MEDAREX INC
Form 10-K
March 31, 2003
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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, 2002

Commission File No. 0-19312

MEDAREX, INC.

(Exact name of registrant as specified in its charter)

New Jersey	22-2822175
(State of Incorporation)	**(I.R.S. Employer Identification No.)**
707 State Road, Princeton, New Jersey	08540
(Address of principal executive offices)	**(Zip Code)**

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

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

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

Title of Class	Name of Each Exchange on Which Registered
Common Stock ($0.01 par value)	The NASDAQ Stock Market 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 28, 2003, the registrant had outstanding 77,257,478 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 $447,971,830 as of June 28, 2002, 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 13,561,285 shares held by directors, officers and stockholders whose ownership exceeded five percent of the Registrant s outstanding Common Stock as of June 28, 2002. 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 28, 2003 (the Proxy Statement) are incorporated by reference in Parts II and III of this Report. Other documents incorporated by reference in this report are listed in the Exhibit Index.

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MEDAREX, INC.

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PART I

In this Annual Report, Medarex or the company, we, us and our refer to Medarex, Inc. and our wholly owned subsidiaries. This Annual Rep 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.

Item 1. Business

Overview

We are a biopharmaceutical company focused on the discovery and development of human antibody-based therapeutic products. Our UltiMAb Human Antibody Development System℠ enables us to rapidly create and develop therapeutic products 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 twelve antibody-based therapeutic products for sale in the United States. In 2002, these products generated aggregate worldwide sales in excess of $4.5 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℠ technology.

Ten antibodies derived from our technology are currently in human clinical trials or have had regulatory applications submitted for such trials for a wide range of diseases, such as cancer (including various lymphomas), rheumatoid arthritis, multiple sclerosis and psoriasis. Three of these products are fully owned by Medarex: MDX-010 (Phase II), MDX-060 (Phase I/II) and MDX-070 (Phase I/II IND in effect), all for the treatment of cancer or lymphoma. One antibody for autoimmune disease, MDX-018 (Phase I/II CTA approved), is being jointly developed with our partner, Genmab A/S, and two are being developed by Genmab: HuMax-CD4 (Phase II) for psoriasis and lymphoma and HuMax-IL15 (Phase II) for rheumatoid arthritis. Another partner, Immuno-Designed Molecules S.A., or IDM, is developing Osidem (Phase III) for ovarian cancer. Additionally, our licensing partners Novartis Pharma AG and Centocor, Inc. (a subsidiary of Johnson & Johnson) are developing three antibodies, for anti-inflammatory and autoimmune diseases, that are currently in early clinical trials. We and our partners also have a number of product candidates in preclinical development.

As of March 1, 2003, we have more than 40 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to enable other companies to use our proprietary technology in their development of new therapeutic products. These

companies include industry leaders such as Amgen, Inc., Centocor, Eli Lilly & Company, Human Genome Sciences, Inc., Abbott 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

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manufacturing facility in Annandale, New Jersey currently has the capacity to develop 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.

We are working 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 have implemented a business strategy involving the expansion and diversification of our product pipeline and partnerships and an increase in our resources to develop, manufacture and commercialize products. We intend to capitalize on the value of our own human antibody products by developing them through late stage clinical trials and/or regulatory approval. We believe this will allow us to retain substantial commercial rights or profit sharing opportunities with regard to these products. In addition, we are enhancing and expanding our partnerships, which provide us the opportunity to participate in the development and commercialization of substantially more product candidates than we could using only our own resources. We believe our business strategy will allow us to build and maximize value by delivering a productive clinical pipeline of medically important and commercially successful products.

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 twenty-five 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 affinities for their respective targets.

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Products in Development

We have identified a number of potentially promising monoclonal antibodies, which we are developing on our own or in collaborations with our partners. A number of therapeutic antibody product candidates generated by us and by our partners using our proprietary technology are in various stages of human clinical testing. In addition, our preclinical development pipeline includes product candidates for a variety of indications, such as oncology, autoimmune/inflammatory diseases and infectious diseases.

The following table summarizes the potential therapeutic applications and development stages for our active product candidates and those of our partners (in those cases where our partners have made specific public announcements regarding such product candidates), and is followed by brief descriptions of each specific program.

