

MEDAREX INC  
Form 10-K  
March 15, 2004

---

**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, 2003

Commission File No. 0-19312

---

**MEDAREX, INC.**

(Exact name of registrant as specified in its charter)

**New Jersey**  
(State of Incorporation)

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

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

**08540**  
(Zip Code)

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

---

Edgar Filing: MEDAREX INC - Form 10-K

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

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

<u>Title of Class</u>	<u>Name of Each Exchange on Which Registered</u>
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 x 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 checkmark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes x No "

As of February 27, 2004, the registrant had outstanding 79,087,401 shares of Common Stock, \$0.01 par value ( Common Stock ), which is registrant's only class of Common Stock.

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$448.9 million as of June 30, 2003, 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 8,561,734 shares held by directors, officers and stockholders whose ownership exceeded 5% of the Registrant's outstanding Common Stock as of June 30, 2003. 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.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement for the Annual Meeting of Shareholders to be held on May 19, 2004 (the Proxy Statement ) are incorporated by reference in Parts II and III of this Report. Other documents incorporated by reference in this report are listed in the Exhibit Index.

**MEDAREX, INC.**

**TABLE OF CONTENTS**

**FORM 10-K**

	<u>Page</u>
<b>PART I</b>	
Item 1. <u>Business</u>	1
Item 2. <u>Properties</u>	43
Item 3. <u>Legal Proceedings</u>	43
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	43
<b>PART II</b>	
Item 5. <u>Market for Registrant's Common Equity and Related Shareholder Matters</u>	44
Item 6. <u>Selected Consolidated Financial Data</u>	45
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	46
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risks</u>	60
Item 8. <u>Consolidated Financial Statements and Supplementary Data</u>	F-1
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	61
Item 9A. <u>Controls and Procedures</u>	61
<b>PART III</b>	
Item 10. <u>Directors and Executive Officers of the Registrant</u>	61
Item 11. <u>Executive Compensation</u>	61
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters</u>	61
Item 13. <u>Certain Relationships and Related Transactions</u>	120
Item 14. <u>Principal Accountant Fees and Services</u>	120
<b>PART IV</b>	
Item 15. <u>Exhibits, Financial Statement Schedules and Reports on Form 8-K</u>	63
<u>Signatures</u>	67
Certifications	

## PART I

In this Annual Report, Medarex or the company, we, us and our refer to Medarex, Inc., and our wholly owned subsidiaries. This Annual Report contains forward-looking statements that involve risk and uncertainties. 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 document. Actual events or results may differ materially from those discussed in this Annual Report.

Medarex<sup>®</sup>, HuMAb-Mouse<sup>®</sup>, GenPharm<sup>®</sup>, KM-Mouse<sup>®</sup>, UltiMAb Human Antibody Development System<sup>®</sup> and Trans-Phage Technology<sup>®</sup> are registered U.S. trademarks of Medarex, Inc. UltiMAb and Ultra-Potent Toxin are trademarks of Medarex, Inc. All other company names, registered trademarks, trademarks and service marks included in this Annual Report are trademarks, registered trademarks, service marks or trade names of their respective owners.

### Item 1. Business

#### Overview

We are a biopharmaceutical company focused on the discovery and development of fully human antibody-based therapeutic products. We believe that our UltiMAb Human Antibody Development System<sup>®</sup> enables us to rapidly create and develop fully human antibodies for a wide range of diseases, including cancer, inflammation, autoimmune disease and other life-threatening and debilitating diseases.

We believe that antibodies are proven candidates for therapeutic products. To date, the United States Food and Drug Administration, or FDA, has approved 17 antibody-based therapeutic products for sale in the United States. In 2003, 15 of these products generated aggregate worldwide sales in excess of \$5.0 billion. We intend to participate in this market and, to this end, are developing an expanding pipeline of therapeutic antibody products generated through the use of our proprietary UltiMAb human antibody development technology.

Currently, 17 antibody products derived from our UltiMAb human antibody development technology are in human clinical trials, or have had regulatory applications submitted for such trials. These antibodies are designed to treat a wide range of diseases, such as cancer (including various lymphomas), rheumatoid arthritis and other inflammatory and autoimmune diseases. Five of these antibody products are fully owned by Medarex: MDX-010 (Phase II clinical trials), MDX-060 (Phase II clinical trials), MDX-070 (Phase I/II clinical trials), MDX-214 (Phase I/II clinical trials) and MDX-1307 (Phase I clinical trials), for the treatment of cancer, lymphoma and/or HIV. One antibody product for autoimmune disease, MDX-018 (Phase I/II clinical trials), is being jointly developed with our licensing partner, Genmab A/S, and four are being developed separately by Genmab: HuMax-CD4 (Phase II clinical trials) for cutaneous T-cell lymphoma, HuMax-IL15 (Phase II clinical trials) for rheumatoid arthritis, HuMax-EGFr (Phase I/II clinical trials) for head and neck cancer and HuMax-CD20 (Phase I/II clinical trials) for non-Hodgkin's lymphoma. Additionally, our licensing partners, including Novartis Pharma AG and Centocor, Inc. (a subsidiary of Johnson & Johnson), among others, are developing a total of seven antibody products for inflammatory and/or autoimmune diseases and cancer that are currently in early clinical trials. We and our partners also have a number of product candidates in preclinical development. The preceding information regarding the clinical status of antibody products is based on our and our partners' public disclosures and other publicly available information.

As of March 1, 2004, we have more than 45 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 Amgen, Inc., Centocor, Pfizer, Inc., Eli Lilly & Company, Human Genome Sciences, Inc., Abbott

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

Laboratories, Novartis, Novo Nordisk A/S and Schering AG. Some of our partnerships are licensing partnerships, with the potential to pay us licensing fees, milestone payments and royalty payments; others are collaborative partnerships and provide for the sharing of product development costs, as well as any revenues, expenses and profits associated with products arising under the collaboration.

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 up to 15 new antibody projects per year 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, development and commercialization of antibody-based products for us and for our partners. We intend to add sales and marketing and additional manufacturing capabilities as needed.

Our business strategy is to build one of the industry's largest clinical pipelines of human antibody-based therapeutics for the treatment of cancer and other life-threatening and debilitating diseases. To this end, we intend to capitalize on the value of our own human antibody products by developing them, ourselves or with partners, through late stage clinical trials and/or regulatory approval. We believe that this will allow us to retain substantial commercial rights or profit sharing opportunities with regard to these products. In addition, we are expanding our number of partnerships, which we believe provides us with the opportunity to participate in the development and commercialization of substantially more product candidates than we could using only our own resources.

### **Scientific Background**

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. Each monoclonal antibody has a unique molecular structure that directs it to a specific target.

About thirty years ago, scientists recognized that if antibodies could be created in the laboratory, they could potentially function as a powerful tool for the treatment of many diseases. These efforts were partially successful when scientists discovered a way to make monoclonal antibodies using laboratory mice. Mouse-generated monoclonal antibodies, however, were often rejected by patients whose immune systems recognized them as foreign because they were not human proteins, and the patients produced a human anti-mouse antibody, or HAMA, response. This response reduces the effectiveness of the antibody by neutralizing the binding activity and by rapidly clearing the antibody from circulation in the body. The HAMA response can also cause significant toxicities with subsequent administrations of mouse antibodies.

Subsequent generations of antibodies have been re-engineered to address these immunogenic complications, resulting in monoclonal antibodies that are less mouse and more human. Scientists developed chimeric antibodies, which still contain mouse protein sequences (approximately 33%) but also contain human protein sequences (approximately 66%). Although chimeric antibodies are more human and theoretically, less likely to trigger an immune reaction, they nonetheless can trigger a human anti-chimeric antibody response by the human immune system. Scientists then developed CDR-grafted or humanized antibodies which contain approximately 5% to 10% mouse protein sequences.

Through our UltiMAB Human Antibody Development System, we can create all types of antibodies that are fully human (100% human protein sequences) by using transgenic 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 monoclonal 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 monoclonal 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.

---

**Products in Development**

We and our partners have generated and are developing a number of potentially promising monoclonal antibodies using our proprietary fully human antibody technology, 17 of which are currently in various stages of human clinical trials. In addition, our preclinical development pipeline includes product candidates for a variety of indications, such as cancer, autoimmune/inflammatory diseases and infectious diseases.

The following table summarizes potential therapeutic indications and development stages for our active product candidates and those of our partners (based on our and our partners' public disclosure and other publicly available information), and is followed by brief descriptions of each specific program.

**Medarex Product Candidates in Clinical Development**

<u>PRODUCT</u>	<u>INDICATION</u>	<u>CLINICAL STATUS</u>	<u>OWNER</u>
MDX-010 + gp100 Peptides	Melanoma	Pivotal*	Medarex
MDX-010	Melanoma, Prostate, Breast, Renal Cell Cancers	Phase II	Medarex
MDX-010	HIV	Phase I/II	Medarex
MDX-010 Combination/	Melanoma and other cancers	Early Clinical	Medarex
Exploratory Studies			
MDX-060	Hodgkin's disease, anaplastic large cell lymphoma	Phase II	Medarex
MDX-070	Prostate cancer	Phase I/II	Medarex
MDX-214	Cancer	Phase I/II	Medarex
MDX-018	Autoimmune disease	Phase I/II	Medarex,
			co-developing
			with Genmab A/S
<u>MDX-1307</u>	Cancer	Phase I**	Medarex***

\* Phase II data has been evaluated, and pivotal trials are expected to be initiated in the first half of 2004, subject to ongoing end of Phase II discussions with the FDA.

\*\* An IND filing to commence a Phase I clinical trial was accepted by the FDA in February 2004.

\*\*\* We are in the process of a possible public offering of a portion of the common stock of our wholly-owned subsidiary Celldex Therapeutics, Inc. As part of this transaction, we intend to assign our rights to this product, including the associated IND, to Celldex. In such event, 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.





**Medarex Licensing Partners Product Candidates in Clinical Development**

<u>PRODUCT</u>	<u>INDICATION</u>	<u>CLINICAL STATUS</u>	<u>LICENSEE</u>
HuMax-CD4	Cutaneous T-cell lymphoma (CTCL)	Phase II	Genmab A/S in North America; Eisai Co. Ltd. in Asia and Europe <sup>ñ</sup>
HuMax-IL15	Rheumatoid arthritis	Phase II	Genmab A/S under agreement with Immunex Corporation
CNTO 1275	Anti-inflammatory disease	Phase II	Centocor, Inc. <sup>ñ</sup>
HuMax-EGFr	Head and neck cancer	Phase I/II	Genmab A/S
HuMax-CD20	Non-Hodgkin s lymphoma	Phase I/II	Genmab A/S
CNTO 148	Anti-inflammatory disease	Phase I	Centocor, Inc. <sup>ñ</sup>
CNTO 95	Cancers	Phase I	Centocor, Inc. <sup>ñ</sup>
Novartis Antibody-1	Autoimmune disease	Phase I	Novartis Pharma AG <sup>ñ</sup>
Novartis Antibody-2	Autoimmune disease	Phase I	Novartis Pharma AG <sup>ñ</sup>
Fibrogen Antibody	Idiopathic pulmonary fibrosis	Phase I	Fibrogen, Inc. <sup>ñ</sup>
Undisclosed	Undisclosed	Phase I	Undisclosed <sup>ñ</sup>

**Medarex Product Candidates in Clinical Development**

**MDX-010 (Anti-CTLA-4 Antibody)** *Melanoma; Prostate Cancer; Breast Cancer; Renal Cancer; HIV; Combination/Exploratory Studies.* 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, can 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.

We are currently conducting the following human clinical trials for this product:

*Melanoma:* Medarex is conducting a number of clinical studies investigating MDX-010 for the treatment of melanoma. A Phase II trial of MDX-010 in combination with a melanoma peptide vaccine based on gp100 has completed treatment of 41 patients with metastatic melanoma who have failed prior therapies. Patients were treated with one of two dose regimens. Of the 14 patients treated in the high-dose treatment cohort, two patients

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.

<sup>ñ</sup> We expect to receive milestone payments, as these products move through clinical trials, and royalties, should commercialization occur.

experienced complete responses ongoing for over 15 months and one patient experienced a partial response ongoing for over 20 months. Of the 27 patients treated in the low-dose treatment cohort, three patients experienced partial responses, two of which have ongoing responses of approximately one year or more. Out of the total of 41 patients, 11 reported drug-related autoimmune breakthrough events, or ABEs, such as dermatitis, pruritis and diarrhea, and responded to medical therapy. Of the patients who experienced ABEs, approximately 50% also experienced anti-tumor responses. Based on these observations, we believe that these ABEs may be associated with the induction of anti-cancer immune responses. We expect to initiate a pivotal program for MDX-010 in combination with the gp100 vaccine in the first half of 2004, subject to end of Phase II discussions with the FDA.

A separate Phase II trial designed to study MDX-010 both as a single agent and in combination with DTIC<sup>®</sup> (dacarbazine) has completed treatment of 72 chemotherapy naïve patients with metastatic melanoma. In this ongoing study, certain patients have experienced partial responses or stable disease. Patients in this study are still being followed and evaluated for response duration.

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. Some patients in our melanoma trials have experienced anticipated drug-related autoimmune adverse events, such as dermatitis and colitis, 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. We believe that these adverse events will not materially affect our ability to continue with clinical trials of this product as planned.

*Prostate Cancer:* A Phase II prostate cancer trial, initiated in October 2002, is designed to study MDX-010 as a single agent and in combination with Taxotere<sup>®</sup> (docetaxel), is expected to accrue up to 40 chemotherapy naïve patients with hormone refractory prostate cancer, or HRPC.

*Breast Cancer:* A multi-center, open-label Phase II breast cancer trial was initiated in September 2003, and 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 24 patients with renal cell cancer.

*Other Cancers:* MDX-010 is under investigation for a variety of cancer indications. In addition to melanoma, prostate cancer, breast cancer and renal cell cancer, 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, initiated in June 2003, 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. The trial is designed to establish safety and tolerability of MDX-010 in patients infected with HIV, and to preliminarily evaluate clinical efficacy.

*Additional Combination Studies:* As part of our MDX-010 clinical development program, separate clinical trials of MDX-010 in combination with various agents, including IL-2, chemotherapy and tumor vaccines, are currently underway. In addition to the Phase II trial of MDX-010 in combination with gp100 melanoma peptides, a Phase I/II trial of MDX-010 in combination with a different melanoma peptide vaccine based on multiple melanoma antigens has completed the full enrollment of 19 patients with advanced resected melanoma. There is also a Phase I study in 16 previously vaccinated metastatic melanoma and ovarian cancer patients underway to obtain a preliminary assessment of the biologic activity

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

of MDX-010. Pursuant to a May 2003 research and development collaboration with Cell Genesys, Inc., we expect to initiate a Phase I clinical study in 2004 involving the use of Cell Genesys' GVA~~X~~ prostate cancer vaccine in combination with MDX-010. Under the terms of our collaboration, the cost of this clinical trial will be shared equally by both companies.

**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, MDX-060 may facilitate the elimination of such cells by the human immune system. In a preclinical study, MDX-060 showed activity in human tumor engrafted mice.

Findings from an ongoing Phase II clinical trial of MDX-060 in 31 patients with relapsed or refractory HD, ALCL or other CD30-positive lymphomas indicated that MDX-060 demonstrated clinical activity, including one complete response and two partial responses. In addition, stable disease was observed in nine patients. 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. All patients had failed multiple prior treatments and most had failed bone marrow transplantation. Enrollment of approximately 30 patients is ongoing in the Phase II portion of the trial to further explore the safety and activity profile of MDX-060.

**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. Preclinical data suggests that the antibody will target live prostate tumor cells. An ongoing, single-dose, dose-escalation Phase I/II study is expected to accrue up to 40 patients with metastatic prostate cancer. The study is intended to evaluate safety and tumor response based on objective tumor response and decreases in PSA serum levels. In 2004, we expect to initiate a separate multi-dose, dose-escalation Phase II clinical study of MDX-070 in patients with hormone refractory prostate cancer.

**MDX-214 (Anti-EGFr/CD89 Antibody) *Cancer.*** MDX-214 is a bifunctional 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.

**MDX-018 (Anti-inflammatory Antibody) *Autoimmune Disease.*** MDX-018, also known as HuMax-Inflam, is a fully human antibody that we are co-developing with Genmab. The Phase I/II European clinical trial is expected to enroll up to 44 patients. The disease and target mechanism for MDX-018 have not yet been made public.

**MDX-1307 (Anti-Mannose Receptor/hCG- $\beta$  Antibody) *Colorectal, Pancreatic and/or Bladder Cancers.*** MDX-1307 is a fusion protein composed of a mannose receptor-specific human antibody conjugated to the beta chain of human chorionic gonadotropin, or hCG. The 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 which is expected to enroll up to 18 patients with metastatic or locally advanced colorectal, pancreatic or bladder cancers.

#### ***Selected Medarex Product Candidates in Preclinical Development***

We have an active preclinical development program 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 include, among others, the following:

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

**MDX-1100 (Anti-IP-10 Antibody)** *Inflammatory Diseases*. We are working with our partner, Ability Biomedical Corporation, to develop 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 and multiple sclerosis.

**MDX-1185 and MDX-1103 (Anti-Type 1 IFN Antibodies)** *Systemic Lupus Erythematosus*. MDX-1185 and MDX-1103 are fully human antibodies that target two different Type 1 IFN pathways that are believed to be

involved with systemic lupus erythematosus, or SLE, disease activity. MDX-1185 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.

***Medarex Licensing Partners Product Candidates in Development***

Our licensing partners are currently conducting the following human clinical trials of product candidates developed using our UltiMAb Human Antibody Development System:

**HuMax-CD4 (Anti-CD4 Antibody)** *Cutaneous T-cell Lymphoma.* Genmab is developing HuMax-CD4, a fully human antibody that targets the CD4 receptor on cells known as T-cells, which are believed to be involved in promoting autoimmune disease. Genmab has reported that preclinical and clinical studies to date suggest that an antibody that targets CD4 may be useful for the treatment of cutaneous T-cell lymphomas, or CTCL.

In December 2003, Genmab announced interim results from two Phase II clinical studies for HuMax-CD4 for the treatment of CTCL. Based on the interim data, Genmab announced that it is enrolling additional patients in both studies and has increased the weekly dose in each trial. Treatment of these additional patients is expected to continue for up to 16 weeks. In February 2004, Genmab announced that HuMax-CD4 achieved positive interim results in the extended Phase II studies for CTCL.

In December 2003, Genmab announced that it had no further plans to develop HuMax-CD4 for the treatment of psoriasis because statistically significant results were not achieved in a Phase IIb clinical study.

**HuMax-IL15 (Anti-IL-15 Antibody)** *Rheumatoid Arthritis.* HuMax-IL15 is a fully human antibody against Interleukin-15 (IL-15), an immune system signaling molecule that appears early in the cascade of events that ultimately lead to inflammatory disease. Immunex Corporation, a wholly owned subsidiary of Amgen, Inc., acquired the rights associated with HuMax-IL15 from Genmab, which continues to support some related activities as part of the binding agreement. According to Amgen, findings from a Phase I trial in patients with rheumatoid arthritis indicated that HuMax-IL15 was generally well tolerated with early evidence of biologic activity.

