8,992	1,645
Thereafter	8,992	1,645
	<b>66,401</b>	<b>12,146</b>

For the years ended December 31, 2004, 2003 and 2002, the Group recorded rent expenses of DKK 17,123 thousand, DKK 12,235 thousand and DKK 12,565 thousand, respectively. The Group has established bank guarantees totaling DKK 3,046 thousand as collateral for the operating lease arrangements. In addition to the office leases, the Group has entered into minor agreements with respect to operating leases for cars and office equipment. The total commitments under operating leases of cars and office equipment amount to DKK 4,173 thousand.

**Finance Leases**

The Group has entered into finance lease contracts with respect to cars and laboratory equipment. The lease liability regarding these contracts has been recognized in the balance sheet and covers various periods up to 2009. The average effective interest rate in the Group's lease arrangements is approximately 4.1%. Future minimum lease payments under such finance leases and the net present value as of the end of December 2004 are as follows:

	DKK 000	USD 000 (Unaudited)
<b>Minimum lease payments</b>		
Within 1 year	8,773	1,605
From 1 to 5 years	22,210	4,062
	30,983	5,667
Future finance charges	(2,112 )	(387 )
<b>Total</b>	<b>28,871</b>	<b>5,280</b>
<b>Net present value of future payments</b>		
Within 1 year	8,611	1,575
From 1 to 5 years	20,260	3,705
<b>Total</b>	<b>28,871</b>	<b>5,280</b>

One of the parent company's bank accounts has been registered as collateral for a part of the Group's finance lease obligations. The balance of this account is included in cash and cash equivalents as per

**Genmab A/S (A development stage company)**  
**Notes to the Consolidated Financial Statements (Continued)**

**16. Commitments and Contingencies (Continued)**

December 31, 2004, at an amount of DKK 18,668 thousand. In addition, the parent company has established a bank guarantee of DKK 6,013 thousand towards a lessor of Genmab B.V.

**Other Purchase Obligations**

The Group has entered into a number of agreements which are mainly within the area of manufacturing services related to the research and development activities. Under the current development plans, the contractual obligation will lead to the following future payments:

	<b>DKK 000</b>	<b>USD 000</b>
		<b>(Unaudited)</b>
2005	91,565	16,747
2006	6,200	1,134
2007	1,500	274
2008	750	137
2009	450	82
Thereafter	566	104
	<b>101,031</b>	<b>18,478</b>

**License Agreements**

The Group is a party to a number of license agreements. If and when the Group commercializes products utilizing the licensed technology, royalties will fall due, determined on the sales of such products.

**17. Subsequent Events**

No significant events have occurred since the balance sheet date which could significantly affect the financial statements as of December 31, 2004.



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

None.

**Item 9A. Controls and Procedures**

*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, 2004. 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, 2004.

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:* Such evaluation did not identify any significant changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2004 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, 2004, 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, 2004, 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, 2004, 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, 2003 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, 2004 and our report dated March 15, 2005 expresses an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey  
March 15, 2005

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**PART III**

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

The information required herein will be reported in our definitive Proxy Statement for the Annual Meeting of Shareholders which we expect will be filed on or before April 29, 2005, and is incorporated herein by reference.

**Item 11. Executive Compensation**

The information required herein will be reported in our definitive Proxy Statement for the Annual Meeting of Shareholders which we expect will be filed on or before April 29, 2005, and is incorporated herein by reference.

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

The information required herein will be reported in our definitive Proxy Statement for the Annual Meeting of Shareholders which we expect will be filed on or before April 29, 2005 and is incorporated herein by reference.

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

The information required herein will be reported in our definitive Proxy Statement for the Annual Meeting of Shareholders which we expect will be filed on or before April 29, 2005, and is incorporated herein by reference.