PRODUCT (Target)	INDICATION	STATUS	OWNER/LICENSEE
Medarex Product Candidates in Clinical Development			
MDX-010[1] (CTLA-4)	Melanoma	Phase II	Medarex
MDX-010 (CTLA-4)	Prostate cancer	Phase II	Medarex
MDX-010 + gp100 peptides (CTLA-4)	Melanoma	Phase II	Medarex
MDX-010 + Melacine® (CTLA-4)	Melanoma	Phase I/II	Medarex[2]
MDX-010 + melanoma peptides (CTLA-4)	Melanoma	Phase I/II	Medarex
MDX-060 (CD30)	Hodgkin s lymphoma, anaplastic large cell lymphoma	Phase I/II	Medarex
MDX-070 (PSMA)	Prostate cancer	Phase I/II[3]	Medarex
MDX-018 (undisclosed)	Autoimmune disease	Phase I[3]	Medarex, co-developing with Genmab A/S
Selected Medarex Product Candidates in Preclinical Development			
MDX-214	Cancer	Preclinical	Medarex

(EGFr/CD89)			
MDX-067 (heparanase)	Breast and other cancers	Preclinical	Medarex, co-developing with Oxford GlycoSciences plc
MDX-1307 (undisclosed)	Colon cancer	Preclinical	Medarex

[1] We expect to initiate additional Phase II clinical trials of MDX-010 in patients with breast cancer, HIV viremia and renal cell cancer, respectively, in 2003.

[2] Melacine® is a product of Corixa Corporation approved for sale in Canada.

[3] An IND is in effect for MDX-070; patient enrollment is expected to begin for Phase I/II clinical trials of MDX-070 in the second quarter of 2003. Clinical trial applications have been approved in Finland and Denmark for MDX-018; patient enrollment is expected to begin for Phase I clinical trials of MDX-018 in the second quarter of 2003.

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PRODUCT (Target)	INDICATION	STATUS	OWNER/LICENSEE
Out-Licensed Product Candidates in Development			
Osidem (IDM-1)[4] (Her2/CD64)	Ovarian cancer	Phase III	Licensed to Immuno-Designed Molecules S.A.[5] for the field of Cell Therapy
HuMax-CD4 (CD4)	Psoriasis	Phase II	Licensed to Genmab A/S in North America[5]; licensed to Eisai Co. Ltd. in Asia and Europe
HuMax-CD4 (CD4)	Lymphoma	Phase II	Licensed to Genmab A/S in North America[5]; licensed to Eisai Co. Ltd. in Asia and Europe
HuMax-IL15 (IL-15)	Rheumatoid arthritis	Phase II	Licensed to Genmab A/S[5]
CNTO148 (TNFα)	Anti-inflammatory disease	Phase I	Licensed to Centocor, Inc.
CNTO 1275 (undisclosed cytokine)	Psoriasis, multiple sclerosis	Phase I	Licensed to Centocor, Inc.
Novartis Antibody (undisclosed)	Autoimmune Disease	Phase I	Licensed to Novartis Pharma AG
HuMax-EGFR (EGFr)	Cancer	Preclinical	Licensed to Genmab A/S[5]
HuMax-CD20 (CD20)	Cancer	Preclinical	Licensed to Genmab A/S[5]

Medarex Product Candidates in Clinical Development

MDX-010 (Anti-CTLA-4 Antibody) *Melanoma; Prostate Cancer; Melanoma Vaccines.* 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 in the treatment of melanoma and prostate cancer. In January 2002, we expanded our focus and announced plans for a multi-pronged tumor vaccine clinical program employing different melanoma vaccines used in conjunction with MDX-010. Preclinical data suggests that MDX-010, when combined with certain tumor vaccines, may enhance the anti-tumor effects of such vaccines.

We are currently conducting the following trials for this product:

Melanoma; Prostate Cancer: Findings from Phase I/II clinical trials of MDX-010, begun in 2000, in patients with melanoma and prostate cancer, respectively, indicated that MDX-010 was generally well tolerated with evidence of immunologic and anti-tumor activity. Based on these results, we initiated two Phase II clinical trials of MDX-010 in October 2002 designed to assess potential anti-tumor activity, one in patients with metastatic melanoma and one in patients with hormone refractory prostate cancer, or HRPC.

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[4] Formerly referred to by us as MDX-210.

[5] We received an equity interest in this partner in exchange for a license of our proprietary antibody technology. We are not entitled to licensing, milestone or other payments from the license of this product.

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The metastatic melanoma Phase II trial is designed to study MDX-010 both as a single agent and in combination with DTIC® (dacarbazine) and is expected to initially accrue a total of 46 chemotherapy naïve patients with metastatic disease. MDX-010 is being given in a regimen of four monthly intravenous infusions of 3.0 mg/kg alone or in combination with DTIC. Patients will be followed until tumor progression and will be evaluated based on objective tumor responses.

The prostate cancer Phase II trial is designed to study MDX-010 as a single agent and in combination with Taxotere® (docetaxel) and is expected to initially accrue 40 chemotherapy naïve patients with HRPC. MDX-010 is being given in a regimen of four monthly intravenous infusions of 3.0 mg/kg alone or in combination with Taxotere. Patients will be followed until tumor progression and will be evaluated based on decreases in serum prostate specific antigen, or PSA, and tumor regression as well as time to tumor progression. An elevated PSA level is considered a marker of disease burden in prostate cancer patients.