**CNTO 1275 (Anti-IL-12 Antibody)** ♦ *Anti-inflammatory Diseases.* In September 2002, Centocor reported that it was developing CNTO 1275, a high affinity, fully human antibody for the treatment of anti-inflammatory diseases such as moderate to severe psoriasis and multiple sclerosis. According to publicly available information, clinical trials are underway, including a randomized, double-blind, placebo-controlled, parallel Phase II clinical trial of single and multiple dose regimens in patients with moderate to severe psoriasis.

**HuMax-EGFr (Anti-EGFr Antibody)** *Head and Neck Cancer.* 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, breast, colon, prostate, lung and ovary. In September 2003, Genmab announced the commencement of a Phase I/II clinical trial for the treatment of head and neck cancer with HuMax-EGFr. According to Genmab, preclinical studies have indicated that blocking the interaction between EGFr and its ligands has the potential to inhibit tumor growth leading to cell death.

**HuMax-CD20 (Anti-CD20 Antibody)** *Lymphoma.* Genmab is developing HuMax-CD20, a fully human antibody targeting CD20, a molecule found on B cells. In December 2003, Genmab announced the filing of an Investigational New Drug application, or IND, in the US and a Clinical

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

Trial Application in England to start an open label Phase I/II clinical trial using HuMax-CD20 in patients with relapsed or refractory follicular lymphoma. According to Genmab, preclinical studies have indicated that HuMax-CD20 may kill tumor cells that are resistant to rituximab.

**CNTO 148 (Anti-TNF $\alpha$  Antibody)** ♦ *Anti-inflammatory Diseases*. In September 2002, Centocor reported that it was developing CTNO 148, a high affinity, fully human antibody for anti-inflammatory diseases, including Crohn's disease, rheumatoid arthritis and uveitis. According to publicly available information, Phase I trials of

---

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.

- ♦ We expect to receive milestone payments, as these products move through clinical trials, and royalties, should commercialization occur.

---

CTNO 148 are currently underway, and a Phase I/IIa clinical trial is underway in patients with intermediate uveitis, posterior uveitis or panuveitis.

**CTNO 95 (Anti-integrin receptors Antibody) ♦ Cancers.** In December 2003, we announced that Centocor had commenced a multi-dose 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 plays an important role in tumor growth and metastasis.

**Novartis Antibodies ♦ Autoimmune Disease.** In December 2002, and May 2003, respectively, we reported that Novartis had begun Phase I clinical trials with two separate antibody product candidates for the treatment of an autoimmune disease.

**Fibrogen Antibody ♦ Idiopathic Pulmonary Fibrosis.** In December 2003, we announced that Fibrogen had commenced a Phase I clinical trial of a fully human antibody therapeutic in patients with idiopathic pulmonary fibrosis (IPF). The product candidate is Fibrogen's lead anti-CTGF (connective tissue growth factor) therapeutic antibody, also known as FG-3019. The multi-center, open-label, dose-escalating study is expected to enroll up to 27 patients with IPF and is designed to evaluate the safety, tolerability, pharmacokinetics and immunogenicity of the antibody.

## 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<sup>®</sup> 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 on 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 market 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 market our human antibody technology (a) for large multi-target (five or more targets) partnerships to any European 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 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



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

- ◆ We expect to receive milestone payments, as these products move through clinical trials, and royalties, should commercialization occur.

rights to market 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.

In addition, under the terms of the Genomics Agreement, we granted Genmab an option to receive certain rights in Europe with respect to the development and commercialization of up to four antibody products we may obtain through our agreement with Eos Biotechnology, Inc., which was acquired by Protein Design Labs., Inc. in 2003. Finally, the Genomics Agreement grants Genmab certain rights to access technologies acquired by us from Biosite Incorporated and Kirin Brewery Co., Ltd.

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, 2001, 2002 and 2003, the Company recognized \$2.0 million of revenue from this agreement.

In September 2000, we entered into an amended agreement, or the Amended Genomics Agreement, with Genmab, pursuant to which we agreed to assign to Genmab 100% of our economic interest in each product we jointly develop with Oxford GlycoSciences plc, or a Medarex/OGS product, and sell in Europe, and 50% of our economic interest in each Medarex/OGS product sold outside of North America and Europe. We retained 100% of our economic interest in Medarex/OGS products to be sold in North America. Oxford GlycoSciences plc, or OGS, was subsequently acquired by Celltech Group plc, or Celltech. Under the terms of the Amended Genomics Agreement, if a Medarex/OGS product is intended to be sold only in Europe, Genmab will reimburse us for 100% of our research, development, manufacturing and commercialization expenses associated with such product. If the Medarex/OGS product is to be sold only in North America, Genmab will not be obligated to reimburse us for any such expenses. In all other cases, Genmab will reimburse us for 50% of such expenses. In addition, we sold one-half of our equity interest in OGS to Genmab for \$2.5 million, which was our original cost of such equity interest. In 2002, the value of our remaining interest in OGS was written down to approximately \$0.2 million due to a decline in its fair value, which was considered to be other than temporary. In June 2003, we exchanged our remaining equity interest in OGS for approximately \$0.3 million in cash in connection with the acquisition of OGS by Celltech.

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 has been reduced to approximately 32%. 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 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

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

additional equity of approximately \$5.2 million. Our current equity position in IDM is approximately 9%. 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 26%, 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 public offering of a portion of the common stock of our wholly-owned subsidiary Celldex Therapeutics, Inc. As part of this transaction, we intend to assign or license 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 proceeds, we anticipate that we will continue to hold approximately 75% of the outstanding shares of common stock of Celldex. We cannot assure you that this transaction will be consummated.

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

As of March 1, 2004, we have more than 45 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 and commercialization of new therapeutic and, in some cases, diagnostic products. We expect that substantially all of our operating revenues over the next few years will come from licensing fees and milestone payments from our existing and future partners. These partnerships typically provide our partners with access to our human antibody technology for the purpose of generating fully human antibodies to specific disease targets identified by such partners. In some cases, we provide our mice to our partners who then immunize the mice to generate fully human antibodies. In other cases, we may immunize the mice with a partner's antigen.

In general, our partnerships fall into two major categories: (1) collaborative partnerships in which we collaborate with partners to jointly generate, develop and commercialize human antibody products; and (2) licensing partnerships in which we license our human antibody generation technology to our partners in exchange for license fees, milestone payments and royalties.

#### ***Our Collaborative Partnerships to Jointly Develop Fully Human Antibodies with Our Partners***

We are increasing our access to novel therapeutic targets by establishing collaborations with 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, 2004, we had agreements with more than 25 collaborators with whom we plan to jointly develop and commercialize human antibody products, including, among others, Ability Biomedical, Avalon Pharmaceuticals, Inc., Corixa Corporation, Immusol, Inc., Tularik, Inc. and Xerion Pharmaceuticals AG. Typically, a collaborator will provide a target antigen, and we will generate and develop antibodies against that antigen using our UltiMab Human Antibody Development System. We and our collaborators typically agree to share equally costs of clinical development and manufacturing as well as revenues, expenses and profits associated with the 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 for the Development of Fully Human Antibodies by Our Partners***

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 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, 2004, 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 to \$10 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 marketing of any products.

*Our Agreement with Kirin*

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<sup>®</sup>, a unique crossbred mouse which

combines the traits of our HuMAb-Mouse<sup>®</sup> with Kirin's TC Mouse. Under the Collaboration and License Agreement, we are exchanging cross-licenses with Kirin with respect to the KM-Mouse and other antibody-generating mice. In addition, certain of the cross-licenses granted under the Collaboration and License Agreement are subject to license, milestone and royalty payments by one party to the other.

Through December 31, 2003, we have not made any milestone payments to Kirin and have made licensing and other payments of approximately \$0.2 million. Based on a total of three products we are developing which use or we believe may use Kirin technology and that (i) are currently in clinical trials, or (ii) we anticipate may enter clinical trials through the end of 2005, we may be required to make milestone payments to Kirin aggregating up to approximately \$12.8 million with respect to such products, or a maximum of approximately \$4.3 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.

#### ***Other in-licensed technology***

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 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, 2003, we have made no milestone payments 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 2005, we may be obligated to make future milestone payments aggregating up to approximately \$30.6 million with respect to such products. In general, potential milestone payments for our antibody products

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

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.

## **Our Human Antibody Technology**

### ***The UltiMab Technology Platform***

Our solution to making antibodies with fully human protein sequences is to use transgenic strains of mice in which mouse antibody gene expression is suppressed and effectively replaced with human antibody gene expression. 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 the TC Mouse. In total these technologies constitute our UltiMab Human Antibody Development System.

*Our HuMAB-Mouse Technology.* In these transgenic mice, 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  $10^{12}$ .

*Kirin's TC Mouse Technology.* Through our collaboration with Kirin, we have access to the Kirin TC Mouse. Kirin has developed mice that contain complete sets of the variable and constant genes found in the corresponding natural human immunoglobulin loci. These mice are transchromosomal, meaning that the mouse genes for creating antibodies have been disrupted and functionally replaced by the human chromosomes containing all of the human antibody genes, 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.

*The KM-Mouse.* Together with our partner, Kirin, we have developed the KM-Mouse, a crossbred mouse that combines the characteristics of our HuMAB-Mouse with Kirin's TC Mouse that retains the capability to produce all human antibody isotypes with an immune response we believe previously unseen in any human antibody producing mouse system.

*Other Technologies.* To enhance our ability to create products from genomics research, we have also coupled the UltiMab Human Antibody Development System with other technologies, such as Biosite Incorporated's Omniclon phage display technology. We believe the result of this combination, referred to as Trans-Phage Technology<sup>®</sup>, is a high throughput method for generating large volumes of human antibody fragments, which can then be used to help validate new target opportunities, i.e., to determine which targets are most appropriate for therapeutic antibody development. In addition, we acquired Corixa's proprietary Ultra-Potent Toxin



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

technology for creating antibody-toxin conjugates. The toxins we acquired include small molecules known as duocarmycins, which have been designed to overcome multi-drug resistance. We believe this

technology 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 United States. 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, working 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 106 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 2002 and currently use approximately 75,000 square feet in these facilities, accommodating approximately 140 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 material 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 discussions are ongoing with respect to terms of a commercial supply agreement. 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.

**Significant Partner Revenue**

Revenue from partners representing 10% or more of total revenues for the years ended December 31, 2001, 2002 and 2003 is as follows:

<u>Partner</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>
----------------	-------------	-------------	-------------

Edgar Filing: MEDAREX INC - Form 10-K

Genmab	12%	37%	48%
Amgen	2%	3%	15%
Lilly	7%	11%	7%
Kirin	14%		2%
IDM	48%	36%	

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

## **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 52 issued patents and allowed patent applications in the United States, and over 170 issued patents in foreign countries with respect to our HuMAb-Mouse technology and products, our bispecific molecule technology and products, and to other technology and products.

Of these, 16 of our issued patents and allowed patent applications in the United States and 21 of our issued patents in foreign countries, including European countries, Japan, Korea, Canada 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 2011. We also have more than 70 related pending United States 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 of technology created at the University of California relating to aspects of our anti-CTLA-4 human monoclonal antibody product candidate and a license from medac GmbH relating to certain aspects of our anti-CD30 human antibody product candidate. We have been assigned patent rights from Northwest Biotherapeutics relating to aspects of our anti-PSMA human antibody product candidate and have a non-exclusive license from Millennium Pharmaceuticals relating to aspects of our anti-PSMA human antibody product candidate. In addition, we have acquired patent rights from Corixa relating to tumor-activated prodrugs, Ultra-Potent Toxins and interferon alpha receptor.

We own registrations for the following trademarks in the listed jurisdictions: Medarex® in the United States, the European Union, Canada, Australia and Switzerland; HuMAb-Mouse® and KM-Mouse® in the United States and European Union; UltiMAb Human Antibody Development System®, GenPharm®, Trans-Phage Technology® and Putting the Immune System to Work® in the United States; 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 United States and in other countries. In the United States, 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 United States, govern the clinical and non-clinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, 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 United States 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 United States includes:

submission to the FDA of an application for an Investigational New Drug Application, or 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. 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,

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

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 United States 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 are used 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.

United States 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 can take 10 years or more to complete, and there can be no assurance that the data collected will be in compliance with GCP regulations, 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 review boards, who must review and approve all research involving human subjects. Side effect 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 United States, 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, following a recent reorganization at FDA, 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 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 \$0.5 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

Edgar Filing: MEDAREX INC - Form 10-K

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. Certain products employing our human antibody technology might 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 may also 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.

#### ***Other U.S. Regulatory Requirements***

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

In the United States, 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 United States Department of Health and Human Services (e.g., the Office of Inspector General), 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. 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 United States 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.

### **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 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

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

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, Inc., Amgen, Biogen Idec, Inc., Novartis, Genentech, Inc., Protein Design Labs, Inc. and Wyeth have generated therapeutic antibody-based products that are currently 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 that are 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 ImClone Systems Incorporated, Johnson & Johnson, Wyeth, Amgen, Abbott, Celltech Group plc, Biogen Idec, Abgenix, CAT, MorphoSys AG, Tanox, Inc., Genentech, Millennium and Protein Design Labs are addressing diseases and disease indications that are being targeted by us and our partners. 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. 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.

## **Employees**

As of December 31, 2003, we employed 423 persons, of whom approximately 348 are engaged in research and development activities. There are 75 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**

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

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 <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 <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 will, 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 are in early stages of development, and they have not been and may not ever be approved for sale and/or commercialized.**

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Active product candidates employing our human antibody technology are in the early and middle stages of clinical development. Based on public disclosures, regulatory applications, including INDs, have been submitted to the FDA or comparable foreign authorities, for 17 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 the early or middle stages of product 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. None of these products employed 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.**

We have incurred large operating losses and we anticipate that these losses will continue for the foreseeable future. In particular, as of December 31, 2003, we had an accumulated deficit of approximately \$412.9 million. Our net loss was \$129.3 million for the year ended December 31, 2003. Our losses have resulted principally from:

research and development costs relating to the development of our technology and antibody product candidates;

costs associated with the establishment of our new 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;

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

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. However, this 24-month period assumes the use of a portion of the proceeds we received from the sale of our convertible notes. To the extent our convertible notes are converted into shares of our common stock on or before their maturity dates, we will have use of that portion of the principal amount of the notes so converted 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 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.

**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 a significant amount of debt and debt service obligations, which, unless converted to shares of our common stock or redeemed, will mature in 2006 (\$142.0 million) and 2010 (approximately \$147.0 million), respectively. Our ability to make payments on our debt 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

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

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;

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

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

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. None of these products employed our core fully human antibody technology. 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 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 dermatitis and colitis, 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. We believe that these adverse events will not materially affect our ability to continue with clinical trials of this product as planned. 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 is in the process of moving several product categories currently 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. The effect that this reorganization 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

Edgar Filing: MEDAREX INC - Form 10-K

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

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 United States 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.**

New 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 United States government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the United States 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

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

the event Medicare cost increases exceed a certain level. These cost containment measures could include some sorts of limitations on prescription drug prices. Our results of operations could be materially harmed by 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 continues to rise 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 United States 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 current Secretary of Health and Human Services has indicated that there is not a basis to make such a certification at this time. However, it is possible that this Secretary or 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. In September 2003, we 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. 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 commercial supply on acceptable terms or in a timely manner, if at all.

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. 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.

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

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 not be completed or may be terminated, and we may not be able to establish additional partnerships.**

We have entered into binding letters of intent or memoranda of understanding with Genmab A/S, Athersys, Inc., and Regeneron Pharmaceuticals, Inc. These binding letters of intent or memoranda of understanding include the principal terms of these transactions, which will be incorporated into definitive agreements. By their terms, these letters of intent and memoranda of understanding will remain in full force and effect and the parties will operate in accordance with their terms until such time as definitive agreements are executed. If we are unable to agree on the terms of a definitive agreement with respect to one or more of these partners, our business, financial condition and results of operations may be materially harmed.

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. We have generated only a limited number of fully human antibody therapeutic product candidates pursuant to our collaboration agreements and only seventeen product candidates generated with our human antibody technology have entered clinical testing. 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 interest in Genmab, we are currently required to account for our equity 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, 2001, 2002 and 2003, our share of Genmab's losses were approximately

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

\$7.3 million, \$19.6 million and \$15.0 million, respectively. We expect that during the second half of 2004, 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.

**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, Northwest Biotherapeutics and Tularik, 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. 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. Because these securities are not publicly traded, the value of our investments in these companies are inherently more difficult to estimate than our investments in publicly traded companies. We estimate the value of these investments by using information acquired from industry trends, the management of these companies, financial statements, and other external sources. 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 and 2003, we recorded impairment charges of approximately \$2.4 million and \$1.4 million, respectively, on our investments in privately-held companies. 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 are in the process of applying for 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 United States 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 United States 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 United States.

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 or the antibody's target. For example, we are aware of certain United States 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. In particular, we are aware of certain United States and foreign patents and patent applications owned by third parties that pertain to monoclonal antibodies against CTLA-4, such as MDX-010, and their uses. We are also aware of certain United States 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 MDX-214, and anti-PSMA antibodies, such as MDX-070, as well as other antibody products under development by us.

We are also aware of a United States patent owned by Genentech, Inc., 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. If we are unable to obtain a license on commercially reasonable terms, 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 United States 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 expect to seek to obtain 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 International, Inc., GenPharm entered into a cross-license and settlement agreement with Abgenix, Inc., 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.

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

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 employing our antibody technology.**

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 dermatitis and colitis, 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. We believe that these adverse events will not materially affect our ability to continue with clinical trials of this product as planned. 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.

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

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. 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, Inc., Amgen, Biogen Idec, Novartis, Genentech, Inc., Protein Design Labs, Inc., Wyeth, Abbott and Corixa Corporation have generated therapeutic products that are currently 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 biological response modifiers. 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.**

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

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, 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 United States 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 United States 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 United States 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

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

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. 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 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.

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

During the two-year period ended December 31, 2003, the sale prices of our common stock ranged between \$2.69 and \$18.46. 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 27, 2004, we had 11,594,497 shares of common stock reserved for issuance pursuant to options which had been granted under our stock option plans having a weighted average exercise price of \$8.31 per share and we had reserved 3,423,694 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 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 384,207 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 four years. We have filed a registration statement on Form S-8 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 27, 2004, we had reserved 677,063 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 covering 177,063 of those shares. The remaining 500,000 shares have not yet been registered but we intend to file a registration statement covering these shares prior to issuance under this plan. Upon the effectiveness of such registration statement, 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, Inc. or NASDAQ, 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 27, 2004, we had 4,923,717 shares of common stock reserved for issuance pursuant to the conversion of \$142.0 million aggregate principal amount of our 4.50% Convertible Subordinated Notes due 2006. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 34.6789 shares per each \$1,000 principal amount of notes (\$28.84 per share), subject to adjustment. Shares issued upon conversion of these notes will be freely tradable in the open market 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.