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

The information required herein will be reported in our definitive Proxy Statement for the Annual Meeting of Shareholders which we expect will be filed on or before April 29, 2005, and is incorporated herein by reference.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

**Item  
Number**

- (a).1.(a) Consolidated Financial Statements **Medarex, Inc.**  
 Report of Independent Registered Public Accounting Firm.  
 Consolidated Balance Sheets as of December 31, 2003 and 2004.  
 Consolidated Statements of Operations for the Years Ended December 31, 2002, 2003 and 2004.  
 Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2002, 2003 and 2004.  
 Consolidated Statements of Cash Flows for the Years Ended December 31, 2002, 2003 and 2004.  
 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.  
 Consolidated Statements of Operations for the twelve months ended December 31, 2004, 2003 and 2002.  
 Consolidated Balance Sheets as of December 31, 2004 and 2003.  
 Consolidated Statements in Shareholders' Equity for the years ended December 31, 2004, 2003 and 2002.  
 Consolidated Statements of Cash Flows for the twelve months ended December 31, 2004, 2003 and 2002.  
 Notes to Consolidated Financial Statements.
- (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.
- 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 Employment Agreement between the Registrant and Dr. Nils Lonberg, dated January 5, 2004.
- 10.31 Employment Agreement between the Registrant and W. Bradford Middlekauff, dated January 5, 2004.
- 10.32 Employment Agreement between the Registrant and Dr. Geoffrey M. Nichol, dated January 5, 2004.
- 10.33 Employment Agreement between the Registrant and Dr. Ronald A. Pepin, dated January 5, 2004.

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10.34	Employment Agreement between the Registrant and Christian S. Schade, dated January 5, 2004.
10.40	Form of Employee Incentive Stock Option Agreement.
10.41	Form of Employee Nonqualified Stock Option Agreement.
10.42	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.
10.81(33)	Rights Exchange Agreement dated as of June 10, 1998 between the Registrant and BCC Acquisition I LLC, together with the exhibits thereto.
10.84(36)**	Shareholders Agreement dated February 25, 1999, among Medarex, Inc., GenPharm International, Inc., BankInvest, BI Asset Management, Fondsmæglersekskab 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.
10.99(51)**	Agreement dated December 21, 1999, among the Registrant, GenPharm, and Immuno-Designed Molecules S.A.
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.
10.111	Medarex, Inc. 2004 Restricted Stock Unit Award and Deferred Compensation Program.
10.112	Medarex, Inc. Second 2004 Restricted Stock Unit Award and Deferred Compensation Program.
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.

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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.
21	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP.
23.2	Consent of PriceWaterhouseCoopers.
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.

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- (33) Incorporated by reference to the identically numbered exhibit to the Registrant's Current Report on Form 8-K filed on June 15, 1998.
- (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.
- (51) Incorporated by reference to Exhibit Number 10.9 to the Registrant's Current Report on Form 8-K filed on January 26, 2000.
- (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 4(b) to the Registrant's Registration Statement on Form S-8 (File Number 333-39084) filed on June 12, 2000.
- (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.
- (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.
- (64) Incorporated by reference to Exhibit No. 4.2 to Registrant's Current Report on Form 8-K filed on May 25, 2001.

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(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.

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- (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.

\* A signed original of this written statement required by Section 906 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.

**(b) Reports on Form 8-K**

Form 8-K filed on November 8, 2004, relating to a press release regarding a collaboration between the Company and Bristol-Myers Squibb Company.

Form 8-K filed on November 8, 2004, relating to a press release of the Company's financial results for the quarter ended September 30, 2004.

Form 8-K filed on November 8, 2004, relating to a confidential treatment request regarding the agreements signed between the Company and Pfizer, Inc.

Form 8-K file on November 23, 2004, relating to a press release regarding a collaboration between the Company and MedImmune, Inc.

Form 8-K filed on December 14, 2004, relating to a press release regarding the FTC request for an extension of the review period of the collaboration with Bristol-Myers Squibb Company.

Form 8-K filed on December 15, 2004, relating to a press release regarding the redemption of the Company's 4.25% Convertible Senior Notes.

Form 8-K filed on December 23, 2004, relating to an impairment charge with respect to the Company's investment in IDM S.A.