Melanoma Vaccines: As part of our tumor vaccine program, separate clinical trials of MDX-010 in combination with three different melanoma vaccines are currently underway. A Phase II trial of MDX-010 in combination with a melanoma peptide vaccine based on gp100 is open to accrue up to 55 patients with metastatic melanoma. In this trial, patients receive MDX-010 every three weeks together with the melanoma peptide vaccine. 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. We also have completed enrollment of all 14 patients in a Phase I/II study of MDX-010 in combination with the Melacine® vaccine for melanoma.

In 2003, we expect to initiate additional Phase II clinical trials of MDX-010 in patients with ongoing HIV viremia, renal cell cancer and breast cancer, as well as a Phase I/II clinical trial of MDX-010 in combination therapy with IL-2 in patients with melanoma.

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 and anaplastic large cell lymphoma 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.

Based on our prior experience with a first generation bispecific antibody where four of 10 refractory Hodgkin s lymphoma patients achieved partial responses (including one complete remission), we are currently conducting a multi-center, multi-dose, dose-escalation Phase I/II clinical study to evaluate the fully human MDX-060 antibody in up to 40 patients with refractory or relapsed Hodgkin s lymphoma, anaplastic large cell lymphoma and other CD30-positive lymphomas. Patients receive the MDX-060 antibody weekly for four weeks and will be followed to assess disease response.

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. In December 2002, we acquired full therapeutic development and commercialization rights to MDX-070 from Northwest Biotherapeutics, Inc., superceding a previous agreement to share such rights. In January 2003, we filed an Investigational New Drug, or IND, application with the FDA to initiate Phase I/II clinical trials of MDX-070 for metastatic prostate cancer. The multi-center, 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.

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 our partner, Genmab A/S. Clinical trial applications, or CTAs, were filed in Finland and Denmark in December 2002 for use of MDX-018 in the treatment of an autoimmune disease. These applications were both approved in March, 2003. The disease and target mechanism for MDX-018 have not yet been made public.

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Selected Medarex Product Candidates in Preclinical Development:

MDX-214 (Anti-EGFr/CD89 Antibody) *Cancer.* MDX-214 is a bifunctional protein consisting of human epidermal growth factor, or EGF, linked to an 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 has the ability to direct CD89 positive effector cells to EGFr-overexpressing tumor cells, potentially facilitating the interaction of the immune system with the cancer. EGFr is a receptor molecule that has been found in excess on many tumor cells, including carcinoma of the head and neck, breast, colon, prostate, lung and ovary.

MDX-067 (Anti-heparanase I Antibody) *Breast and Other Cancers.* We are working with our partner, Oxford GlycoSciences plc, to create fully human antibody therapeutics and/or tumor vaccines based on an initial set of disease targets. The first product candidate emerging from the program is a fully human antibody that binds to and neutralizes the heparanase I enzyme, which is involved in invasion and metastasis in many tumor types, including breast cancer. Our economic interest in this product candidate may be subject to our Amended Genomics Agreement with Genmab (see the section below entitled **Strategic Investments**).

MDX-1307 *Colon Cancer and other cancers expressing ßhCG.* We are working to develop a therapeutic vaccine for the treatment of colon and other cancers by linking ßhCG, a cancer antigen, to an antibody that targets dendritic cells. The vaccine is designed to induce antibody and cytotoxic T-cell responses directed at cancer cells in patients with ßhCG-expressing tumors. The ßhCG antigen is frequently expressed in colon, pancreatic, kidney, lung and breast cancers.

Other Medarex Candidates We have an active clinical and preclinical development program, which includes a number of identified projects that we anticipate will lead to new antibodies 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.

Out-Licensed Product Candidates in Development

Osidem (IDM-1)[6,7] (Anti-Her2 & CD64 Antibody) *Ovarian Cancer.* Osidem (IDM-1), currently being developed by our partner, IDM, is a humanized, bispecific antibody-based Cell Drug for the treatment of ovarian cancer. Phase III trials for Osidem (IDM-1) targeting patients with Stage III ovarian cancer began in Europe in early 2000, and additional trials in Australia and Canada were added in 2001. In May 2002, IDM received permission from the FDA to commence Phase III trials in the United States. IDM has reported that the aim of the Phase III studies is to prolong remission of Stage III ovarian cancer after a positive response to a standard protocol consisting of surgery, followed by two chemotherapies.

HuMax-CD4 (Anti-CD4 Antibody) *Psoriasis; T-cell Lymphoma.* HuMax-CD4, being developed by our partner, Genmab[7], is 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 psoriasis and T-cell lymphomas. Genmab has reported that it is conducting the following clinical trials for this product:

Psoriasis: Genmab initiated a Phase II clinical trial of HuMax-CD4 in January 2001 for the treatment of moderate to severe psoriasis. Genmab reported that HuMax-CD4 appeared to be safe and well tolerated and that mean Psoriasis Area Severity Index, or PASI, was reduced in all treatment groups. In September 2002, Genmab reported that it initiated a Phase IIb study to evaluate the antibody in patients with moderate to

severe psoriasis. The study is expected to accrue up to 300 patients at 40 trial sites in the United States, Canada and Europe. Patients will receive one of three dose levels of HuMax-CD4 or placebo for 13 weeks and will be evaluated based on mean PASI scores.