As of February 27, 2004, we had 21,872,917 shares of common stock reserved for issuance pursuant to the conversion of \$146.986 million aggregate principal amount of our 4.25% Convertible Senior Notes due August 15, 2010. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 148.8261 shares per each \$1,000 principal amount of the notes (\$6.72 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 27, 2004, we had 79,087,401 shares of common stock outstanding, of which 1,407,667 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 a filed 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 stockholders. 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 \$297.15 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 our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010, and up to 18,601,190 shares of our common stock which may be issued upon the conversion of the notes. These notes and 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 limitation of Rule 144. We also intend to file a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of our \$21.986 million 4.25% Convertible Senior Notes due August 15, 2010, and up to 3,271,727 shares of our common stock which may be issued upon the conversion of the notes. Upon the effectiveness of this registration statement, the notes and shares of common stock will be freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitation 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 redemption, repurchase, cancellation, conversion or otherwise); and (iv) two years after the respective effective dates of these registration statements.

**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 4.50% convertible subordinated notes due 2006. As of February 27, 2004, \$142.0 million aggregate principal amount of these notes was outstanding. In addition, in such event we will be required to offer to repurchase all of our outstanding 4.25% convertible senior notes due August 15, 2010. As of February 27, 2004, approximately \$147.0 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, 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.**

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

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 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 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, potential new accounting pronouncements and higher insurance costs may impact our future financial position or results of operations.**

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

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. For example, effective January 1, 2003, we changed our method of accounting for asset retirement obligations in accordance with Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations* (SFAS No. 143). 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 or \$0.01 per share.

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. Insurance costs are increasing as a result of this uncertainty and other factors. 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.

**Item 2. Properties**

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

**Leased/Owned Properties**

<u>Location</u>	<u>Leased/Owned</u>	<u>Square Feet</u>	<u>Use</u>	<u>Lease Expiration Date</u>
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
Clinton, New Jersey	Leased	11,000	Office	2004

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, 2003, 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:

	Common Stock Price	
	High	Low
<b>Year ended December 31, 2002</b>		
First Quarter	\$ 18.46	\$ 13.31
Second Quarter	\$ 16.83	\$ 6.71
Third Quarter	\$ 9.00	\$ 3.26
Fourth Quarter	\$ 5.35	\$ 2.55
<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

The number of shares of our common stock outstanding as of February 27, 2004 was 79,087,401. As of February 27, 2004, there were approximately 600 record holders of our common stock. As of April 4, 2003, the record date for our last Annual Meeting of Shareholders held on May 28, 2003, there were approximately 700 record holders of common stock (which includes individual holders) and approximately 19,314 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 to be held on May 19, 2004, which will be filed on or before April 30, 2004, and is incorporated herein by reference.

**Item 6. Selected Consolidated Financial Data**

	<b>For the Year Ended December 31,</b>				
	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
	<b>(Dollars in thousands, except per share data)</b>				
<b>Statement of Operations Data:</b>					
Revenues:					
Sales	\$ 1,079	\$ 264	\$ 191	\$ 176	\$ 25
Contract and license revenues	8,593	19,619	37,140	24,552	5,833
Sales, contract and license revenues from Genmab	252	2,574	4,973	14,751	5,316
<b>Total revenues</b>	<b>9,924</b>	<b>22,457</b>	<b>42,304</b>	<b>39,479</b>	<b>11,174</b>
Costs and expenses:					
Cost of sales	709	1,189	642	8,327	3
Research and development	19,929	33,942	38,626	82,626	95,459
General and administrative	8,036	18,142	19,344	22,852	21,727
Write-off of facility costs				11,294	
Acquisition of in-process technology				16,312	6,500
<b>Total costs and expenses</b>	<b>28,674</b>	<b>53,273</b>	<b>58,612</b>	<b>141,411</b>	<b>123,689</b>
<b>Operating loss</b>	<b>(18,750)</b>	<b>(30,816)</b>	<b>(16,308)</b>	<b>(101,932)</b>	<b>(112,515)</b>
Equity in net loss of affiliate		(353)	(7,334)	(50,625)	(14,997)
Interest and dividend income	1,205	21,158	24,728	18,495	12,342
Impairment loss on investments in partners				(11,886)	(1,400)
Additional payments related to asset acquisition				(2,425)	(31)
Interest expense	(8)	(3)	(4,615)	(9,065)	(11,777)
Gain on disposition of Genmab stock			1,442		
<b>Loss before provision (benefit) for income taxes</b>	<b>(17,553)</b>	<b>(10,014)</b>	<b>(2,087)</b>	<b>(157,438)</b>	<b>(128,378)</b>
Provision (benefit) for income taxes	(522)	(13,075)	600	103	69
<b>Income (loss) before cumulative effect of change in accounting principle</b>	<b>(17,031)</b>	<b>3,061</b>	<b>(2,687)</b>	<b>(157,541)</b>	<b>(128,447)</b>
Cumulative effect of change in accounting principle					(830)
<b>Net income (loss)</b>	<b>\$ (17,031)</b>	<b>\$ 3,061</b>	<b>\$ (2,687)</b>	<b>\$ (157,541)</b>	<b>\$ (129,277)</b>
Basic and diluted net income (loss) per share <sup>(1)</sup> :					
Income (loss) before cumulative effect of change in accounting principle	\$ (0.27)	\$ 0.04	\$ (0.04)	\$ (2.09)	\$ (1.64)
Cumulative effect of change in accounting principle					\$ (0.01)
<b>Net income (loss)</b>	<b>\$ (0.27)</b>	<b>\$ 0.04</b>	<b>\$ (0.04)</b>	<b>\$ (2.09)</b>	<b>\$ (1.65)</b>
Weighted average common shares outstanding <sup>(1)</sup>					
basic	63,840	71,532	73,937	75,231	78,314
diluted	63,840	73,232	73,937	75,231	78,314

December 31,

Edgar Filing: MEDAREX INC - Form 10-K

	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>
(Dollars in thousands)					
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$ 30,147	\$ 343,603	\$ 466,952	\$ 350,046	\$ 358,458
Working capital	22,382	329,807	447,326	339,480	350,437
Total assets	40,482	558,107	720,427	549,051	557,726
Long term obligations	23		175,000	175,000	300,000
Cash dividends declared per common share					
Accumulated deficit	(126,436)	(123,375)	(126,062)	(283,603)	(412,880)
Total shareholders' equity	22,299	485,289	482,562	352,143	234,011

(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 the Company's 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 the Company's 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 will, 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 and development of fully human antibody-based therapeutic products. We believe that our UltiMab Human Antibody Development System<sup>®</sup> enables us to rapidly create and develop fully human antibodies for a wide range of diseases, including cancer, inflammation, autoimmune disease and other life-threatening and debilitating diseases.

We believe that antibodies are proven candidates for therapeutic products. To date, the United States Food and Drug Administration, or FDA, has approved 17 antibody-based therapeutic products for sale in the United States. In 2003, 15 of these products generated aggregate worldwide sales in excess of \$5.0 billion. We intend to participate in this market and, to this end, are developing an expanding pipeline of therapeutic antibody products generated through the use of our proprietary UltiMab human antibody development technology.

Currently, 17 antibody products derived from our UltiMab human antibody development technology are in human clinical trials, or have had regulatory applications submitted for such trials. These antibodies are designed to treat a wide range of diseases, such as cancer (including various lymphomas), rheumatoid arthritis and other inflammatory and autoimmune diseases. Five of these antibody products are fully owned by Medarex: MDX-010 (Phase II clinical trials), MDX-060 (Phase II clinical trials), MDX-070 (Phase I/II clinical trials), MDX-214 (Phase I/II clinical trials) and MDX-1307 (Phase I clinical trials), for the treatment of cancer, lymphoma and/or HIV. One antibody product for autoimmune disease, MDX-018 (Phase I/II clinical trials), is being jointly developed with our licensing partner, Genmab A/S, and four are being developed separately by Genmab: HuMax-CD4 (Phase II clinical trials) for cutaneous T-cell lymphoma, HuMax-IL15 (Phase II clinical trials) for rheumatoid arthritis, HuMax-EGFr (Phase I/II clinical trials) for head and neck cancer and HuMax-CD20 (Phase I/II clinical trials) for non-Hodgkin's lymphoma. Additionally, our licensing partners, including Novartis Pharma AG and Centocor, Inc. (a subsidiary of Johnson & Johnson), among others, are developing a total of seven antibody products for inflammatory and/or autoimmune diseases and cancer that are currently in early clinical trials. We and our partners also have a number of product candidates in preclinical development. The preceding information regarding the clinical status of antibody products is based on our and our partners' public disclosures and other publicly available information.

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

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

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, 2003, we had an accumulated deficit of approximately \$412.9 million. Over the next several years, we expect to incur substantial expenses as we continue to identify, develop and manufacture our potential products, invest in research and move forward with our product development. Our commitment of resources to research and the continued development 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 products are selected as clinical candidates for further 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 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 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 IND, commencement of Phase I, II or III clinical trials, submission of a 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.

#### ***Investments***

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

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 less than 1% of total marketable securities as of December 31, 2002, and approximately 1.5% of total marketable securities as of December 31, 2003.

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 \$59.4 million as of December 31, 2003. These securities are carried at original investment cost. 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. 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***

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

In-Process Technology expense 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 our company 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 antibody 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, 2001, 2002 and 2003*

#### *Contract and license revenues*

Contract and license revenues totaled \$37.1 million, \$24.6 million and \$5.8 million in 2001, 2002 and 2003, respectively. Contract and license revenues for 2002 decreased by \$12.6 million or 34% as compared to 2001. This decrease relates primarily to a decrease in revenue of \$6.0 million from Kirin as a result of the completion in December 2001 of the recognition of revenue associated with a December 1999 binding letter of intent and \$6.0 million from IDM as a result of the completion in September 2002 of the recognition of non-cash revenue associated with a transfer of technology to IDM in July 2000. 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 IDM of \$14.3 million as a result of the completion of the recognition of revenue associated with the transfer of technology to IDM, as well as a decrease in revenue of \$3.4 million from Eli Lilly. 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 were \$5.0 million, \$14.8 million and \$5.3 million in 2001, 2002 and 2003, respectively. Sales, contract and license revenues from Genmab for 2002 increased by \$9.8 million or 197% as compared to 2001. This increase is primarily due to sales of MDX-CD4 and MDX-015 totaling \$11.4 million in 2002 to support Genmab's clinical trials, offset, in part, by lower contract and license revenues from Genmab in 2001. There were no sales of such material to Genmab in 2001 or 2003. Sales, contract and license revenues from Genmab for 2003 decreased by \$9.4 million or 64% as compared to 2002 as there were no sales of MDX-CD4 and MDX-015 to Genmab in 2003. This decrease was offset, in part, by increased contract and license revenues from Genmab in 2003.

#### *Cost of Sales*

Cost of sales were \$0.7 million, \$8.3 million and \$3 thousand for the years ended December 31, 2001, 2002 and 2003. Cost of sales increased by \$7.7 million in 2002, or 1,197% as compared to 2001. The increase primarily reflects the production cost of MDX-CD4 and MDX-015, which were sold to Genmab in 2002. Cost of sales in 2003 decreased by \$8.3 million, as compared to 2002. The decrease is a result of no sales of these materials to Genmab in 2003 as discussed above.

#### *Research and Development Expenses*

Research and development expenses for our products in development were \$38.6 million, \$82.6 million and \$95.5 million for the years ended December 31, 2001, 2002 and 2003, respectively. Research and development expenses in 2002 increased by \$44.0 million, or 114% as compared to 2001 and research and development expenses in 2003 increased by \$12.8 million, or 16% as compared to 2002. 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: research and product development and by the types of costs as outlined below. We separate

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

research and development expenditures on the basis of amounts associated with research and amounts associated with product development. 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,		
	2001	2002	2003
Research	\$ 11,561	\$ 34,659	\$ 37,495
Product Development	27,065	47,967	57,964
Total	\$ 38,626	\$ 82,626	\$ 95,459



*Research Costs*

Research costs in 2002 increased by \$23.1 million, or 200% as compared to 2001. Research costs in 2003 increased by \$2.8 million, or 8% as compared to 2002. The increases in research costs primarily relate to the following:

Personnel costs in 2002 were \$10.2 million, an increase of \$5.9 million or 138% as compared to 2001. Personnel costs in 2003 were \$12.7 million, an increase of \$2.6 million or 25% as compared to 2002. The increased personnel costs are a result of the increased staff needed to support higher levels of research, 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, but at a slower rate, as we continue to increase our research activities.

Facility costs in 2002 were \$5.2 million, an increase of \$3.5 million or 196% as compared to 2001. Facility costs in 2003 were \$7.5 million, an increase of \$2.3 million or 44% as compared to 2002. The increase in facility costs primarily relates to the substantial investments made in our research facilities during 2001 and 2002 as well as a full year of operation of our Sunnyvale, California facility in 2003. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for each of 2002 and 2003, as compared to the prior year periods. We expect to incur increased facility costs as a result of continued capital expansion, renovations and replacements but at a slower rate.

Research supply costs in 2002 were \$4.6 million, an increase of \$2.5 million or 120% as compared to 2001. Research supply costs in 2003 were \$5.1 million, an increase of \$0.5 million or 11% as compared to 2002. Included in these costs are materials and small equipment associated with the development of new products. We expect these costs to increase as we continue to expand our research activities.

Funding of outside research in 2002 was \$3.3 million, an increase of \$5.0 million or 285% as compared to a credit balance of \$1.7 million for 2001. The credit balance for 2001 was principally due to the April 2001 refund of a \$5.0 million fee previously paid (in 2000). Excluding the 2001 refund, funding of outside research in 2001 and 2002 was comparable. Funding of outside research in 2003 was \$3.4 million, an increase of \$0.1 million or 3% over 2002. Funding of outside research includes funds paid to certain partners for research services.

License and technology access fees in 2002 were \$7.2 million, an increase of \$5.0 million or 234% as compared to 2001. License and technology access fees in 2003 were \$3.1 million, a decrease of \$4.1 million or 58% as compared to 2002. These costs represent fees paid to certain partners and research organizations in connection with certain of our collaboration and license agreements. Included in the 2002 cost are payments to Northwest Biotherapeutics, Tularik and Millennium Pharmaceuticals 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 2002 increased by \$20.9 million, or 77% as compared to 2001. Product development costs increased by \$10.0 million in 2003, or 21% as compared to 2002. The increases in product development costs primarily relate to the following:

Personnel costs in 2002 were \$18.1 million, an increase of \$8.1 million or 80% as compared to 2001. Personnel costs in 2003 were \$20.6 million, an increase of \$2.5 million or 14% as compared to 2002. The increased personnel costs are a result of the increased staff needed to support higher levels of clinical trial manufacturing activities and more extensive clinical trial activities. Personnel costs primarily include salary, benefits, payroll taxes and recruiting costs. We expect personnel costs to continue to increase, but at a slower rate, as we continue to increase our product development activities and progress our products through clinical trials.



Facility costs in 2002 were \$10.9 million, an increase of \$4.6 million or 73% as compared to 2001. Facility costs in 2003 were \$11.1 million, an increase of \$1.8 million or 16% as compared to 2002. The increase in facility costs primarily relates to the substantial investments made in our product development facilities during 2001 and 2002. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for each of 2002 and 2003, as compared to the prior year periods. We expect to incur increased facility costs as a result of continued capital expansion, renovations and replacements but at a slower rate.

Supply costs in 2002 were \$10.1 million, an increase of \$5.0 million or 100% as compared to 2001. In 2002 we manufactured larger quantities of material for Phase I and Phase II clinical trials for ourselves and our partners resulting in significant increase in supply costs. Supply costs in 2003 were \$5.7 million, a decrease of \$4.3 million or 44% as compared to 2002. In 2003 we completed a change to our method of production which resulted in comparatively lower supply costs. 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. Such costs in the future may also include payments to third party commercial manufacturers to support the advancement of our clinical pipeline.

Clinical research fees in 2002 were \$1.6 million, a decrease of \$0.4 million or 18% as compared to 2001. 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. These costs 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:

<u>Clinical Phase</u>	<u>Estimated Completion Period</u>
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.

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

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 II. 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 \$19.3 million, \$22.9 million and \$21.7 million for the years ended December 31, 2001, 2002 and 2003, respectively. General and administrative expenses increased by \$3.5 million in 2002, or 18% as compared to 2001. This increase is primarily attributable to higher personnel costs of \$0.7 million, increased depreciation expense of \$0.7 million, increased insurance expense of \$0.5 million and increased legal fees of \$0.5 million. General and administrative expenses in 2003 decreased by \$1.1 million, or 5% as compared to 2002. The 2003 decrease is primarily 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 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 relates to a determination we made during the second quarter of 2002 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, 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 discussions are ongoing with respect to terms of a commercial supply agreement.

#### ***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 diseases, cancer and infectious diseases) of Corixa 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, \$16.3 million of the cost of the acquisition was charged to operations as acquisition of in-process technology in 2002. During the fourth quarter of 2003, we entered into an Amended and Restated License Agreement with Kyowa Hakko Kogyo Co. Ltd., or the Kyowa License. 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, which 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.

*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, 2001, 2002 and 2003. 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 second half of 2004 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 \$7.3 million, \$50.6 million and \$15.0 million for the years ended December 31, 2001, 2002 and 2003. Equity in net loss of affiliate in 2002 increased by \$43.3 million or 590% as compared to

2001. Included in equity in net loss of affiliate for 2002 is an impairment loss on our investment in Genmab of \$31.0 million resulting from an approximate 60% decrease in the market value of Genmab 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. 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 this impairment charge, equity in net loss of affiliate in 2002 was \$19.6 million, an increase \$12.3 million, or 168% over 2001. This increase reflects an increase in Genmab's net loss as a result of its expanded research and development efforts. Equity in net loss of affiliate in 2003 decreased by \$35.7 million or 71% as compared to 2002. Excluding the impact of the impairment in 2002, equity in net loss of affiliate 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 recorded by Genmab during 2003.

### ***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 \$24.7 million, \$18.5 million and \$12.3 million for the years ended December 31, 2001, 2002 and 2003, respectively. Interest and dividend income in 2002 decreased by \$6.2 million, or 25% as compared to 2001. The decrease reflects lower interest income due to lower average cash balances as we funded our operations and capital expenditures from our cash reserves as well as lower interest rates. 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 which, on average, was also lower during the period. 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 \$0, \$9.5 million and \$0 for the years ended December 31, 2001, 2002 and 2003, 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. Losses on these securities were determined to be temporary as of December 31, 2001, as each of these securities with an unrealized loss as of December 31, 2001 had traded at or above its cost basis within six months of December 31, 2001. 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 \$0, \$2.4 million and \$1.4 million for the years ended December 31, 2001, 2002 and 2003, respectively, related to investments in certain of our partners whose securities are not publicly traded. The amount of the impairment charge was based on the estimated values as determined by our management and our original cost basis of these investments. 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 Related to Asset Acquisitions***

Additional payments related to asset acquisition of \$2.4 million and \$31 thousand for the years ended December 31, 2002 and 2003, respectively, represent additional purchase payments to Northwest Biotherapeutics, Millennium Pharmaceuticals and Corixa in 2002 and to Northwest Biotherapeutics in 2003. Pursuant to the terms of our agreements with these companies, under certain circumstances we were

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

required to pay 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 4.25% Convertible Senior Notes issued in July 2003, or the 4.25%, notes and our 4.50% Convertible Subordinated Notes issued in June 2001, or the 4.50% notes. Interest expense was \$4.6 million, \$9.1 million and \$11.8 million for the years ended



December 31, 2001, 2002 and 2003, respectively. Interest expense in 2002 increased by \$4.5 million, or 96% over 2001. This increase reflects a full year of interest expense incurred on our 4.50% notes. The 4.50% notes are due in July 2006 and interest is payable semi-annually on January 1 and July 1 of each year. Interest expense in 2003 increased by \$2.6 million, or 28% as compared to 2002 reflecting the addition of approximately five months of accrued interest on our 4.25% notes. The 4.25% notes are due in August 2010 and interest is payable semi-annually on February 15 and August 15 of each year.