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[6] Formerly referred to by us as MDX-210.

[7] We received an equity interest in this partner in exchange for a license of our proprietary antibody technology. We are not entitled to licensing, milestone or other payments from the license of this product.

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T-cell Lymphoma: In January 2003, Genmab reported that the FDA has approved the start of two Phase II open label studies for HuMax-CD4 in the treatment of cutaneous T-cell lymphomas, or CTCL. Both studies will run concurrently. One study will focus on refractory patients, and the other study will focus on patients with persistent early stage disease. Each study will involve an initial 12 patients who will receive a 280 mg dose of HuMax-CD4 once a week for 16 weeks. Patients will be followed for at least four weeks or until disease progression.

HuMax-IL15 (Anti-IL-15 Antibody) *Rheumatoid Arthritis.* HuMax-IL15 is a fully human antibody against Interleukin-15 (IL-15). Genmab[8] has reported that it is developing HuMax-IL15 through an agreement with Amgen, Inc. IL-15 is a cytokine, an immune system signaling molecule that appears early in the cascade of events that ultimately lead to inflammatory disease. Genmab reported that findings from a multi-dose Phase I/II trial in patients with rheumatoid arthritis indicated that HuMax-IL15 was generally well tolerated with evidence of immunologic activity. At the end of 2002, Genmab reported that a Phase II trial of HuMax-IL15 was initiated in Europe. In January 2003, Genmab reported that it received permission from the FDA to commence a Phase II trial in the United States.

CNTO 148 (Anti-TNFα Antibody)[9] *Anti-inflammatory Diseases.* Centocor has reported that it is developing CTNO 148, a high affinity, fully human antibody for anti-inflammatory diseases, including Crohn s disease and rheumatoid arthritis. Centocor has reported that Phase I trials of CTNO 148 are currently underway. The antibody product candidate was developed using our UltiMAb Human Antibody Development System. No further information has been made public regarding this antibody product candidate.

CNTO 1275 (Anti-Cytokine Antibody)[9] *Psoriasis, Multiple Sclerosis.* Centocor has reported that it is 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 and that the antibody is currently in clinical trials. The antibody product candidate was developed using our UltiMAb Human Antibody Development System. No further information has been made public regarding this antibody product candidate.

Novartis Antibody[9] *Autoimmune Disease.* Novartis has reported that it has begun Phase I clinical trials with an antibody product candidate for the treatment of an autoimmune disease. The antibody product candidate was developed using our UltiMAb Human Antibody Development System. No further information has been made public regarding this antibody product candidate.

HuMax-EGFr (Anti-EGFr Antibody) *Cancer.* Genmab[8] has reported that it is developing HuMax-EGFr, a fully human antibody targeting EGFr. EGFr is a receptor molecule that has been found in excess on many tumor cells, including carcinoma of the head and neck, breast, colon, prostate, lung and ovary. Genmab reported that 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) *Non-Hodgkin s Lymphoma.* Genmab[8] has reported that it is developing HuMax-CD20, a fully human antibody targeting CD20, a molecule found on B-cells. Genmab reported that preclinical studies have indicated that HuMax-CD20 may kill tumor cells that are resistant to rituximab.

Strategic Investments

Genmab

In March 1999, we and a group of unrelated third party investors formed Genmab, a Danish biotechnology company. Genmab was established to develop and commercialize a portfolio of fully human antibodies derived

[8] We received an equity interest in this partner in exchange for a license of our proprietary antibody technology. We are not entitled to licensing, milestone or other payments from the license of this product.

[9] We expect to receive licensing milestones as these products move through clinical trials and royalties, should commercialization occur.

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from our HuMAb-Mouse® technology. Initially, we contributed a license to our human antibody technology for producing antibodies to particular targets in exchange for approximately 44% of Genmab s share capital. During Genmab s initial 12 months of operation, Genmab raised additional equity and, in connection therewith, we agreed to expand 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 connection with a private placement in May 2000, we made an additional cash investment in Genmab thus maintaining our approximately 44% ownership interest in Genmab. In August 2000, we received additional equity in connection with the Genomics Agreement (as described below) 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 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, 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/Synthélabo and Boehringer Ingelheim, and (b) for non-multi-target (less than five targets) partnerships, to any company worldwide. We also have the right to participate in Genmab s multi-target (five or more targets) partnerships, thereby sharing in certain costs and commercial benefits (see the section below entitled *Our Joint Collaborations with Genmab*). We retain all rights to market our technology to companies headquartered outside of Europe and to all companies for non-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 alliance with Eos Biotechnology, Inc. 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 the years ended December 31, 2000, 2001 and 2002, the Company recognized $0.7 million, $2.0 million and $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 OGS, 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. 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. The first potential product candidate which may be subject to this arrangement is MDX-067, an anti-heparanase I antibody (see the section above entitled **Products in Development**). 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.

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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 31%. We currently account for our investment in Genmab under the equity method of accounting.

IDM

During the past few years, the focus of our business has 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. IDM initiated a Phase III clinical trial of MDX-210, referred to by IDM as Osidem, or IDM-1, in ovarian cancer in connection with IDM s macrophage activated killer, or MAK, cells in 2000 and received regulatory approval for additional trials in 2001. IDM also acquired certain rights to MDX-220 and MDX-447 in all fields. We originally developed MDX-447 in conjunction with Merck KGaA.

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). The Company recognized this gain as non-cash contract revenue over a two year period ending in September 2002 for financial reporting purposes (see Note 13 to the Consolidated Financial Statements). In October 2000, we participated in a private placement of equity interests in IDM and purchased additional equity of approximately $5.2 million. Our current equity position in IDM is approximately 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.

Our Human Antibody Partnering Business

As of March 1, 2003, we have more than 40 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to enable other companies to use our proprietary technology in their development and commercialization of new therapeutic 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, and as listed below, our partnerships fall into three categories: (1) collaborative partnerships in which we collaborate with partners to jointly generate, develop and commercialize human antibody products; (2) licensing partnerships in which we license our human antibody generation technology to our partners; and (3) other collaborations involving a combination of licenses and/or joint development and commercialization.

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1. Collaborative Partnerships	Date of Agreement
Oncomab, Ltd., a subsidiary of PRIMABioMed Limited	March 2003
dia Dexus, Inc.	January 2003
Eos Biotechnology, Inc.*	January 2003
Ability Biomedical Corporation	December 2002
Corixa Corporation	May 2002, June 2000
ZYCOS Inc.	January 2002
Tularik, Inc.	January 2002
Ambit Biosciences Corporation	November 2001
m-phasys GmbH	November 2001
Incyte Genomics, Inc.	October 2001
Epicyte Pharmaceuticals, Inc.	July 2001
Genmab A/S	June 2001
Sangamo BioSciences, Inc.	June 2001
deCODE genetics, Inc.	June 2001
NeuroTherapeutics, Inc.	April 2001
Northwest Biotherapeutics, Inc.	April 2001
Immusol, Inc.	February 2001
Seattle Genetics, Inc.	February 2001
Gemini Genomics plc	December 2000
Epigen, Inc.	November 2000
Oxford GlycoSciences plc	September 2000
Athersys, Inc.	August 2000
Regeneron Pharmaceuticals, Inc.	March 2000

2. Licensing Partnerships	Date of Agreement
Ferric Technologies, Inc.	January 2003
dia Dexus, Inc.	January 2003
MedImmune, Inc.	January 2003, June 2000
Amgen, Inc.	December 2002, September 1999
Schering AG	December 2002
Abbott Laboratories, Inc.	July 2002
Genesto A/S	August 2001
Human Genome Sciences, Inc.	July 2001
NovImmune, S.A.	May 2001
Schering-Plough Corporation	March 2001
Kyto Biopharma, Inc. (formerly B. Twelve, Inc.)	January 2001
Novo Nordisk A/S	January 2001
Eli Lilly & Company	January 2001, November 2000
ZymoGenetics, Inc.	October 2000
Oxford GlycoSciences plc	September 2000
Genmab A/S	August 2000, March 1999
Corixa Corporation	June 2000
Centocor, Inc. (subsidiary of J&J)	May 2000, February 1997
Raven Biotechnologies, Inc.	March 2000
Millennium Pharmaceuticals, Inc.	February 1999, January 1995
Immunex Corporation (subsidiary of Amgen)	January 1999
Novartis Pharma AG	November 1998
FibroGen, Inc.	July 1998

* Eos has announced a pending merger with Protein Design Labs, Inc., or PDL, whereby PDL would acquire 100% of the stock of Eos. According to Eos, the merger is expected to close in the first quarter of 2003, subject to governmental filings and other customary conditions.

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3. Other Collaborations	Date of Agreement
Kirin Brewery Co., Ltd.	September 2002, December 1999
Sangamo BioSciences, Inc.	January 2002
Biosite Incorporated	June 2000

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

General. Industry analysts have suggested that scientists in the fields of genomics and proteomics may eventually identify as many as 10,000 novel target antigens in the human genome. Many of these antigens may be appropriate for monoclonal antibody-based products. We are pursuing an Applied Genomics strategy in order to gain access to new target antigens as they are identified, while also sharing the risks and rewards of the related antibody development and commercialization. To this end, we have established a number of collaborations with leading companies in the fields of genomics and proteomics. We and our Applied Genomics collaborators plan to jointly develop and commercialize human antibody products. Typically, our collaborator will provide a target antigen, and we will generate 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.