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

Our provision for income taxes for the year ended December 31, 2001 of \$0.6 million was the result of deferred foreign tax assets reversing during 2001. The provision for income taxes of \$0.1 million and \$0.1 million for the years ended December 31, 2002 and 2003, 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 2001, 2002, and 2003, we received net proceeds of \$293.5 million from sales of our equity and debt securities.

At December 31, 2002 and 2003, we had \$350.0 million and \$358.5 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 \$7.7 million, \$64.0 million, and \$89.3 million for the years ended December 31, 2001, 2002 and 2003, respectively. This reflects an increase of \$56.3 million in 2002 as compared to 2001 and an increase of \$25.3 million in 2003 as compared to 2002. The increases are primarily the result of the following:

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

An increase of \$44.0 million and \$9.7 million in 2002 and 2003, respectively, in funding of research and development related to the development of our product pipeline.

A decrease of \$6.2 million and \$6.2 million in 2002 and 2003, respectively, in interest and dividend income primarily due to lower interest rates as well as lower average cash balances.

An increase of \$4.4 million and \$2.7 million in 2002 and 2003, respectively, in interest expense. The increased interest expense in 2002 was the result of a full year of interest on our 4.50% notes. The increased interest expense in 2003 represents approximately five months of interest on our 4.25% notes which were issued in July 2003.

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 used in investing activities was \$208.9 million in 2001 and \$22.6 million in 2003 and net cash provided by investing activities was \$93.9 million in 2002. Cash was provided by and used in investing activities primarily as follows:

Capital expenditures of \$55.0 million, \$43.7 million and \$8.9 million in 2001, 2002 and 2003, respectively. The capital expenditures in 2001 reflect an investment in building improvements and the purchase of machinery and equipment as well as furniture and fixtures related to the renovation of our Bloomsbury, New Jersey, facility, which we purchased in January 2001. 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 reflected an investment in laboratory automation as well as the addition of machinery and equipment.

Net purchases of marketable securities of \$168.0 million in 2001 were primarily the result of the proceeds received from the sale of our 4.50% notes in June 2001 (see further discussion in the section entitled "Cash Used in Financing Activities" below).

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 (see further discussion below).

We expect 2004 capital expenditures to be approximately \$15.0 million representing the purchase of machinery and scientific equipment, additional investment in lab automation, and the planned expansion of our Bloomsbury facility to accommodate the relocation of our clinical staff from our Clinton, New Jersey, facility whose lease expires in late 2004.

#### ***Cash Provided by Financing Activities***

Cash provided by financing activities was \$169.5 million, \$0.6 million and \$123.0 million in 2001, 2002 and 2003, respectively. In 2001, cash provided by financing activities consisted primarily of \$169.1 million in net proceeds from the sale of our 4.50% notes in June 2001 (see further discussion below). 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 (see further discussion below) and \$0.9 million from the issuance of common stock under our employee stock purchase plan.

In June 2001, we issued \$175 million of our 4.50% notes. The 4.50% notes are initially convertible into shares of our common stock at the rate of 34.6789 shares per each \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$28.84 per

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

share, subject to anti-dilution adjustments. Interest is payable on January 1 and July 1 of each year. We made our first interest payment on the 4.50% notes on January 1, 2002.

The 4.50% notes mature on July 1, 2006, and are redeemable at our option on or after July 1, 2004, or earlier if the price of our common stock exceeds specified levels. Holders of the 4.50% 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

issuance of the 4.50% notes of approximately \$169.5 million. The costs of issuance of the 4.50% notes of approximately \$5.9 million have been deferred and are being amortized over the term of the 4.50% notes.

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 are 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 is payable on February 15 and August 15 of each year beginning February 15, 2004.

The 4.25% notes mature on August 15, 2010 and are redeemable at our option on or after August 15, 2006, or earlier if the price of our common stock exceeds specified levels. Holders of the 4.25% 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 4.25% notes of approximately \$121.3 million (after deducting the initial purchasers discounts and offering expenses). Approximately \$15.8 million of the net proceeds have been used to purchase U.S. Treasury security strips to collateralize the notes in an amount sufficient to pay the initial six interest payments on the 4.25% notes. Such amount has been classified as segregated cash in our December 31, 2003, consolidated balance sheet and is comprised of the current portion of approximately \$5.6 million and the non-current portion of approximately \$10.2 million. 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.

In January 2004, we and certain holders of our 4.50% notes completed in a limited number of transactions, 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% Convertible Senior Notes due August 15, 2010. As a result of this exchange and cancellation, our total convertible debt was reduced by \$11.014 million.

In July 2006, 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 (\$142.0 million) of the 4.50% notes. If our cash is not sufficient to meet our obligations under the 4.50% notes, we would be required to seek additional financing.

#### *Other Liquidity Matters*

As of December 31, 2003, we had federal net operating loss (NOL) carryforwards of approximately \$297.4 million. These NOL carryforwards will expire in the years 2004 - 2023 (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, 2003 the amount of NOL subject to the limitation was \$43.8 million and the amount not subject to limitation was \$253.6 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, 2003. 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.

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

On May 23, 2002, we entered into an Asset Purchase Agreement with Corixa pursuant to which we 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 for an aggregate purchase price of \$21.0 million (excluding transaction costs of \$0.4 million). In addition, we retained approximately 30 Corixa employees related to such product candidates and programs.

A total of 3,086,075 shares of common stock with a fair value of \$19.25 million were issued to Corixa along with a cash payment of \$1.75 million as payment of the \$21.0 million purchase price. In addition, pursuant to the terms of the Asset Purchase Agreement, we paid an additional \$2.3 million in 2002 representing the net cash shortfall experienced by Corixa from the sale of the 3,086,075 shares of our common stock.

On October 17, 2003, we entered into an Amended and Restated License Agreement with Kyowa, referred to herein as the Kyowa License. Under the terms of the Kyowa License, we received certain intellectual property rights relating to the development and commercialization of the Ultra-Potent Toxin technology. As partial consideration for these rights, we agreed to pay 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 to Kyowa on October 28, 2003, with the balance of \$0.4 million paid in cash, representing applicable withholding taxes.

Under the terms of the Corixa Asset Purchase Agreement, upon the execution of the Kyowa License, we were required to make a final payment to Corixa in the amount of \$2.5 million. Such amount was paid, through the issuance of 353,807 shares of our common stock in October 2003. We have no further obligation to Corixa in connection with the Corixa Asset Purchase Agreement.

We are in the process of a possible public offering of a portion of the common stock of our wholly-owned subsidiary Celldex Therapeutics, Inc. As part of this transaction, we intend to assign or license 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 proceeds, we anticipate that we will continue to hold approximately 75% of the outstanding shares of common stock of Celldex. We cannot assure you that this transaction will be consummated.

### **Contractual Obligations**

Our material contractual obligations under lease, debt and research funding agreements for the next five years, and thereafter, as of December 31, 2003, are as follows:

	Payments Due by Period				
	Less Than			After	
	1 Year	1-3 Years	4-5 Years	5 Years	Total
	(in thousands)				
<b>Contractual Obligations<sup>(1)</sup></b>					
Convertible notes <sup>(2)</sup>	\$	\$ 175,000	\$	\$ 125,000	\$ 300,000
Research funding	3,000	6,000	5,250		14,250
Operating leases and other	3,666	5,857	4,593	690	14,806
<b>Total contractual cash obligations</b>	<b>\$ 6,666</b>	<b>\$ 186,857</b>	<b>\$ 9,843</b>	<b>\$ 125,690</b>	<b>\$ 329,056</b>

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

2. Our convertible notes may be converted to common stock prior to the maturity date and, therefore, may not require the use of our capital resources. In January 2004, we and certain holders of our 4.50% notes completed in a limited number of transactions, 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

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

of a new series of 4.25% Convertible Senior Notes due August 15, 2010. As a result of this exchange and cancellation, our total convertible debt was reduced by \$11.014 million.

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

Effective September 4, 2002, we entered into a Collaboration and License Agreement with Kirin Brewery Co., Ltd., 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 superceded by the Collaboration and License Agreement, we and Kirin developed the KM-Mouse<sup>®</sup>, a unique crossbred mouse which combines the traits of our HuMab-Mouse<sup>®</sup> with Kirin's TC Mouse. Under the Collaboration and License Agreement, we are exchanging cross-licenses with Kirin with respect to the KM-Mouse and other antibody-generating mice. In addition, certain of the cross-licenses granted under the Collaboration and License Agreement are subject to license, milestone and royalty payments by one party to the other.

Through December 31, 2003, we have not made any milestone payments to Kirin. Based on a total of three products we are developing which use or, we believe may use, Kirin technology that (i) are currently in clinical



trials, or (ii) we anticipate may enter clinical trials through the end of 2005, we may be required to make milestone payments to Kirin aggregating up to approximately \$12.75 million with respect to such products, or a maximum of approximately \$4.25 million per product. Our future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

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

the type of license requested (research or commercial);

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

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

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

We have also entered into a number of other agreements that contain licenses of third-party technology which may be used together with our own platform technologies for the generation, development and/or manufacture of our antibody products. In addition, we have entered into other third-party agreements that contain licenses associated with antibody products that target specific antigens. Many of these agreements contain milestone payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of our products currently under development trigger such milestone payments. Through December 31, 2003, we have made no milestone payments 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 2005, we may be obligated to make future milestone payments aggregating up to approximately \$30.625 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; however, this 24-month period assumes the use of a portion of the \$142.0 million and/or the \$146.986 million required to meet our repayment obligations with respect to our convertible notes due on July 1, 2006, and August 15, 2010, respectively. To the extent our convertible notes are converted into shares of our common stock on or before their respective maturity dates, we will have use of that

portion 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 January 2003, the FASB issued Interpretation No. 46 ( FIN 46 ), *Consolidation of Variable Interest Entities*, an interpretation of ARB 51. The primary objectives of this interpretation are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights ( variable interest entities ) and how to determine when and which business enterprise (the primary beneficiary ) should consolidate the variable interest entity. This new model for consolidation applies to an entity in which either (i) the equity investors (if any) do not have a controlling financial interest; or (ii) the equity investment at risk is insufficient to finance that entity's activities without receiving additional subordinated financial support from other parties. In addition, FIN 46 requires that the primary beneficiary, as well as all other enterprises with a significant variable interest in a variable interest entity, make additional disclosures. Certain disclosure requirements of FIN 46 were effective for financial statements issued after January 31, 2003.

In December 2003, the FASB issued FIN No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* ( FIN 46-R ) to address certain FIN 46 implementation issues. The effective dates and impact of FIN 46 and FIN 46-R are as follows:

- (i) *Special purpose entities ( SPEs ) created prior to February 1, 2003.* We must apply either the provisions of FIN 46 or early adopt the provisions of FIN 46-R at the end of the first interim or annual reporting period after December 15, 2003.
- (ii) *Non-SPEs created prior to February 1, 2003.* We are required to adopt FIN 46-R at the end of the first interim or annual reporting period ending after March 15, 2004.
- (iii) *All entities, regardless of whether a SPE, that were created subsequent to January 31, 2003.* The provisions of FIN 46 were applicable for variable interests in entities obtained after January 31, 2003. We are required to adopt FIN 46-R at the end of the first interim or annual reporting period ending after March 15, 2004.

The adoption of the provisions applicable to SPEs and all other variable interests obtained after January 31, 2003 had no impact on our financial statements. We are currently evaluating the impact of adopting FIN 46-R applicable to *Non-SPEs created prior to February 1, 2003* but do not expect a material impact on our financial statements.

In March 2003, the Emerging Issues Task Force ( EITF ) reached a consensus on Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, which provides guidance on accounting for arrangements involving the delivery or performance of multiple products, services and/or rights to use assets. Specifically, EITF 00-21 addresses: (1) how to determine whether an arrangement with multiple deliverables contains more than one unit of accounting, and (2) how the arrangement consideration should be measured and allocated among the separate units of accounting. The provisions of EITF 00-21 are effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 did not have a material impact on our results of operations or financial position.

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

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ( SFAS 150 ). SFAS 150 establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise effective at the beginning of the interim period commencing July 1, 2003. The FASB has indefinitely deferred implementation of certain provisions of SFAS 150. The adoption of SFAS No. 150 did not have an effect on our financial position or 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.

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

**Index to Consolidated Financial Statements**

	<b>Page</b>
<b>Medarex, Inc.</b>	
<u>Report of Independent Auditors</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2002 and 2003</u>	F-3
<u>Consolidated Statements of Operations for the years ended December 31, 2001, 2002 and 2003</u>	F-4
<u>Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2001, 2002 and 2003</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2002 and 2003</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
	<b>Page</b>
<b>Genmab A/S (A Development Stage Company)</b>	
<u>Report of Independent Auditors</u>	F-24
<u>Consolidated Balance Sheets as of December 31, 2003 and 2002</u>	F-25
<u>Consolidated Statements of Operations for the twelve months ended December 31, 2003, 2002 and 2001 and the total since inception</u>	F-27
<u>Consolidated Statements of Shareholders' Equity for the years ended December 31, 2003, 2002 and 2001 and for the period from inception (June 11, 1998) to December 31, 2003</u>	F-28
<u>Consolidated Statements of Cash Flows for the twelve months ended December 31, 2003, 2002 and 2001 and the total since inception</u>	F-32
<u>Notes to Consolidated Financial Statements</u>	F-33

**Report of Independent Auditors**

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, 2002 and 2003, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2003. 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 32% interest, which represents 3.9% and 2.0% of total assets as of December 31, 2002 and 2003, respectively, and equity in net loss of affiliate constitutes 351% in 2001, 32% in 2002 and 12% in 2003 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 auditing standards generally accepted in the 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, 2002 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States.

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.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey

February 20, 2004

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31,	
	2002	2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 61,812	\$ 72,998
Marketable securities	288,234	285,460
Segregated cash		5,617
Prepaid expenses and other current assets	10,143	6,244
	<u>360,189</u>	<u>370,319</u>
Total current assets	360,189	370,319
Property, buildings and equipment:		
Land	6,624	6,624
Buildings and leasehold improvements	71,277	74,764
Machinery and equipment	31,821	37,006
Furniture and fixtures	3,963	4,081
Construction in progress	2,148	4,384
	<u>115,833</u>	<u>126,859</u>
Less accumulated depreciation and amortization	(18,522)	(31,494)
	<u>97,311</u>	<u>95,365</u>
Investments in Genmab	21,206	10,976
Investments in IDM	48,199	48,199
Investments in, and advances to, other partners	11,982	11,182
Segregated cash	1,300	11,579
Other assets	8,864	10,106
	<u>549,051</u>	<u>557,726</u>
Total assets	\$ 549,051	\$ 557,726
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Trade accounts payable	\$ 2,686	\$ 2,197
Accrued liabilities	15,377	13,878
Deferred contract revenue - current	2,646	3,807
	<u>20,709</u>	<u>19,882</u>
Total current liabilities	20,709	19,882
Deferred contract revenue - long-term	1,152	661
Other long-term liabilities	47	3,172
Convertible senior notes		125,000
Convertible subordinated notes	175,000	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; 77,725,376 shares issued and 76,929,984 outstanding at December 31, 2002 and 79,501,080 shares issued and 79,007,564 shares outstanding at December 31, 2003	777	795
Capital in excess of par value	630,279	639,784



Edgar Filing: MEDAREX INC - Form 10-K

Treasury stock, at cost 795,392 shares in 2002 and 493,516 shares in 2003	(2,001)	(1,242)
Deferred compensation	1,311	994
Accumulated other comprehensive income	5,380	6,560
Accumulated deficit	(283,603)	(412,880)
	<u>          </u>	<u>          </u>
Total shareholders' equity	352,143	234,011
	<u>          </u>	<u>          </u>
Total liabilities and shareholders' equity	\$ 549,051	\$ 557,726
	<u>          </u>	<u>          </u>

See notes to these consolidated financial statements.

## MEDAREX, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	For the Year Ended December 31,		
	2001	2002	2003
Sales	\$ 191	\$ 176	\$ 25
Contract and license revenues	37,140	24,552	5,833
Sales, contract and license revenues from Genmab	4,973	14,751	5,316
<b>Total revenues</b>	<b>42,304</b>	<b>39,479</b>	<b>11,174</b>
Costs and expenses:			
Cost of sales	642	8,327	3
Research and development	38,626	82,626	95,459
General and administrative	19,344	22,852	21,727
Write-off of facility costs		11,294	
Acquisition of in-process technology		16,312	6,500
<b>Total costs and expenses</b>	<b>58,612</b>	<b>141,411</b>	<b>123,689</b>
Operating loss	(16,308)	(101,932)	(112,515)
Equity in net loss of affiliate	(7,334)	(50,625)	(14,997)
Interest and dividend income	24,728	18,495	12,342
Impairment loss on investments in partners		(11,886)	(1,400)
Additional payments related to asset acquisitions		(2,425)	(31)
Interest expense	(4,615)	(9,065)	(11,777)
Gain on disposition of Genmab stock	1,442		
<b>Pre tax loss</b>	<b>(2,087)</b>	<b>(157,438)</b>	<b>(128,378)</b>
Provision for income taxes	600	103	69
<b>Loss before cumulative effect of change in accounting principle</b>	<b>(2,687)</b>	<b>(157,541)</b>	<b>(128,447)</b>
Cumulative effect of change in accounting principle			(830)
<b>Net loss</b>	<b>\$ (2,687)</b>	<b>\$ (157,541)</b>	<b>\$ (129,277)</b>
Basic and diluted net loss per share:			
Loss before cumulative effect of change in accounting principle	(\$0.04)	(\$2.09)	(\$1.64)
Cumulative effect of change in accounting principle			(0.01)
<b>Net loss</b>	<b>(\$0.04)</b>	<b>(\$2.09)</b>	<b>(\$1.65)</b>
Weighted average number of common shares outstanding			
- basic and diluted	73,937	75,231	78,314

Edgar Filing: MEDAREX INC - Form 10-K

See notes to these consolidated financial statements.