Our Joint Collaborations with Genmab. Under the terms of the Genomics Agreement with Genmab, we have established multi-target joint collaborations with Genmab and each of deCODE genetics and Gemini Genomics. These collaborations are similar in structure to the collaborative partnerships discussed above, except that our interest in the collaboration is shared with Genmab. Specifically, with respect to the Genmab/Medarex 50% interest in such collaborations, we assume 100% of the economic costs and benefits associated with the development and commercialization of products intended to be sold in North America; Genmab assumes 100% of such costs and benefits for products intended to be sold in Europe; and we share such costs and benefits equally with Genmab with respect to other territories.

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 we expect will allow these partners to develop and commercialize antibody-based products using our technology. We could receive license fees, milestones 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 monoclonal antibodies to a particular target. In some cases, once a partner has obtained a commercial license for monoclonal antibodies to a given target, we can no longer license our human antibody technology to a different company for that particular target.

The financial terms of our licensing partnerships typically include license fees and a series of milestone payments commencing upon initiation of clinical trials and continuing through to commercialization. These fees and milestones may total up to $7 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.

Other Collaborations

Kirin. As contemplated by a December 1999 binding letter of intent, 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. The Collaboration and License Agreement superceded the

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binding letter of intent. Pursuant to the letter of intent, we and Kirin developed the KM-Mouse, a unique crossbred mouse which combines the traits of our HuMAb-Mouse® with Kirin s TC Mouse. Under the Collaboration and License Agreement, we are exchanging cross-licenses with Kirin with respect to the KM-Mouse and other antibody-generating mice. In addition, 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.

Biosite. In June 2000, we entered into an agreement with Biosite Incorporated aimed at accelerating drug research via Trans-Phage Technology®. This high throughput method to create fully human antibodies combines the immunological power of our human antibody technology with the speed of Biosite s Omniclonal phage display technology. Through this partnership, we believe that we and Biosite will be able to offer pharmaceutical and biotechnology companies access to large volumes of high-affinity, fully human antibodies to validate genomic targets and to identify promising drug candidates. Under the terms of the agreement, Biosite will receive research funding of $3 million per year over eight years from us, along with research fees and, if any products are generated through the partnership, milestone payments and royalties. Biosite may also receive diagnostic rights to targets identified through the partnership. We anticipate, as a result of this agreement, receiving payments from third-party partners, including milestone payments, royalties and reimbursement payments, that may partially offset the research funding being paid to Biosite. Several of our licensing partners are using Trans-Phage Technology in their efforts to create fully human antibodies.

Sangamo. In January 2002, we entered into an agreement with Sangamo BioSciences, Inc. to create cell lines with the ability to express antibodies at enhanced levels, using Sangamo s zinc finger DNA binding protein gene regulation technology platform.

Our Human Antibody Technology

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 Kirin s TC Mouse. In total these technologies constitute our UltiMAb Human Antibody Development System, and we believe they offer the broadest and most powerful set of human antibody technologies in the industry.

Our HuMAb-Mouse Technology. In these transgenic mice, the mouse genes for creating antibodies have been inactivated and 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 transchromosomic, meaning that the mouse genes for creating antibodies have been inactivated and have been 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

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produce all human antibody isotypes with an immune response we believe previously unseen in any human antibody producing mouse system.

Trans-Phage Technology. To enhance our ability to create products from genomics research, we have also coupled the UltiMAb Human Antibody Development System with Biosite s Omniclonal phage display technology. We believe the result of this combination, referred to as Trans-Phage Technology, 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.

Ultra-Potent Toxins. In May 2002, we acquired Corixa s proprietary Ultra-Potent Toxin 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 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 quickly and efficiently.

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

- *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, 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 100 to 1000 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 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.

- *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

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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 and Development 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 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, which has the capacity to develop up to 15 new antibody projects per year.

We are increasing our access to novel therapeutic targets by establishing collaborations with leading companies that have expertise in genomics and/or proteomics. We are collaborating with companies 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. We expect to enter into additional collaborations in the future. Along with our collaborative partners, we plan to share equally all costs of clinical development and will share equally in the revenues, expenses and any potential profits associated with the products that are sold commercially. 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.

Research, Development and Manufacturing Facilities

We own a research facility in Milpitas, California that currently contains an animal facility to house the HuMAb-Mice and KM-Mice, as well as research and development laboratories and office space. In 2002, we renovated and expanded this facility from approximately 57,000 square feet to approximately 60,000 square feet. We currently employ approximately 104 people at the Milpitas facility.

In July 2002, we entered into a lease for approximately 37,000 square feet of laboratory and office space in Sunnyvale, California. This facility replaces the South San Francisco facility of Corixa Corporation that was occupied by 30 employees retained in connection with our acquisition of certain assets of Corixa. We currently have approximately 40 employees working at the Sunnyvale facility.

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Our Bloomsbury, New Jersey research and development facility, purchased in 2001, 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 150 employees engaged in antibody research, development and manufacturing.

During the second quarter of 2002, we made a determination to delay indefinitely the planned construction of a large-scale manufacturing facility at our Bloomsbury location and, instead, to pursue late-stage clinical and commercial supply agreements with third party manufacturers with available capacity to meet our current internal production timetables. We are negotiating with third party manufacturers the relevant clinical and commercial supply contracts necessary for our future production requirements. As of March 1, 2003, we had not entered into any such supply agreements.

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. 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. We currently employ approximately 116 people at our Annandale facility.

Significant Partner Revenue

Revenue from partners representing 10% or more of total revenues for the years ended December 31, 2000, 2001 and 2002 is as follows:

Partner	2000	2001	2002
Genmab	11%	12%	37%
IDM	27%	48%	36%
Lilly		7%	11%
Scil	18%	4%	2%
Kirin	27%	14%	

Further information regarding revenues from partners is included in Notes 11 through 13 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.

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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 50 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 CD30 human antibody product candidate. We have been assigned patent rights from Northwest Biotherapeutics relating to aspects of our PSMA human antibody product candidate and have a non-exclusive license from Millennium Pharmaceuticals relating to aspects of our PSMA human antibody product candidate.

In addition to patent coverage for our HuMAb-Mouse technology, 17 of our patents and allowed patent applications in the United States and over 70 of our patents in foreign countries, including European countries, Japan, Korea, Canada and Australia among others, relate to aspects of our bispecific molecule technology and bispecific products. These patents have expiration dates from 2007-2018. In addition, we have more than 75 pending United States and foreign patent applications also relating to aspects of our bispecific molecule technology and bispecific products. In particular, we hold United States and European patents claiming our trigger antibody, which binds to the human CD64 molecule, as well as bispecific molecules, which incorporate the trigger antibody. We also hold exclusive and non-exclusive licenses to technologies owned by third parties relating to certain aspects of our bispecific and human monoclonal antibody technologies. For example, we hold a license from Chiron Corporation for its anti-HER-2/neu antibody used in the production of IDM-1, or Osidem, a bispecific antibody directed against the HER-2/neu receptor. We also hold a license from Polaroid Corporation covering the proprietary linking technology employed in many of our bispecific products.

In May 2002, we acquired patent rights from Corixa relating to tumor-activated prodrugs, Ultra-Potent Toxins, interferon alpha receptor and CD44.

We own registrations for the trademark Medarex® in the United States, the European Union, Canada, Australia and Switzerland, and the marks HuMAb-Mouse®, GenPharm®, Trans-Phage Technology® and Putting the Immune System to Work® in the United States. HuMAb-Mouse is also registered in the European Union. We have filed applications for registration of the marks KM-Mouse, UltiMAb℠ and UltiMAb Human Antibody Development System℠ in the United States, Canada and the European Union. These applications are pending.

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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 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 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 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:

- preclinical laboratory and animal tests and analysis;
- 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, 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.

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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.

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 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 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 is regulated as a biologic, such as antibodies, 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 monoclonal antibodies, cytokines, growth factors, enzymes, interferons and certain proteins. The FDA Center for Biologics Evaluation and Research, or CBER, has responsibility for other biologics. 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 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

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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% percent of the user fee as a penalty. The FDA has established performance goals for the review of NDAs and BLAs six months for priority applications and 10 months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an action letter that describes additional work that must be done before the application can be approved. The FDA s review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, 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.

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.

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Other U.S. Regulatory Requirements.

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, 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.

Medarex and Partner Products.

Currently, a number of products employing our antibody technology have entered into clinical trials. We are conducting Phase II clinical trials of MDX-010 for the treatment of prostate cancer and malignant melanoma and for use with one melanoma vaccine. We are also conducting Phase I/II clinical trials of MDX-010 for use with two additional melanoma vaccines. We are conducting Phase I/II clinical trials of MDX-060 for the treatment of Hodgkin s lymphoma and anaplastic large cell lymphoma and have made regulatory filings for clinical trials of MDX-070 and MDX-018 for the treatment of prostate cancer and autoimmune disease, respectively.

Osidem (IDM-1), which is being developed by IDM, has entered into Phase III clinical trials for the treatment of ovarian cancer. HuMax-CD4, which is being developed by Genmab, has entered into Phase II trials for the treatment of psoriasis and for the treatment of lymphoma. HuMax-IL15, also being developed by Genmab, has entered into Phase II clinical trials for the treatment of rheumatoid arthritis. Centocor is developing two antibody products, one for the treatment of inflammation (CNTO 148) and psoriasis and one for the treatment of multiple sclerosis (CNTO 1275). These products are in Phase I clinical trials. Novartis is developing an antibody product for the treatment of autoimmune

disease that is in Phase I clinical trials. To date, no products employing our human antibody technology have been approved by the FDA for sale.