F-4

Edgar Filing: MEDAREX INC - Form 10-K

MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(Dollars in thousands)

	Common stock		Capital	Treasury Stock		Accumulated other comprehensive			Total
	Number of shares	Amount of par value	in excess of par value	Number of shares	Amount	Deferred Compensation	income (loss)	Accumulated deficit	shareholders equity
Balance at December 31, 2000	73,802,666	\$ 738	\$ 607,440	(1,205,000)	\$ (3,031)	\$ 2,234	\$ 1,283	\$ (123,375)	\$ 485,289
Issuance of common stock for exercise of options and grant of restricted shares	202,800	2	1,225			165			1,392
Early withdrawal from executive deferred compensation plan			20	75,774	191	(211)			
Change in unrealized appreciation to carrying value of affiliate			(459)						(459)
Net loss								(2,687)	(2,687)
Other comprehensive income (loss) - foreign currency translation adjustment							(3,496)		(3,496)
unrealized gain on securities							2,523		2,523
Comprehensive loss									(3,660)
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

Edgar Filing: MEDAREX INC - Form 10-K

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

See notes to these consolidated financial statements.

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

(In thousands)

	For the Year Ended		
	December 31,		
	2001	2002	2003
Operating activities:			
Net income (loss)	\$ (2,687)	\$ (157,541)	\$ (129,277)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Cumulative effect of change in accounting principle			830
Depreciation	3,432	7,859	10,650
Amortization	1,161	3,084	4,613
Stock options and awards to employees	1,956	631	773
Stock options and warrants to non-employees	114	(8)	
Non cash revenue - IDM	(20,233)	(14,332)	
Non cash revenue - Genmab	(1,333)		(834)
Licenses fee paid with stock		1,500	
Write-off of facility costs		11,294	
Write-off of in-process technology		14,157	6,100
Equity in net loss of Genmab	7,334	50,625	14,997
Gain on disposition of Genmab stock	(1,442)		
Impairment loss on investments in partners		11,886	1,400
Gain on exchange of Eos stock			(393)
Gain on sale of Seattle Genetics stock			(1,137)
Deferred income taxes	600	250	
Changes in operating assets and liabilities			
Other current assets	(6,857)	11,393	3,799
Trade accounts payable	1,676	(453)	(489)
Accrued liabilities	10,700	(985)	214
Deferred contract revenue	(2,111)	(3,329)	(497)
Net cash used in operating activities	(7,690)	(63,969)	(89,251)
Investing activities:			
Purchase of property and equipment	(55,009)	(43,691)	(8,890)
Proceeds from sale of land and equipment		906	
Increase in investments and advances to affiliates and partners	(6,750)		(1,000)
Decrease (increase) in segregated cash	20,768		(15,896)
Purchase of marketable securities	(175,500)	(2,500)	(121,191)
Sales of marketable securities	7,544	139,205	124,407
Net cash provided by (used in) investing activities	(208,947)	93,920	(22,570)
Financing activities:			
Cash received from sales of securities, net	420	680	2,091
Proceeds from sale of convertible subordinated notes, net	169,114		121,239
Principal payments under capital lease obligations	(25)	(88)	(323)
Net cash provided by financing activities	169,509	592	123,007

Edgar Filing: MEDAREX INC - Form 10-K

Net increase in cash and cash equivalents	(47,128)	30,543	11,186
Cash and cash equivalents at beginning of period	78,397	31,269	61,812
	<u>          </u>	<u>          </u>	<u>          </u>
Cash and cash equivalents at end of period	\$ 31,269	\$ 61,812	\$ 72,998
	<u>          </u>	<u>          </u>	<u>          </u>
Non-cash investing and financing activities:			
Issuance of common stock for asset acquisitions and license agreements	\$	\$ 20,725	\$ 7,100
	<u>          </u>	<u>          </u>	<u>          </u>
Supplemental disclosures of cash flow information			
Cash paid during period for:			
Income taxes	\$	\$ 25	\$ 108
	<u>          </u>	<u>          </u>	<u>          </u>
Interest	\$ 1	\$ 7,985	\$ 11,841
	<u>          </u>	<u>          </u>	<u>          </u>

See notes to these consolidated financial statements.

---

**MEDAREX, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2001, 2002 and 2003**

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

**1. Organization and Description of Business**

Medarex, Inc. ( Medarex or the Company ), incorporated in July 1987, is a biopharmaceutical company developing therapeutic products for cancer, inflammation, autoimmune disease and other life-threatening and debilitating diseases based on proprietary technology in the field of immunology. 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 five wholly-owned subsidiaries: Medarex Europe B.V.; Houston Biotechnology Incorporated ( HBI ); GenPharm International, Inc. ( GenPharm ); Medarex Belgium, S.A.; and Celldex Therapeutics, Inc. As of December 31, 2003, 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.

**2. Significant Accounting Policies**

***Cash Equivalents***

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

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

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



In addition, the Company has investments in several of its partners whose securities are not publicly traded. 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. Based on the information acquired through these sources, the Company records an investment impairment charge when it believes an investment has experienced a decline in value that is considered to be other than temporary.

The Company recorded investment impairment charges of \$0, \$9.5 million and \$0 related to investments in partners whose securities are publicly traded for the years ended December 31, 2001, 2002 and 2003, respectively. In addition, the Company recorded investment impairment charges of \$0, \$2.4 million and \$1.4 million in partners whose securities are privately held for the years ended December 31, 2001, 2002 and 2003, respectively.

### ***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, 2002 and 2003. 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.

---

**MEDAREX, INC. AND SUBSIDIARIES**

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

**December 31, 2001, 2002 and 2003**

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

***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 related lease terms, whichever is shorter.

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

Long-lived assets and certain identifiable intangible assets to be held and used are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to 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 equity transaction under Accounting Principles Board ( APB ) Opinion No. 18 and Staff Accounting Bulletin ( SAB ) No. 51. Such transactions are reflected as equity transactions in the accompanying statement of shareholders' equity. If an equity method investee's common stock is listed on a national market and the Company's investment in the equity method investee is not accounted for under the equity method, then the investment is classified as marketable securities and carried at fair market value.

***Revenue Recognition***

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

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 beginning after both the license period has begun and the technology has been delivered.

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

Milestone payments are recognized as revenue upon the achievement of mutually agreed milestones, provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there are no continuing performance obligations associated with the milestone payment.

Revenue arrangements entered into after June 15, 2003, 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.

---

**MEDAREX, INC. AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2001, 2002 and 2003****(Dollars in thousands, unless otherwise indicated, except share data)***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, 2003, the Company has fifteen 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. No stock-based employee compensation cost is reflected in net income (loss), as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income (loss) per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	Year ended December 31		
	2001	2002	2003
Net loss, as reported	\$ (2,687)	\$ (157,541)	\$ (129,277)
Add: Non-cash employee compensation	358	631	773
Deduct: Total stock-based employee compensation expense determined under fair value method	(24,459)	(11,876)	(11,303)

Edgar Filing: MEDAREX INC - Form 10-K

Pro forma net loss	\$ (26,788)	\$ (168,786)	\$ (139,807)
	<u>          </u>	<u>          </u>	<u>          </u>
Loss per share:			
Basic and diluted, as reported	\$ (0.04)	\$ (2.09)	\$ (1.65)
	<u>          </u>	<u>          </u>	<u>          </u>
Basic and diluted, pro forma	\$ (0.36)	\$ (2.24)	\$ (1.79)
	<u>          </u>	<u>          </u>	<u>          </u>

**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, 2003, the accumulated unrealized foreign exchange translation gain included in other comprehensive income was approximately \$4.8 million.

**Reclassifications**

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

**Net Income (Loss) Per Share**

Basic and diluted earnings per share is calculated in accordance with SFAS No. 128, *Earnings per Share*. Basic earnings per share is based upon the number of weighted average shares of common stock outstanding. Diluted earnings 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 are outstanding stock options. Potentially dilutive securities have been excluded from the computation of 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.

---

**MEDAREX, INC. AND SUBSIDIARIES**

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

**December 31, 2001, 2002 and 2003**

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

The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately \$1.4 million, recognition of an asset retirement obligation liability of approximately \$2.2 million and a cumulative effect of a change in accounting principle of approximately \$0.8 million. Adoption of SFAS No. 143 had no material impact on net loss before the cumulative effect of adoption in the year ended December 31, 2003 nor would it have had a material impact on a pro forma basis in 2002 and 2001 assuming an adoption of SFAS No. 143 at such time.

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

In January 2003, the FASB issued Interpretation No. 46 ( FIN 46 ), *Consolidation of Variable Interest Entities*, an interpretation of ARB 51. The primary objectives of this interpretation are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights ( variable interest entities ) and how to determine when and which business enterprise (the primary beneficiary ) should consolidate the variable interest entity. This new model for consolidation applies to an entity in which either (i) the equity investors (if any) do not have a controlling financial interest; or (ii) the equity investment at risk is insufficient to finance that entity's activities without receiving additional subordinated financial support from other parties. In addition, FIN 46 requires that the primary beneficiary, as well as all other enterprises with a significant variable interest in a variable interest entity, make additional disclosures. Certain disclosure requirements of FIN 46 were effective for financial statements issued after January 31, 2003.

In December 2003, the FASB issued FIN No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* ( FIN 46-R ) to address certain FIN 46 implementation issues. The effective dates and impact of FIN 46 and FIN 46-R are as follows:

- (iv) *Special purpose entities ( SPEs ) created prior to February 1, 2003.* We must apply either the provisions of FIN 46 or early adopt the provisions of FIN 46-R at the end of the first interim or annual reporting period after December 15, 2003.
- (v) *Non-SPEs created prior to February 1, 2003.* We are required to adopt FIN 46-R at the end of the first interim or annual reporting period ending after March 15, 2004.
- (vi) *All entities, regardless of whether a SPE, that were created subsequent to January 31, 2003.* The provisions of FIN 46 were applicable for variable interests in entities obtained after January 31, 2003. We are required to adopt FIN 46-R at the end of the first interim or annual reporting period ending after March 15, 2004.

The adoption of the provisions applicable to SPEs and all other variable interests obtained after January 31, 2003 had no impact on our financial statements. We are currently evaluating the impact of adopting FIN 46-R applicable to *Non-SPEs created prior to February 1, 2003*, but do not expect a material impact on our financial statements.

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

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ( SFAS 150 ). This statement establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise effective at the beginning of the interim period commencing July 1, 2003. The FASB has indefinitely deferred implementation of certain provisions of SFAS 150. The adoption of SFAS 150 did not have any effect on the financial position or results of operations of the Company.

F-10

## MEDAREX, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2001, 2002 and 2003

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

**3. Available for Sale Investments**

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

	2002				2003			
	Cost	Unrealized	Unrealized	Estimated	Cost	Unrealized	Unrealized	Estimated
		Gain	Loss	Fair Value		Gain	Loss	Fair Value
Money market funds (included in cash and cash equivalents)	\$ 53,227	\$	\$	\$ 53,227	\$ 64,459	\$	\$	\$ 64,459
U.S. Treasury Obligations	34,130	195		34,325	18,175	27	(109)	18,093
U.S. Corporate Debt Securities	249,140	2,624		251,764	264,029	761	(1,687)	263,103
Equity Securities	1,631	517	(3)	2,145	1,509	2,755		4,264
	<u>\$ 338,128</u>	<u>\$ 3,336</u>	<u>\$ (3)</u>	<u>\$ 341,461</u>	<u>\$ 348,172</u>	<u>\$ 3,543</u>	<u>\$ (1,796)</u>	<u>\$ 349,919</u>

The Company's available for sale investments have the following maturities at December 31, 2003:

Due in one year or less	\$ 170,953
Due after one year, less than five years	170,903
Due after five years	8,063

For the years ended December 31, 2001, 2002 and 2003, realized gains totaled \$1.5 million, \$1.8 million and \$2.1 million, respectively, and realized losses totaled \$0, \$0 and \$0.1 million, respectively. The cost of securities sold is based on the specific identification method.

**4. Balance Sheet Detail**

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



Edgar Filing: MEDAREX INC - Form 10-K

	<u>2002</u>	<u>2003</u>
Receivable from Genmab	\$ 3,127	\$
Receivables from other partners	1,610	190
Interest and dividends receivable	2,072	2,422
Employee receivables	634	454
Prepaid insurance	1,686	1,745
Other	1,014	1,433
	<u>\$ 10,143</u>	<u>\$ 6,244</u>

Other assets consist of the following as of December 31:

	<u>2002</u>	<u>2003</u>
Deferred debt issuance costs, net	\$ 4,104	\$ 6,502
Patents, net	4,197	3,276
Acquired workforce, net	563	328
	<u>\$ 8,864</u>	<u>\$ 10,106</u>

Accrued liabilities consist of the following as of December 31:

	<u>2002</u>	<u>2003</u>
Accrued construction and equipment costs	\$ 808	\$ 817
Accrued interest	3,938	2,317
Accrued compensation	5,035	5,746
Accrued license fees	1,000	
Accrued professional fees	893	980
Due to Essex Chemical Corp.	667	667
Accrued clinical trial expenses	588	699
Other	2,448	2,652
	<u>\$ 15,377</u>	<u>\$ 13,878</u>

---

**MEDAREX, INC. AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2001, 2002 and 2003****(Dollars in thousands, unless otherwise indicated, except share data)****5. Taxes**

Income tax expense is determined using the liability method.

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

	<b>Year ended December 31</b>		
	<b>2001</b>	<b>2002</b>	<b>2003</b>
	<b>—</b>	<b>—</b>	<b>—</b>
Federal			
Current	\$	\$	\$
Deferred			
	<b>—</b>	<b>—</b>	<b>—</b>
Total federal			
State			
Current		103	34
Deferred			
	<b>—</b>	<b>—</b>	<b>—</b>
Total state		103	34
Foreign			
Current			35
Deferred	600		
	<b>—</b>	<b>—</b>	<b>—</b>
Total foreign	600		35
	<b>—</b>	<b>—</b>	<b>—</b>
Total	\$ 600	\$ 103	\$ 69
	<b>—</b>	<b>—</b>	<b>—</b>

The current and deferred foreign tax provisions relate to foreign withholding taxes. The current state tax provision in 2002 and 2003 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 income before provision for income tax is as follows:

Edgar Filing: MEDAREX INC - Form 10-K

	Year ended December 31		
	2001	2002	2003
Computed at statutory rate	\$ (637)	\$ (53,529)	\$ (43,649)
State income taxes, net of federal tax effect		68	(7,733)
Loss of foreign subsidiary	2,705	56	24
Foreign withholding taxes	600		23
R&D credit carryforward benefit			(2,876)
Other	15		74
Other change in deferred tax valuation reserve	(2,083)	53,508	54,206
	<u>\$ 600</u>	<u>\$ 103</u>	<u>\$ 69</u>

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

	2002	2003
Deferred tax assets:		
Net operating loss carryforwards	\$ 81,574	\$ 113,718
Accrued compensation	962	271
R&D capitalized for tax purposes	4,217	4,217
Deferred revenue	1,365	1,293
Research credits	4,287	8,449
Unrealized losses	8,709	15,463
Capitalized license fees		1,049
Asset acquisition price adjustment		905
In-process technology		8,628
Cumulative effect asset retirement obligation		332
Other	1,145	919
	<u>102,259</u>	<u>155,244</u>
Deferred tax asset valuation allowance	(101,381)	(154,225)
	<u>878</u>	<u>1,019</u>
Net deferred tax liabilities:		
Unrealized gain		157
Fixed assets and amortization	878	862
	<u>878</u>	<u>1,019</u>
Net deferred tax assets	<u>\$</u>	<u>\$</u>

---

**MEDAREX, INC. AND SUBSIDIARIES**

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

**December 31, 2001, 2002 and 2003**

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

At December 31, 2003, approximately \$16.8 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, 2003, the Company had federal NOL carryforwards of approximately \$297.4 million. The NOL carryforwards expire in 2004 (\$0.5 million), 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) and 2023 (\$111.7 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, 2003, the amount of NOL subject to the limitation was \$43.8 million and the amount not subject to limitation was \$253.6 million.

The Company had federal research tax credit carryforwards at December 31, 2003 of approximately \$7.5 million which expire between 2005 and 2023. 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, 2003, the Company had state NOL carryforwards of approximately \$161.0 million. These NOL carryforwards will expire in varying amounts between 2006 and 2012.

**6. Convertible Subordinated 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 are 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 mature in July 2006. The Company received net proceeds from the public offering of approximately \$169.1 million. As of December 31, 2003, the Company had 6,067,961 shares of common stock reserved for issuance pursuant to the conversion of the 4.50% Notes. The costs of issuance of the 4.50% Notes of approximately \$5.9 million have been deferred and are being amortized over the term of the 4.50% Notes. The amortization of these costs are reflected in interest expense.

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

The Company pays interest on the 4.50% Notes on January 1 and July 1 of each year. The first interest payment was made on January 1, 2002 and carried with it an interest payment of \$23.125 per \$1,000 principal amount of notes due to the additional five days of interest that had been accrued based on the closing date of June 26, 2001. Interest payable per \$1,000 principal amount of notes for each subsequent interest period will be \$22.50. Interest is calculated on the basis of a 360-day year consisting of twelve 30-day months.

The Company may redeem the 4.50% Notes in whole or in part, at its option, at any time prior to July 1, 2004, 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, if the closing price of its common stock has exceeded 150% of the conversion price for at least

F-13

---

**MEDAREX, INC. AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2001, 2002 and 2003****(Dollars in thousands, unless otherwise indicated, except share data)**

20 trading days in the consecutive 30-day trading period ending on the trading day prior to the date the Company mails the notice of redemption.

If the Company redeems the 4.50% Notes under these circumstances, it will make an additional make whole payment on the redeemed notes equal to \$135 per \$1,000 principal amount of the notes, minus the amount of any interest actually paid or accrued and unpaid on the notes prior to the date the Company mails the notice of redemption. The Company may make these make whole payments, at its option, either in cash or, subject to the satisfaction of the conditions of the indenture, in shares of its common stock or a combination of cash and common stock. Payments made in common stock will be valued at 95% of the average of the closing sales prices of the Company's common stock for the five consecutive trading days immediately preceding the third trading day prior to the redemption date.

On and after July 1, 2004, the Company may redeem the 4.50% Notes, in whole or in part, at its option, at the redemption prices specified below. The redemption price, expressed as a percentage of principal amount, is as follows for the 12-month periods beginning on July 1 of the following years:

<u>Redemption Year</u>	<u>Price</u>
2004	101.8%
2005	100.9%

In each case the Company will also pay accrued interest to the redemption date.

The holders of the 4.50% Notes have the option, subject to certain conditions, to require the Company to repurchase any notes held by such holders 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 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.

**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 million of 4.25% Convertible Senior Notes due August 15, 2010 (the 4.25% Notes) to qualified institutional investors. The 4.25% Notes are

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

initially convertible into shares of the Company's common stock at the rate of 148.8261 per each \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$6.72 per share, subject to anti-dilution adjustments. As of December 31, 2003, the Company had 18,601,190 shares of common stock reserved for issuance pursuant to the conversion of the 4.25% Notes.

The Company will pay interest on the 4.25% Notes on February 15 and August 15 of each year beginning on February 15, 2004. Interest payable per \$1,000 principal amount of the 4.25% Notes for the period from the issue date to February 15, 2004 will be approximately \$23.85. Interest payable per \$1,000 amount of the 4.25% Notes for each subsequent interest payment will be \$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). Approximately \$15.8 million of the net proceeds have been used to purchase U.S. Treasury security strips to collateralize the notes in an amount sufficient to pay the initial six interest payments on the 4.25% Notes. Such amount has been classified as segregated cash in the Company's December 31, 2003 consolidated balance sheet and is comprised of the current portion of approximately \$5.6 million and the non-current portion of approximately \$10.2 million. 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.

---

**MEDAREX, INC. AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2001, 2002 and 2003****(Dollars in thousands, unless otherwise indicated, except share data)**

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

On and after August 15, 2006, the Company may redeem the 4.25% Notes, in whole or in part, at its option, at the redemption prices specified below. The redemption price, expressed as a percentage of the principal amount, is as follows for the 12-month periods beginning on August 15, 2006 of the following years:

<u>Redemption Year</u>	<u>Price</u>
2006	102.4%
2007	101.8%
2008	101.2%
2009	100.6%

The holders of the 4.25% 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 stock will be valued at 95% of the average 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. Shareholders' Equity**

In May 2001, the Company's 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 the Company's common stock. Each right entitles shareholders to buy 1/1000th of a share of the Company's Series A junior participating preferred stock at an exercise price of \$150.00. Each right will become exercisable following the tenth day after person or group announces an acquisition of 20% or more of the Company's common stock. The Company 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 the Company's common stock.



## 8. Stock Options

The Company has fifteen 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, 2003, a total of 3,395,090 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

## MEDAREX, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2001, 2002 and 2003

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

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, 2001, 2002 and 2003 is as follows:

	2001		2002		2003	
	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	3,894,592	\$ 7.47	6,765,191	\$ 17.21	9,935,072	\$ 13.64
Granted	3,111,850	18.66	3,663,900	7.25	5,018,019	6.43
Exercised	(202,800)	5.49	(163,300)	5.64	(451,897)	2.52
Canceled	(38,451)	34.01	(330,719)	20.42	(2,871,600)	24.25
Outstanding at end of year	6,765,191	17.21	9,935,072	13.64	11,629,594	8.32
Exercisable at end of year	3,653,341	7.30	6,271,172	17.38	5,093,394	10.04
Weighted average fair value of options granted during the year		\$ 15.64		\$ 4.69		\$ 3.63

Stock options outstanding at December 31, 2003 are summarized as follows:

Range of Exercise Price	Outstanding Options at December 31, 2003	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable Options at December 31, 2003	Weighted Average Exercise Price

Edgar Filing: MEDAREX INC - Form 10-K

\$1.47 to \$5.50	2,335,131	5.00	\$ 3.11	2,012,629	\$ 2.95
\$5.51 to \$6.46	5,809,927	9.28	\$ 6.36	1,544,860	\$ 6.35
\$6.52 to \$12.50	1,639,362	9.57	\$ 7.36	199,189	\$ 8.21
\$12.90 to \$53.41	1,845,174	7.42	\$ 21.93	1,336,716	\$ 25.27
	11,629,594			5,093,394	

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:

	2001	2002	2003
Expected dividend yield	0%	0%	0%
Expected stock price volatility	120.10%	76.7%	64.0%
Risk-free interest rate	4.0%	3.5%	2.75%
Expected life of options	5 years	5 years	5 years

#### 9. 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. During 2001, one individual elected to withdraw 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, one 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, there were further distributions from this plan totaling 301,876 shares, reducing the balance in treasury stock and reducing deferred compensation by \$0.8 million.

As of December 31, 2003, a total of 459,676 shares of common stock remain to be distributed.

---

**MEDAREX, INC. AND SUBSIDIARIES**

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

**December 31, 2001, 2002 and 2003**

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

**10. Research and Development Agreements**

In December 1999, the Company entered into a binding letter of intent with Kirin Brewery Co., Ltd., ( Kirin ) providing for the global commercialization of technology for creating fully human monoclonal antibodies. Under the terms of this letter of intent, Kirin paid the Company \$12.0 million in upfront fees in December 1999. The Company recognized \$6.0 million as revenue in each of 2000 and 2001, as the required work was performed.

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<sup>®</sup>, a unique crossbred mouse which combines the traits of the Company's HuMAb-Mouse<sup>®</sup> 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, 2003, the Company has not made any milestone payments to Kirin. Based on a total of three products the Company is developing, which use or the Company believes may use Kirin technology and that (i) are currently in clinical trials, or (ii) the Company anticipates may enter clinical trials through the end of 2005, the Company may be required to make milestone payments to Kirin aggregating up to approximately \$12.75 million with respect to such products, or a maximum of approximately \$4.25 million per product. The Company's future milestone payment obligations to Kirin may or may not be triggered, and may vary in size, depending on a number of variables, almost all of which are currently unknown, including the following:

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

the type of license requested (research or commercial);

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

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

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

payment.

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

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

## **11. Transactions with Genmab**

In February 1999, the Company 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 the Company's HuMAb-Mouse<sup>®</sup> 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, the Company contributed a license to its 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 on 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, the Company expanded its license to provide Genmab with broader rights to its human antibody technology in exchange for further equity, thereby maintaining the Company's level of ownership in Genmab's share

---

**MEDAREX, INC. AND SUBSIDIARIES**

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

**December 31, 2001, 2002 and 2003**

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

capital. Specifically, in exchange for equity, the Company 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, the Company made an additional cash investment of \$18.0 million in order to maintain its approximate 44% ownership interest in Genmab. In August 2000, the Company 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 its equity interest in Genmab to approximately 45%.

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 European 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.

In addition, under the terms of the Genomics Agreement, the Company granted Genmab an option to receive certain rights in Europe with respect to the development and commercialization of up to four antibody products the Company may obtain through its agreement with Eos Biotechnology, Inc., which was acquired by Protein Design Labs., Inc. in 2003. 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 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, 2001, 2002 and 2003, the Company recognized \$2.0 million of revenue from this agreement.

In September 2000, the Company entered into an amended agreement, or the Amended Genomics Agreement, with Genmab, pursuant to which the Company agreed to assign to Genmab 100% of its economic interest in each product it jointly develops with Oxford GlycoSciences plc (a Medarex/OGS product), and sells in Europe, and 50% of its economic interest in each Medarex/OGS product sold outside of North America and Europe. The Company retained 100% of its economic interest in Medarex/OGS products to be sold in North America. Oxford GlycoSciences plc

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

( OGS ) was subsequently acquired by Celltech Group plc ( Celltech ). Under the terms of the Amended Genomics Agreement, if a Medarex/OGS product is intended to be sold only in Europe, Genmab will reimburse the Company for 100% of its research, development, manufacturing and commercialization expenses associated with such product. If the Medarex/OGS product is to be sold only in North America, Genmab will not be obligated to reimburse the Company for any such expenses. In all other cases, Genmab will reimburse the Company for 50% of such expenses. In addition, the Company sold one-half of its equity interest in OGS to Genmab for \$2.5 million, which was its original cost of such equity interest. In 2002, the value of the Company's remaining interest in OGS was written down to approximately \$0.2 million due to a decline in its fair value, which was considered to be other than temporary. In June 2003, the Company exchanged its remaining equity interest in OGS for approximately \$0.3 million in cash in connection with the acquisition of OGS by Celltech.

In October 2000, Genmab announced the completion of the initial public offering of its ordinary shares. The global offering consisted of an issue of 6,000,000 new ordinary shares at a price of approximately \$33.00 per share (based on the exchange rate at the time of the global offering). The issuance of the new ordinary shares resulted in gross proceeds to Genmab of approximately \$187.0 million (based on the then current exchange rate). As the result of this

---

**MEDAREX, INC. AND SUBSIDIARIES**

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

**December 31, 2001, 2002 and 2003**

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

offering the Company's equity investment in Genmab was reduced to approximately 33%. The difference between the cost of the investment and the amount of the underlying equity in net assets of Genmab after the initial public offering was accounted for in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investment in Common Stock*, and SAB No. 51, *Accounting for Sales of Stock by a Subsidiary*. This transaction is reflected as an equity transaction in the accompanying statement of shareholders' equity.

In December 2001, 88,600 shares of the Company's Genmab stock were awarded as a bonus to the President of the Company, further reducing the Company's ownership percentage in Genmab to approximately 32.6% and resulting in additional non-cash compensation of approximately \$1.6 million which was offset by the gain on disposition of Genmab stock of \$1.4 million.

In June 2002, Genmab announced that one of its corporate partners had invested \$20 million 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 in the third quarter of 2002. 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 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.

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. Until August 1, 2000, the President and Chief Executive Officer of Genmab was an executive officer of the Company; she currently has a consulting agreement with the Company. The Chief Scientific Officer of Genmab also has a consulting agreement with the Company.

As of December 31, 2003, the market value of the Company's investment in Genmab was approximately \$61.7 million.



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

Summary financial information for Genmab is as follows as of and for the years ended December 31, 2001, 2002 and 2003:

	2001	2002	2003
Current Assets	\$ 195,709	\$ 199,648	\$ 178,596
Non Current Assets	19,718	23,890	19,487
Current Liabilities	8,303	22,649	12,606
Non Current Liabilities	3,553	3,328	3,117
Revenue			10,500
Gross Profit			10,500
Net Loss	(22,075)	(62,053)	(47,613)

### 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. 101, *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 \$20.3 million, \$14.3 million and \$0, as non-cash revenue from this transaction during the

**MEDAREX, INC. AND SUBSIDIARIES**

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

**December 31, 2001, 2002 and 2003**

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

years ended December 31, 2001, 2002 and 2003, 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.

In October 2000, the Company participated in a private placement of IDM and purchased additional equity of \$5.2 million which was part of a \$41.5 million offering by IDM.

The Company currently accounts for its interest in IDM under the cost method. The Company's equity ownership in IDM is 9% as of December 31, 2003. 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 26%. 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 leases laboratory, production and office space in New Jersey and California. These leases expire on various dates between November 2004 and July 2009. The Company incurred rent expense of \$3.1 million in 2001, \$4.0 million in 2002 and \$3.5 million in 2003.

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

Future minimum lease commitments as of December 31, 2003 are as follows:

2004	\$ 3,666
2005	3,250

Edgar Filing: MEDAREX INC - Form 10-K

2006	2,607
2007	2,452
2008	2,141
Remainder	690
	\$ 14,806

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 milestones payments that are due with respect to products using/targeting the licensed technology/antigen only if and when certain specified pre-commercialization events occur. Not all of the Company’s products currently under development trigger such milestone payments. Through December 31, 2003, the Company has made no milestone payments under these agreements. In addition, under the agreements the 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 2005, the Company may be obligated to make future milestone payments aggregating up to approximately \$30.625 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.

---

**MEDAREX, INC. AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2001, 2002 and 2003****(Dollars in thousands, unless otherwise indicated, except share data)**

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, 2003.

The Company has commitments for research funding of approximately \$3.0 million per year from 2004 through 2007 and \$2.25 million in 2008.

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 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, 2001, 2002 and 2003 is as follows:

Partners	2001	2002	2003
Genmab	12%	37%	48%
Amgen	2%	3%	15%
Lilly	7%	11%	7%
Kirin	14%		2%
IDM	48%	36%	

No other single partner accounted for more than 10% of the Company's total revenues for the years ended December 31, 2001, 2002 and 2003, 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 2001, 2002 and 2003, the Company made contributions to the plan totaling \$0.2 million, \$0.4 million and \$0.6 million, respectively.

#### **16. Asset Acquisition**

On May 23, 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) payable in six equal monthly installments of \$3.5 million either in cash, or at the Company's election, in shares of its common stock. 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

---

**MEDAREX, INC. AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****December 31, 2001, 2002 and 2003****(Dollars in thousands, unless otherwise indicated, except share data)**

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 has been 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
	<u>          </u>
	<u>\$ 21,405</u>

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 is a significant assumption and is 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.

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

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. 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.

### **18. Employee Stock Purchase Plan**

In May 2002, the Company adopted an Employee Stock Purchase Plan (the ESPP ) authorizing the issuance of 1,000,000 shares of its common stock pursuant to purchase rights granted to eligible employees of the Company. The ESPP provides a means by which employees purchase common stock of the Company through payroll deductions of up to 10% of their base compensation. At the end of each of two purchase periods during the calendar year, the Company uses accumulated payroll deductions to purchase, on behalf of participating employees, shares of common stock at a price equal to the lower of 85% of the fair market value of a share of common stock (i) on July 1, 2002 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

## MEDAREX, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2001, 2002 and 2003

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

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 and 2003, 146,982 shares of common stock and 175,955 shares of common stock were issued under the ESPP resulting in net proceeds to the Company of \$0.5 million and \$1.0 million, respectively.

## 19. Quarterly Financial Information Unaudited

The following is a summary of the quarterly results of operations for the years ended December 31, 2002 and 2003:

2002	March 31,	June 30,	September 30,	December 31,	Total
Sales	\$ 2,408	\$ 576	\$ 6,555	\$ 1,992	\$ 11,531
Contract and license revenues	8,363	7,508	8,074	4,003	27,948
Total revenue	10,771	8,084	14,629	5,995	39,479
Cost of sales	1,477	329	3,923	2,598	8,327
Loss before provision for income taxes	(15,839)	(47,968)	(54,043)	(39,588)	(157,438)
Net loss	(15,839)	(47,968)	(54,118)	(39,616)	(157,541)
Basic and diluted net loss per share	\$ (0.21)	\$ (0.65)	\$ (0.72)	\$ (0.51)	\$ (2.09)
2003	March 31,	June 30,	September 30,	December 31,	Total
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)

## 20. Subsequent Event



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

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% Convertible Senior Notes due August 15, 2010, 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.

F-23

**Report of Independent Auditors**

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 31 December 2003 and 2002, and the results of their operations and their cash flows for the years ended and, cumulatively, for the period from 11 June 1998 (date of inception) to 31 December 2003 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 auditing standards generally accepted in the United States of America, which 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 5 February 2004

/s/ Jens Røder

State Authorized Public Accountant

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

## Consolidated Balance Sheets

	Note	31 December 2003 DKK 000	31 December 2003 USD 000 (Unaudited)	31 December 2002 DKK 000
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents (includes restricted cash of DKK 11,269 thousand in 2003)		308,916	51,852	252,946
Marketable securities	5	726,860	122,006	1,115,789
Other current assets		28,227	4,738	45,203
<b>Total current assets</b>		<b>1,064,003</b>	<b>178,596</b>	<b>1,413,938</b>
<b>Non-current assets:</b>				
Plant and equipment, net	6	73,160	12,279	88,244
Other securities and equity interests	9	5,726	961	11,670
Licenses and rights	7	33,773	5,669	64,600
Deposits and other assets, net		3,446	578	4,684
<b>Total non-current assets</b>		<b>116,105</b>	<b>19,487</b>	<b>169,198</b>
<b>Total Assets</b>		<b>1,180,108</b>	<b>198,083</b>	<b>1,583,136</b>

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

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

## Consolidated Balance Sheets

	Note	31 December 2003 DKK 000	31 December 2003 USD 000 (Unaudited)	31 December 2002 DKK 000
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>				
<b>Liabilities:</b>				
<b>Current liabilities:</b>				
Trade accounts payable		24,033	4,034	94,640
Accrued liabilities		34,009	5,708	48,960
Short-term portion of payable technology rights	10	11,495	1,929	13,650
Short-term portion of lease liabilities	16	5,569	935	3,150
<b>Total current liabilities</b>		<b>75,106</b>	<b>12,606</b>	<b>160,400</b>
<b>Long-term liabilities:</b>				
Long-term portion of payable technology rights	10			12,942
Long-term portion of lease liabilities	16	18,568	3,117	10,625
<b>Total Liabilities</b>		<b>93,674</b>	<b>15,723</b>	<b>183,967</b>
<b>Commitment and contingencies</b>	16			
<b>Shareholders Equity:</b>				
Common stock, DKK 1.00 par value, 22,980,534 shares authorized, issued and outstanding at 31 December 2003, and 22,716,620 at 31 December 2002 and 21,812,020 at 31 December 2001	11	22,981	3,857	22,717
Share Premium		2,093,750	351,441	2,079,994
Deficit accumulated during development stage		(1,016,965)	(170,700)	(706,688)
Accumulated other comprehensive income		(13,332)	(2,238)	3,146
<b>Total Shareholders Equity</b>		<b>1,086,434</b>	<b>182,360</b>	<b>1,399,169</b>
<b>Total Liabilities and Shareholders Equity</b>		<b>1,180,108</b>	<b>198,083</b>	<b>1,583,136</b>

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

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

## Consolidated Statements of Operations

	Note	12 months ended 31 December 2003 DKK 000	12 months ended 31 December 2003 USD 000 (Unaudited)	12 months ended 31 December 2002 DKK 000	12 months ended 31 December 2001 DKK 000	Total since inception DKK 000
Revenues		68,326	11,469			68,326
Costs and expenses:						
Research and development costs	8	345,983	58,074	396,234	194,205	1,015,793
General and administrative expenses	8	64,552	10,836	86,847	53,443	230,642
Impairment loss on manufacturing facility	6			42,907		42,907
Total costs and expenses		410,535	68,910	525,988	247,648	1,289,342
<b>Operating loss</b>		<b>(342,209)</b>	<b>(57,441)</b>	<b>(525,988)</b>	<b>(247,648)</b>	<b>(1,221,016)</b>
Interest income		36,362	6,104	70,424	91,152	227,064
Interest expenses		(2,047)	(344)	(2,184)	(3,182)	(8,478)
Other expense, net	3	(2,449)	(411)	(19,338)	(25,954)	(14,270)
<b>Loss before provision for income taxes</b>		<b>(310,343)</b>	<b>(52,092)</b>	<b>(477,086)</b>	<b>(185,632)</b>	<b>(1,016,700)</b>
Provision (benefit) for income taxes	4	(66)	(11)	326	5	265
<b>Net loss</b>		<b>(310,277)</b>	<b>(52,081)</b>	<b>(477,412)</b>	<b>(185,637)</b>	<b>(1,016,965)</b>
<b>Basic and diluted net loss per share (in DKK/USD)</b>		<b>(13.6)</b>	<b>(2.3)</b>	<b>(21.4)</b>	<b>(8.5)</b>	
<b>Weighted average number of shares outstanding during the year - basic and diluted</b>		<b>22,830,818</b>	<b>22,830,818</b>	<b>22,336,150</b>	<b>21,812,020</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 31 December 2003

	Number of shares	Share Capital	Share Premium	Deficit accumulated during development stage	Accumulated other comprehensive income				
					Unearned compen- sation	Unrealized gains/ (losses) on securities	Cumulative translation adjustments	Shareholders' equity	Shareholders' equity
		DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	USD 000 (Unaudited)
<b>31 December 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>	<b>234,854</b>
Issuance of shares by debt conversion	246,914	247	12,716					12,963	2,176
Expenses related to share issues			256					256	43
Exercise of warrants	17,000	17	784					801	134
Loss for the period				(310,277)				(310,277)	(52,081)
Other comprehensive income:									
Translations gains							359	359	60
Unrealized loss on marketable securities						(6,774)		(6,774)	(1,137)
Unrealized exchange rate loss on marketable securities						(10,063)		(10,063)	(1,689)
Comprehensive loss								(326,755)	(54,847)
<b>31 December 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>182,360</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 31 December 2002

	Number of shares	Share Capital	Share Premium	Deficit accumulated during development stage	Unearned compen- sation	Accumulated other comprehensive income		Shareholders equity
						Unrealized gains/ (losses) on securities	Cumulative translation adjustments	
		DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000
<b>31 December 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>31 December 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 year ended 31 December 2001

	Number of shares	Share Capital	Share Premium	Deficit accumulated during development stage	Unearned compensation	Accumulated other comprehensive income		Shareholders equity
						Unrealized gains/ (losses) on securities	Cumulative translation adjustments	
		DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000
<b>31 December 2000</b>	<b>21,812,020</b>	<b>21,812</b>	<b>1,921,791</b>	<b>(43,639)</b>	<b>(13,161)</b>	<b>(19,215)</b>	<b>0</b>	<b>1,867,588</b>
Expenses related to share issues			58					58
Adjustment of value of warrants granted			9,948		(9,948)			
Expense recognized for warrants granted					10,047			10,047
Loss for the period				(185,637)				(185,637)
Other comprehensive income:								
Translations gains							4	4
Unrealized loss on marketable securities						(1,520)		(1,520)
Unrealized exchange rate gain on marketable securities						21,390		21,390
Comprehensive loss								(165,763)
<b>31 December 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>

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 (11 June 1998) to 31 December 2003

	Number of shares	Share Capital	Share Premium	Deficit accumulated during development stage	Unearned compensation	Accumulated other comprehensive income		Shareholders equity	Shareholders equity
						Unrealized gains/ (losses) on securities	Cumulative translation adjustments		
		DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	DKK 000	USD 000 (Unaudited)
<b>11 June 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>21</b>
Issuance of shares for cash	1,895,566	1,896	563,322					565,218	94,873
Issuance of shares for licenses	437,596	438	94,515					94,952	15,938
Issuance of shares by debt conversion	246,914	247	12,716					12,963	2,176
Exercise of warrants	44,640	44	3,134					3,178	533
Expenses and foreign currency fluctuations related to share issues			(6,560)					(6,560)	(1,101)
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	261,798
Expenses related to initial public offering			(138,546)					(138,546)	(23,255)
Adjustment of value of warrants granted			20,040		(20,040)				
Expense recognized for warrants granted					20,040			20,040	3,363
Transaction entered into by principal shareholder on company's behalf			5,670		(5,670)				
Expensed portion of transaction					5,670			5,670	951

Edgar Filing: MEDAREX INC - Form 10-K

entered into by principal shareholder on company's behalf									
Loss for the period				(1,016,965)			(1,016,965)		(170,700)
Other comprehensive income:									
Translation gains						4,767	4,767		800
Unrealized gain on marketable securities				(5,742)			(5,742)		(964)
Unrealized exchange rate loss on marketable securities					(12,357)		(12,357)		(2,074)
Comprehensive loss							(1,030,297)		(172,938)
<b>31 December 2003</b>	<b>22,980,534</b>	<b>22,981</b>	<b>2,093,749</b>	<b>(1,016,965)</b>	<b>0</b>	<b>(18,099)</b>	<b>4,767</b>	<b>1,086,432</b>	<b>182,360</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 31 December 2003	12 months ended 31 December 2003	12 months ended 31 December 2002	12 months ended 31 December 2001	Total since inception
	DKK 000	USD 000 (Unaudited)	DKK 000	DKK 000	DKK 000
<b>Operating activities:</b>					
Net loss	(310,277)	(52,081)	(477,412)	(185,637)	(1,016,965)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	32,843	5,513	16,971	3,975	54,431
Amortization	30,827	5,174	30,497	30,497	118,711
Impairment loss			42,170		42,170
Non-cash interest expense reversed	5,661	950	8,564	17,410	32,699
Non-cash interest income and non-cash other expense reversed	(18,300)	(3,072)	(9,871)	3,917	(42,525)
Paid technology rights	(13,865)			(16,912)	(30,777)
Expensed value of warrants granted			5,315	10,047	20,040
Other non cash transactions	(402)	(67)	(384)		4,884
Changes in operating assets and liabilities, net of acquisition:					
Other current assets	33,179	5,570	1,379	(18,467)	(569)
Trade accounts payable	(48,317)	(10,437)	51,234	14,505	31,192
Accrued liabilities	(14,951)	(2,510)	23,628	17,442	33,809
<b>Net Cash used in operating activities</b>	<b>(303,602)</b>	<b>(50,960)</b>	<b>(307,909)</b>	<b>(123,223)</b>	<b>(752,900)</b>
<b>Investing activities:</b>					
Deposits on leasehold	1,238	208	(407)	(2,898)	(3,446)
Purchase of plant and equipment, net	(13,123)	(2,203)	(86,865)	(50,299)	(155,357)
Investments in other securities and equity interests, net	1,743	293	(1,839)	(8,411)	(30,012)
Purchase of marketable securities	(1,676,845)	(281,463)	(5,037,176)	(2,954,921)	(11,409,726)
Sales of marketable securities	2,050,130	344,120	5,364,432	3,267,314	10,681,879
<b>Net cash provided by (used in) investing activities</b>	<b>363,143</b>	<b>60,955</b>	<b>238,145</b>	<b>250,785</b>	<b>(916,662)</b>
<b>Financing activities:</b>					
Increase in restricted cash	(11,269)	(1,891)			(11,269)
Cash received from sales of stock, net	256	43	155,494	58	1,979,928
Warrants exercised	801	134	1,355		3,178
Paid installments on lease liabilities	(4,628)	(777)			(4,628)
<b>Net cash provided by (used in) financing activities</b>	<b>(14,840)</b>	<b>(2,491)</b>	<b>156,849</b>	<b>58</b>	<b>1,967,209</b>
	<b>44,701</b>	<b>7,504</b>	<b>87,085</b>	<b>127,620</b>	<b>297,647</b>

Edgar Filing: MEDAREX INC - Form 10-K

<b>Net increase (decrease) in cash and cash equivalents</b>				
Cash and cash equivalents at the beginning of period	252,946	42,457	165,861	38,241
<b>Cash and cash equivalents at the end of period</b>	<b>297,647</b>	<b>49,961</b>	<b>252,946</b>	<b>297,647</b>
Supplemental schedule of non-cash contributions:				
Acquisitions of licenses and rights				57,532
Liabilities assumed	(15,370)		(13,395)	(86,297)
Assets acquired	15,370		13,395	123,717
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 closing spot rate on 31 December 2003, which was USD 1.00 = DKK 5.9576.

**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**

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

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.

F-33

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

**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies, continued**

**Foreign Currency Translations (continued)**

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.

**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 deliveries 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**

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

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.

### **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.



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

## Notes to the Consolidated Financial Statements (Continued)

## 1. Accounting Policies, continued

## Stock-Based Compensation (continued)

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 31 December 2003	12 months ended 31 December 2003	12 months ended 31 December 2002	12 months ended 31 December 2001	Total since inception
	DKK 000	USD 000 (Unaudited)	DKK 000	DKK 000	DKK 000
Net loss, as reported	(310,277)	(52,081)	(477,412)	(185,637)	(1,016,965)
Total stock-based employee compensation expense determined under fair value based method for all awards	(43,004)	(7,218)	(33,625)	(15,955)	(94,484)
Stock-based employee compensation expense included in reported net loss			4,668	2,783	7,451
Pro forma net loss	(353,281)	(59,299)	(506,369)	(198,809)	(1,103,998)
Net loss per share, basic and diluted (in DKK/USD)	(13.6)	(2.3)	(21.4)	(8.5)	
Pro forma net loss per share, basic and diluted (in DKK/USD)	(15.5)	(2.6)	(22.7)	(9.1)	

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.

	2003	2002
Expected dividend yield	0%	0%
Expected stock price volatility	54%	120%
Risk-free interest rate	3.73%	4.04%
Expected life of warrants	4 years	4 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.

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

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%.

F-35

---

**Genmab A/S (A development stage company)**
**Notes to the Consolidated Financial Statements (Continued)****1. Accounting Policies, continued****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 22,830,818, 22,336,150 and 21,812,020 for the years ended 31 December 2003, 2002 and 2001, 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 31 December 2003	4,455,450
Year ended 31 December 2002	4,236,575
Year ended 31 December 2001	3,403,300

**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.

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.

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

**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies, continued**

**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 10,500 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**

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

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.

### **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.

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

**Notes to the Consolidated Financial Statements (Continued)**

**1. Accounting Policies (continued)**

**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 December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-based Compensation Transition and Disclosure* an Amendment of SFAS No. 123. This statement provides two additional transition methods for companies electing to adopt the fair value accounting provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, but does not change the fair value measurement principles of SFAS No. 123. This statement is not expected to have any significant impact on the company's financial position or results of operations.

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

In January 2003, the 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. FIN 46 is effective immediately for all new variable interest entities created or acquired after 31 January 2003.

For variable interest entities created or acquired prior to 1 February 2003, the provisions of FIN 46 must be applied in the first interim or annual period beginning after 15 June 2003. The disclosure (but not the accounting) requirements of FIN 46 are effective for our 2003 financial statements, regardless of the date on which the variable interest entity was created. This statement is not expected to have any significant impact on the company's financial position or results of operations.

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. The Statement establishes standards for how an issuer classifies and measures 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 an asset in some circumstances). It is effective for financial instruments entered into or modified after 31 May 2003, and otherwise is effective at the beginning of the first interim period beginning of the first interim period beginning after 15 June 2003. Management does not believe the adoption of this Statement will have a material impact on The Company financial statements.

In December 2003 the Financial Accounting Standards Board issued FASB Interpretation No. 46R (FIN 46R), Consolidation of Variable Interest Entities Revised. FIN 46R modifies the scope exceptions provided in FIN 46. Entities would be required to replace FIN 46 provisions with FIN 46R provisions for all newly created post 31 January 2003 entities as of the end of the first interim or annual reporting period ending after 15 March 2004. The company reviewed its investment portfolio and did not identify any investments in a Variable Interest Entity, as defined by FIN 46R. Accordingly, the interpretation is not expected to have any significant impact on the company's financial position or results of operations.



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

**Notes to the Consolidated Financial Statements (Continued)**

**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.

During 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 31 December 2003	12 months ended 31 December 2003	12 months ended 31 December 2002	12 months ended 31 December 2001	Total since inception
	DKK 000	USD 000 (Unaudited)	DKK 000	DKK 000	DKK 000
Realized gains on securities	13,996	2,349	13,369	4,679	32,044
Exchange rate gains	33,349	5,598	16,581	10,997	95,469
Realized loss on securities	(1,660)	(279)	(14,059)	(349)	(15,214)
Impairment loss on other securities and equity interests	(4,525)	(760)	(5,858)	(14,227)	(24,610)
Exchange rate losses	(43,609)	(7,319)	(29,371)	(27,054)	(101,959)
	<b>(2,449)</b>	<b>(411)</b>	<b>(19,338)</b>	<b>(25,954)</b>	<b>(14,270)</b>

For a discussion on impairment losses on other securities and equity interests, please refer to Note 9.

## 4. Income Taxes

The provision for income taxes for the twelve-month period ended 31 December 2003, 2002 and 2001 is DKK 0, DKK 200 thousand, and DKK 5 thousand, respectively. In 2003, the company recognized DKK 66 thousand as refunded taxes expensed and paid in prior years. Besides the calculated tax for 2002, a total of DKK 126 thousand related to prior years has been expensed. 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 31 December 2003	12 months ended 31 December 2003	12 months ended 31 December 2002	12 months ended 31 December 2001
	DKK 000	USD 000 (Unaudited)	DKK 000	DKK 000
Income taxes at statutory rate	(93,103)	(15,628)	(143,126)	(55,690)
Permanent differences	1,710	287	2,267	989
Permanent differences related to expensed warrants			1,595	3,014
Change in valuation allowance to unrealized gains and losses	(5,051)	(847)	575	5,962
Other changes	(45)	(7)	(2,035)	
Change in tax rate			(89)	
Adjustment to prior years' deferred tax			(2,737)	

Edgar Filing: MEDAREX INC - Form 10-K

Other changes in deferred tax valuation allowance	<u>96,423</u>	<u>16,184</u>	<u>143,876</u>	<u>45,730</u>
<b>Provision for income taxes</b>	<u><b>(66)</b></u>	<u><b>(11)</b></u>	<u><b>326</b></u>	<u><b>5</b></u>

F-40

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

## Notes to the Consolidated Financial Statements (Continued)

## 4. Income Taxes, continued

At 31 December, 2003, the parent company had net tax loss carry-forwards of approximately DKK 967,653 thousand for income tax purposes of which DKK 199,546 thousand expires in 2004 through 2006. Approximately 5% of the DKK 199,546 thousand expires in 2004. DKK 768,107 thousand can be carried forward without limitation. In addition, the parent company had deductible temporary differences of approximately DKK 40,301 thousand.

For local tax purposes, the subsidiaries had net tax loss carry-forwards and deductible temporary differences totaling DKK 1,252 thousand.

Significant components of the deferred tax assets are as follows:

	31 December 2003	31 December 2003	31 December 2002	31 December 2001
	DKK 000	USD 000 (Unaudited)	DKK 000	DKK 000
Tax deductible losses	970,886	162,966	662,335	199,985
Licenses and rights	35,431	5,947	27,672	11,251
Property and equipment	(1,733)	(291)	(5,509)	(800)
Other securities and equity interests	4,525	760		
Other temporary differences	97	16	3,298	(2,226)
Accumulated temporary differences	1,009,206	169,398	687,796	208,210
Deferred tax asset, calculated at 30%	302,762	50,819	206,339	62,463
Valuation allowance	(302,762)	(50,819)	(206,339)	(62,463)
	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

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

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.

F-41

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

## Notes to the Consolidated Financial Statements (Continued)

## 5. Marketable Securities, continued

	31 December 2003	31 December 2003	31 December 2002
	DKK 000	USD 000 (Unaudited)	DKK 000
Cost at the end of the period	744,584	124,981	1,116,313
Unamortized cost	293	49	737
Total amortized costs at the end of the period	744,877	125,030	1,117,050
Unrealized gain at the end of the period			1,045
Unrealized loss at the end of the period	(5,883)	(987)	(12)
Unrealized foreign exchange loss at the end of the period	(12,134)	(2,037)	(2,294)
<b>Net book value</b>	<b>726,860</b>	<b>122,006</b>	<b>1,115,789</b>

## Specification of Portfolio as of 31 December 2003

	Cost	Cost	Market Value	Market Value
	DKK 000	USD 000 (Unaudited)	DKK 000	USD 000 (Unaudited)
Kingdom of Denmark bonds	437,075	73,364	432,062	72,523
Other Danish securities	213,023	35,756	214,094	35,936
	650,098	109,120	646,156	108,459
US Government and Federal Agency Notes	54,184	9,095	46,412	7,790
US Corporate Notes	40,302	6,766	34,292	5,757
	94,486	15,861	80,704	13,547
<b>Total securities</b>	<b>744,584</b>	<b>124,981</b>	<b>726,860</b>	<b>122,006</b>

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

## Notes to the Consolidated Financial Statements (Continued)

## 5. Marketable Securities, continued

## Scheduled maturities per 31 December 2003

	Cost	Cost	Market Value	Market Value
	DKK 000	USD 000 (Unaudited)	DKK 000	USD 000 (Unaudited)
Maturity within one year	129,802	21,788	122,469	20,557
Maturity from one to four years	614,782	103,193	604,391	101,449
<b>Total securities</b>	<b>744,584</b>	<b>124,981</b>	<b>726,860</b>	<b>122,006</b>

## Specification of Portfolio as of 31 December 2002

	Cost	Market Value
	DKK 000	DKK 000
Kingdom of Denmark bonds	953,882	955,541
US Government and Federal Agency Notes	162,431	160,248
<b>Total securities</b>	<b>1,116,313</b>	<b>1,115,789</b>

## Scheduled maturities per 31 December 2002

All of the marketable securities in the portfolio as of 31 December 2002 had maturities within one year.

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

## Notes to the Consolidated Financial Statements (Continued)

## 6. Plant and Equipment, net

	31 December 2003	31 December 2003	31 December 2002
	DKK 000	USD 000 (Unaudited)	DKK 000
Machinery and other equipment	84,222	14,137	51,652
Fixed assets under construction	47,176	7,918	62,369
Leasehold improvements	30,195	5,068	32,778
Cost at the end of the period	161,593	27,123	146,799
Accumulated depreciation at the end of the period	(46,263)	(7,766)	(16,385)
Impairment loss on fixed assets under construction	(42,170)	(7,078)	(42,170)
<b>Net book value</b>	<b>73,160</b>	<b>12,279</b>	<b>88,244</b>
Net book value of assets under finance lease included above	23,448	13,395	

The impairment loss of DKK 42,170 thousand recorded in 2002 represents the total costs incurred in connection with the development of the planned manufacturing facility, which was postponed in 2002. In addition, related costs totaling DKK 737 thousand were incurred in 2002 after the postponement decision was made. This cost was included in the DKK 42,907 thousand impairment loss shown in the income statement.

## 7. Licenses and Rights, net

	31 December 2003	31 December 2003	31 December 2002
	DKK 000	USD 000 (Unaudited)	DKK 000
Cost at the end of the period	152,484	25,595	152,484
Accumulated amortization at the end of the period	(118,711)	(19,926)	(87,884)
<b>Net book value</b>	<b>33,773</b>	<b>5,669</b>	<b>64,600</b>



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

## Notes to the Consolidated Financial Statements (Continued)

## 8. Depreciation and Amortization

	12 months ended 31 December 2003	12 months ended 31 December 2003	12 months ended 31 December 2002	12 months ended 31 December 2001	Total since inception
	DKK 000	USD 000 (Unaudited)	DKK 000	DKK 000	DKK 000
Licenses and rights (amortized)	30,827	5,174	30,497	30,497	118,711
Property and equipment	32,843	5,513	16,971	3,975	54,430
	<b>63,670</b>	<b>10,687</b>	<b>47,468</b>	<b>34,472</b>	<b>173,141</b>
Depreciation and amortization was classified as follows:					
Research and development costs	56,888	9,549	42,996	33,774	160,805
General and administrative expenses	6,782	1,138	4,472	698	12,336
	<b>63,670</b>	<b>10,687</b>	<b>47,468</b>	<b>34,472</b>	<b>173,141</b>

## 9. Other Securities and Equity Interests

	31 December 2003	31 December 2003	31 December 2002
	DKK 000	USD 000 (Unaudited)	DKK 000
Cost at the end of the period	10,251	1,720	31,755
Impairment loss	(4,525)	(759)	(20,085)
<b>Net book value</b>	<b>5,726</b>	<b>961</b>	<b>11,670</b>

Other securities and equity interests consist of equity shares in a privately held British biotech company, Scancell Ltd., and shares in a privately held British biotech company, Paradigm Therapeutics Ltd. Both companies are strategic partners of Genmab.

As per 31 December 2002, 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.

Edgar Filing: MEDAREX INC - Form 10-K

As of 31 December 2003 and 2002, the company has adjusted the investments by DKK 4,525 thousand and DKK 20,085 thousand, respectively, as the Company experienced significant declines in the value of these held investments which were determined to be other than temporary.

F-45

---

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

**Notes to the Consolidated Financial Statements (Continued)**

**10. Payable Technology Rights**

In 2000, Genmab entered into the Genomics Agreement with Medarex, Inc. See Note 14 for additional details. The agreement requires the company to pay USD 2 million annually for four consecutive years beginning at 26 August 2001. The company has 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 corresponding amount has been recorded as a liability in the balance sheet. The company has recognized imputed interest on the outstanding payment.

**11. Share Capital**

In February 1999, Medarex and Bankforeningernes Erhvervsudviklingsforening Biomedicinsk Udvikling, BI Asset Management Fondsmæglerselskab A/S, Lønmodtagernes Dyrtdidsfond, 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<sup>®</sup> 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.



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

**Notes to the Consolidated Financial Statements (Continued)**

**11. Share Capital, continued**

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 administrative burdens 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. Please refer to Note 14 for additional details on the transaction.

At 31 December 2003, the total number of outstanding shares was 22,980,534. Each share has a nominal value of DKK 1 and one vote.

**12. Warrants**

**Warrant Scheme**

Genmab A/S has a warrant scheme which has 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 scheme is meant to provide an incentive for all group employees, members of the board of directors, members of the management and external consultants.

Warrants are granted by the board of directors in accordance with authorizations given to the board by the company's shareholders.

Under the terms of the warrant scheme, warrants are granted by the board of directors at their meetings at an exercise price equal to the share price on the date of the meeting. According to the company's Articles of Association, the exercise price cannot be established at a price lower than the market price on the grant date.

Warrants granted under the existing warrant scheme cannot be exercised immediately. The terms of the scheme state that one-half of warrants granted 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.

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

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 back clause is not applicable in the event of termination by the company without cause or termination as a result of the company's breach of the

F-47

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

**Notes to the Consolidated Financial Statements (Continued)**

**12. Warrants, continued**

employment or 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.

The warrant scheme contains anti-dilution provisions if changes occur in the company's share capital prior to the exercise.

**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. Accordingly, as per 31 December 2003, the board of directors has been authorized to grant a total of 4,771,263 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.

## 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 31 December 2003	12 months ended 31 December 2002	12 months ended 31 December 2001	12 months ended 31 December 2003	12 months ended 31 December 2003	12 months ended 31 December 2002	12 months ended 31 December 2001
	Number of warrants	Number of warrants	Number of warrants	Weighted average exercise price	Weighted average exercise price	Weighted average exercise price	Weighted average exercise price
				DKK	USD (Unaudited)	DKK	DKK
Outstanding at the beginning of the period	4,236,575	3,403,300	2,289,000	107.48	18.04	108.38	89.47
Granted	235,875	857,775	1,114,300	46.00	7.72	102.40	147.22
Exercised	(17,000)	(24,500)		47.11	7.91	55.29	
<b>Outstanding at the end of the period</b>	<b>4,455,450</b>	<b>4,236,575</b>	<b>3,403,300</b>	<b>104.45</b>	<b>17.53</b>	<b>107.48</b>	<b>108.38</b>
Warrants available for future grants at the end of the year	274,313						



Genmab A/S (A development stage company)

Notes to the Consolidated Financial Statements (Continued)

12. Warrants, continued

Weighted average exercise price of warrants issued in 2003 and 2002:

	12 month period ended 31 December 2003	12 month period ended 31 December 2003	12 month period ended 31 December 2002
	DKK	USD (Unaudited)	DKK
Warrants issued at a discount			
Warrants issued at market price	46,00	7,72	102,40
Warrants issued at a premium			

Weighted average grant date fair value of warrants granted in 2003 and 2002:

	12 month period ended 31 December 2003	12 month period ended 31 December 2003	12 month period ended 31 December 2002
	DKK	USD (Unaudited)	DKK
Warrants issued at a discount			
Warrants issued at market price	20,80	3,49	80,69
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 31 December 2003 compared to DKK 4,668 thousand in 2002 and DKK 2,783 thousand in 2001.

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 31 December 2003 were DKK 0 compared to DKK 647 thousand in 2002 and DKK 7,264 thousand in 2001.

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 6 March 2001 was subsequently re-priced by reducing the exercise price from DKK 222 to DKK 148 following the extraordinary board meeting of Genmab on 30 July 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.

## Genmab 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 31 December 2003 are summarized as follows:

Exercise price	Warrants exercisable from	Warrants outstanding				Warrants exercisable		
		Number of warrants outstanding	Weighted average remaining contractual life (in years)	Weighted average exercise price	Weighted average exercise price	Number of warrants exercisable	Weighted average exercise price	Weighted average exercise price
DKK 33.70	26 September 2003	412,925	3.24	33.70	5.66	205,463	33.70	5.66
DKK 37.00	25 June 2004	146,025	3.98	37.00	6.21			
DKK 48.90	11 February 2001	529,500	0.65	48.90	8.21	529,500	48.90	8.21
DKK 51.50	4 December 2004	7,250	4.42	51.50	8.64			
DKK 59.00	11 November 2004	25,000	4.36	59.00	9.90			
DKK 59.70	26 June 2001	1,411,500	1.06	59.70	10.02	1,411,500	59.70	10.02
DKK 62.50	10 October 2004	57,600	4.28	62.50	10.49			
DKK 116.00	5 December 2002	84,000	2.43	116.00	19.47	84,000	116.00	19.47
DKK 117.50	7 November 2002	254,300	2.35	117.50	19.72	254,300	117.50	19.72
DKK 139.50	28 June 2003	210,000	2.99	139.50	23.42	105,000	139.50	23.42
DKK 148.00	6 March 2002	212,500	1.68	148.00	24.84	212,500	148.00	24.84
DKK 165.00	30 July 2002	563,500	2.08	165.00	27.70	563,500	165.00	27.70
DKK 183.00	20 March 2003	18,750	2.72	183.00	30.72	9,375	183.00	30.72
DKK 190.00	15 February 2003	139,100	2.63	190.00	31.89	69,550	190.00	31.89
DKK 196.00	7 March 2003	75,000	2.68	196.00	32.90	37,500	196.00	32.90
DKK 300.00	6 December 2001	308,500	1.43	300.00	50.36	308,500	300.00	50.36
<b>DKK 33.70 to DKK 300.00</b>		<b>4,455,450</b>	<b>1.83</b>	<b>104.45</b>	<b>17.53</b>	<b>3,790,688</b>	<b>108.32</b>	<b>18.18</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	Number of warrants  held as of
	31 December 2003	31 December 2003
<b>Board of directors</b>		
Lisa N. Drakeman	308,040	505,000
Ernst Schweizer	191,840	57,000
Irwin Lerner		60,000
Michael Widmer		50,000
Karsten Havkrog Pedersen		25,000
Anders Gersel Pedersen		25,000
	<u>499,880</u>	<u>722,000</u>
<b>Management</b>		
Lisa N. Drakeman, see above		
Jan van de Winkel	80,000	280,000
Claus Juan Møller-San Pedro	128,375	330,000
	<u>208,375</u>	<u>610,000</u>
<b>Total</b>	<u>708,255</u>	<u>1,332,000</u>

---

Genmab A/S (A development stage company)

Notes to the Consolidated Financial Statements (Continued)

**14. Related Party Transactions**

**Medarex Inc.**

At 31 December 2003, Medarex, Inc. owned approximately 32% 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 technology and to produce human monoclonal antibodies for 16 antigens to be specified by Genmab. Furthermore, Genmab 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 being 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 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) agreements. In exchange for the rights granted to Genmab by Medarex under the Genomics Agreement, the company issued 27,976 shares to Medarex. Such amounts were assigned at a value of DKK 16,702 thousand, equal to USD 2 million, at the exchange rate prevailing at the date of issuance. Beginning in 2001, the Genomics Agreement states that the company will pay Medarex USD 2 million per year for four years. This obligation has been recorded including imputed interest. For 2001 and 2002, Medarex was paid in cash in the amount of DKK 16,912 thousand and DKK 13,865 thousand, respectively. However, Genmab has 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.

The company has paid Medarex for manufacturing services, licenses and reimbursement of administrative expenses. For 2003, 2002 and 2001, the company has recorded transactions totalling DKK 15,335 thousand, DKK 105,880 thousand, and DKK 23,949 thousand, respectively, in connection with these agreements.

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

**Notes to the Consolidated Financial Statements (Continued)**

**14. Related Party Transactions, continued**

Medarex reimbursed the company DKK 512 thousand for the twelve-month period ended 31 December 2001, for costs incurred on their behalf. No significant costs have been reimbursed in 2003 and 2002. In 2001 and partly in 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, the company has recorded payables to Medarex of DKK 645 thousand as of 31 December 2003, compared to DKK 25,339 thousand as per 31 December 2002.

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 cost associated with the pre-clinical and clinical development of the product and will share the commercialization rights and royalties. In 2003, the development activities led to the recognition of a net cost reimbursement of DKK 5,374 thousand, which reduced our development expenses.

**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 1,663 thousand in 2003 compared to DKK 513 thousand in 2002.

**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 totaling DKK 3,541 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

F-55

---

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

**Notes to the Consolidated Financial Statements (Continued)**

**15. Research and Development Agreements, continued**

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 June 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. The Phase II RA study is ongoing and Amgen is adding additional patients, as drug supply allows.

**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 totaling 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. Under the partnership agreement, Genmab utilizes its 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. In 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



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

## Notes to the Consolidated Financial Statements (Continued)

## 15. Research and Development Agreements, continued

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.

## 16. Commitments and Contingencies

## Leases

The Group leases office space under operating leases, which are non-cancelable for various periods until 2010. At 31 December 2003, future minimum payments under the office leases were as follows:

	DKK 000	USD 000 (Unaudited)
	<u>          </u>	<u>          </u>
2004	18,892	3,171
2005	16,898	2,836
2006	13,126	2,203
2007	11,599	1,947
2008	9,000	1,511
Thereafter	17,999	3,021
	<u>87,514</u>	<u>14,689</u>

For the years ended 31 December 2003, 2002 and 2001, the Group recorded rent expenses of DKK 12,235 thousand, DKK 12,565 thousand and DKK 3,966 thousand, respectively. The Group has established bank guarantees totaling DKK 3,943 thousand as collateral for the operating lease arrangements.



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

## Notes to the Consolidated Financial Statements (Continued)

## 16. Commitments and Contingencies, continued

## 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. Future minimum lease payments under such finance leases and the net present value as of the end of December 2003 are as follows:

	DKK 000	USD 000
	<u>          </u>	<u>          </u>
		(Unaudited)
<b>Minimum lease payments</b>		
Within 1 year	5,897	990
From 1 to 5 years	17,969	3,016
	<u>          </u>	<u>          </u>
	23,866	4,006
Future finance charges	(1,891)	(317)
	<u>          </u>	<u>          </u>
<b>Total</b>	21,975	3,689
	<u>          </u>	<u>          </u>
<b>Net present value of future payments</b>		
Within 1 year	5,774	969
From 1 to 5 years	16,201	2,720
	<u>          </u>	<u>          </u>
<b>Total</b>	21,975	3,689
	<u>          </u>	<u>          </u>

In addition to the above future minimum lease payments, the Group has entered into lease agreements with respect to assets at a total value of DKK 2,021 thousand, for which the amortization profile will be determined in 2004.

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 31 December 2003, at an amount of DKK 11,269 thousand. In addition, the parent company has established a bank guarantee of DKK 9,030 thousand towards a lessor of Genmab B.V.

## Other Purchase Obligations

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

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

	<b>DKK 000</b>	<b>USD 000</b>
		<b>(Unaudited)</b>
2004	48,508	8,142
2005	1,159	195
2006	1,000	168
2007	200	34
	<b>50,867</b>	<b>8,539</b>

### License Agreements

The Group is a party to a number of license agreements which call for royalties to be paid by the Group if and when the Group commercializes products utilizing the licensed technology.

### 17. Subsequent Events

No significant events have occurred since the balance sheet date which could significantly affect the financial statements as of 31 December 2003.

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

None.

**Item 9A. Controls and Procedures**

*Evaluation of disclosure controls and procedures:* We carried out an evaluation, as of December 31, 2003, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14(c) under the Securities Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that material information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

*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, 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting

*Limitations on the Effectiveness of Controls:* Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**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 to be held on May 19, 2004, which will be filed on or before April 30, 2004, 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 to be held on May 19, 2004, which will be filed on or before April 30, 2004, 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 to be held on May 19, 2004, which will be filed on or before April 30, 2004 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 to be held on May 19, 2004, which will be filed on or before April 30, 2004, 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 to be held on May 19, 2004, which will be filed on or before April 30, 2004, and is incorporated herein by reference.

**PART IV**

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

<u>Item Number</u>	
(a).1. (a)	<p>Consolidated Financial Statements <b>Medarex, Inc.</b></p> <p>Report of Independent Auditors.</p> <p>Consolidated Balance Sheets as of December 31, 2002 and 2003.</p> <p>Consolidated Statements of Operations for the Years Ended December 31, 2001, 2002 and 2003.</p> <p>Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2001, 2002 and 2003.</p> <p>Consolidated Statements of Cash Flows for the Years Ended December 31, 2001, 2002 and 2003.</p> <p>Notes to Consolidated Financial Statements.</p>
(a).1.(b)	<p>Consolidated Financial Statements <b>Genmab A/S (A Development Stage Company)</b></p> <p>Report of Independent Auditors.</p> <p>Consolidated Balance Sheets as of December 31, 2003 and 2002.</p> <p>Consolidated Statements of Operations for the twelve months ended December 31, 2003, 2002 and 2001.</p> <p>Consolidated Statements in Shareholders' Equity for the years ended December 31, 2003, 2002 and 2001.</p> <p>Consolidated Statements of Cash Flows for the twelve months ended December 31, 2003, 2002 and 2001.</p> <p>Notes to Consolidated Financial Statements.</p>
(a).2.	<p>Financial Statement Schedules.</p> <p>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.</p>
(a).3.	<p>Exhibits.</p>
2.1(1)	<p>Certificate of Merger, dated June 15, 1989, including Plan of Merger.</p>
2.2(18)	<p>Agreement and Plan of Merger among Medarex, Inc., Medarex Acquisition Corp. and Houston Biotechnology Incorporated dated December 18, 1996, together with the exhibits thereto.</p>
2.3(28)	<p>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.</p>
3.1(56)	<p>Restated Certificate of Incorporation, as amended, of the Registrant.</p>
3.2(64)	<p>Amended and Restated By-laws of the Registrant.</p>
4.1(1)	<p>Form of Specimen of Common Stock Certificate.</p>
10.3(1)	<p>1991 Employee Stock Option Plan.</p>
10.28(1)	<p>Employment Agreement by and between the Registrant and Dr. Donald L. Drakeman, dated as of April 1, 1991, as amended.</p>
10.29(2)	<p>Employment Agreement by and between the Registrant and Dr. Donald L. Drakeman, dated January 5, 2004.</p>
10.37(3)	<p>Employment Agreement by and between the Registrant and Michael A. Appelbaum, dated as of July 29, 1991.</p>
10.51(8)	<p>1992 Employee Stock Option Plan.</p>



Edgar Filing: MEDAREX INC - Form 10-K

- 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).
- 10.57(13)\*\* Letter of Intent dated March 30, 1994 between the Registrant and E. Merck.
- 10.61(9) 1995 Stock Option Plan.

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

---

10.62(9)	Stock Purchase Agreement dated May 16, 1995 between the Registrant and Novartis, Inc.
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.
10.110(63)**	Collaboration and License Agreement, dated September 4, 2002, between the Registrant, Genpharm International, Inc. and Kirin Brewery Co., Ltd.
12.1	Computation of Ratio of Earnings to Fixed Charges.
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 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 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

---

(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.

Edgar Filing: MEDAREX INC - Form 10-K

- (3) Incorporated by reference to the identically numbered exhibit to the Registrant's Report on Form 10-K filed on February 13, 1992.
- (8) Incorporated by reference to the identically numbered exhibit to the Registrant's Annual Report on Form 10-K filed on March 15, 1993.

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

---

- (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 14, 1993.
- (11) Incorporated by reference to the identically numbered exhibit to the Registrant's Quarterly Report on Form 10-Q filed on August 16, 1993.
- (12) Incorporated by reference to the identically numbered exhibit to the Registrant's Annual Report on Form 10-K filed on February 15, 1994.
- (13) Incorporated by reference to the identically numbered exhibit to the Registrant's Registration Statement on Form S-1 (File No. 33-75324) filed on June 28, 1994.
- (18) Incorporated by reference to Exhibit 2.1 of the Registrant's Registration Statement on Form S-4 (File No. 333-20119) filed on January 22, 1997.
- (23) Incorporated by reference to Exhibit Number 10.44 to Cell Genesys, Inc.'s Annual Report on Form 10-K/A filed on May 1, 1997.
- (24) Incorporated by reference to Exhibit Number 10.45 to Cell Genesys, Inc.'s Annual Report on Form 10-K/A filed on May 1, 1997.
- (25) Incorporated by reference to Exhibit Number 10.46 to Cell Genesys, Inc.'s Annual Report on Form 10-K/A filed on May 1, 1997.
- (28) Incorporated by reference to Exhibit Number 2.1 to the Registrant's Registration Statement on Form S-4 (No. 333-29953) filed on June 25, 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.
- (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.

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

- (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.

---

\* 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 October 29, 2003 relating to the Amended and Restated License Agreement with Kyowa Hakko Kogyo Co., Ltd.

Form 8-K filed on November 12, 2003 relating to a press release of the Company's financial results for the quarter ended September 30, 2003.

---

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 15, 2004.

MEDAREX, INC.

By: /s/ DONALD L. DRAKEMAN

---

Donald L. Drakeman

*President and Chief Executive Officer*

**POWER OF ATTORNEY**

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

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

**Principal Executive Officer and Director:**

Director, President and  
Chief Executive Officer

/s/ DONALD L. DRAKEMAN

---

**Donald L. Drakeman**

Date March 15, 2004

**Principal Financial**

**and Accounting Officer**  
Senior Vice President and

Chief Financial Officer

/s/ CHRISTIAN S. SCHADE

---

Christian S. Schade

Date March 15, 2004

**Directors:**

/s/ IRWIN LERNER

---

Date March 15, 2004

**Irwin Lerner**

**Chairman of the Board**

/s/ MICHAEL A. APPELBAUM

---

Date March 15, 2004

**Michael A. Appelbaum**

/s/ FREDERICK B. CRAVES

---

Date March 15, 2004

**Frederick B. Craves**

/s/ MICHAEL W. FANGER

---

Date March 15, 2004

**Michael W. Fanger**

/s/ RONALD J. SALDARINI

---

Date March 15, 2004

**Ronald J. Saldarini**

/s/ CHARLES R. SCHALLER

---

Date March 15, 2004

**Charles R. Schaller**

/s/ W. LEIGH THOMPSON, JR.

---

Date March 15, 2004

**W. Leigh Thompson, Jr.**

/s/ JULIUS A. VIDA

---

Date March 15, 2004

**Julius A. Vida.**