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.

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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 monoclonal antibodies and related fields. Many of these companies have commenced clinical trials 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 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, that, according to Abgenix, is capable of generating 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 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 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. have developed technology that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies in functionally modified mice. Several companies are developing, or have developed, technologies, not involving animal immunization, that result in libraries composed of numerous human antibody sequences. For example, phage and yeast display technology is being used by companies such as Abbott Laboratories, Inc., 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, IDEC Pharmaceuticals Corporation, Novartis, Genentech, Inc., PDL and Wyeth have generated therapeutic products that are currently on the market and are derived from recombinant DNA that comprise human antibody components. Numerous additional companies are developing therapeutic products comprising human antibody components.

We are aware of several pharmaceutical and biotechnology companies which are actively engaged in research and development in areas related to antibody therapy, that have commenced clinical trials of antibody products or have successfully commercialized antibody products. Some of these companies, such as ImClone Systems Incorporated, Johnson & Johnson, Wyeth, Amgen, Abbott, Cell Tech Group plc, IDEC Pharmaceuticals, Abgenix, CAT, MorphoSys AG, Tanox, Inc., Genentech, Millennium and PDL are addressing diseases and disease indications that are being targeted by us and our partners. 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 products, undertaking preclinical testing and human clinical trials, obtaining FDA and other regulatory approvals of products and manufacturing and marketing 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 isotypes 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, erythropoeitin, 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.

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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, 2002, we employed 431 persons, of whom 137 hold advanced degrees. Approximately 340 employees are engaged in research and development activities. There are 91 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.

Research and Development

Research and development expenses are largely comprised of (i) personnel costs, (ii) those expenses related to facilities for our clinical research, development and clinical trial manufacturing efforts, (iii) third party research costs, (iv) supply costs and (v) license and technology access fees. Our total research and development costs from inception to date are $242.2 million. We have incurred research and development expenses for our products in development of $33.9 million, $38.6 million and $82.6 million for the years ended December 31, 2000, 2001 and 2002, respectively. We expect research and development expenses to increase in the future as we continue to develop our therapeutic product pipeline.

Available Information

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

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read or copy any materials we file with the SEC at the SEC s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

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. You can direct requests for literature to the information request section on our website.

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RISK FACTORS

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. Forward-looking statements include, without limitation, statements in Risk Factors, 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 in Risk Factors 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.

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Product candidates employing our human antibody technology are in the early stages of development. Only a limited number of fully human antibody product candidates employing our human antibody technology have been generated by us or pursuant to our partnerships. Investigational New Drug Applications, or INDs, have been submitted to the United States Food and Drug Administration, or FDA, for only a subset of these candidates, and clinical trials have not yet commenced for all of these candidates. 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 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.

Our products are still under development, and no revenues have been generated from their sale.

We have entered into partnerships with a number of companies and are seeking additional alliances that will support the costs of developing our portfolio of antibody-based product candidates. The success of these product candidates is dependent upon the efforts of our partners in developing these product candidates in the future. Neither we nor our partners know if any of these product candidates will be effective. To date, no products employing our human antibody technology have been approved for sale by the FDA.

Successful development of our products is uncertain.

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;

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- 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.

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 is 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. 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 decided, in consultation with our partners, to discontinue our clinical development programs for MDX-33 and MDX-44, respectively. MDX-33 is a humanized antibody targeting CD64 that is designed for the treatment of ideopathic thrombocytopenia purpura, or ITP. MDX-44 is a humanized antibody targeting CD64 that has been studied in connection with atopic dermatitis.

We have incurred large operating losses and these losses may continue.

We have incurred large operating losses and these losses may continue. In particular, as of December 31, 2002, we had an accumulated deficit of approximately $283.6 million. Our losses have resulted principally from:

- research and development costs relating to the development of our technology and antibody product candidates;
- costs associated with the establishment of our 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.

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.

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Our operating results may vary significantly from period-to-period.

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 preclinical testing and clinical trials;
- changes in regulatory requirements for clinical trials;
- costs and expenses associated with preclinical testing and clinical trials;
- the timing of regulatory approvals, if any;
- sales and marketing expenses; and
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business operations and facilities.

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

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

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

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

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

We believe our current sources of liquidity will be sufficient to meet our near term operating, debt service and capital requirements. However, we may require additional financing within this time frame, and we cannot make assurances 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.

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 convertible debt and debt service obligations, which, unless converted to shares of our common stock, will mature in 2006. We may be unable to generate sufficient cash flow or

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otherwise obtain funds necessary to make required payments on our debt. 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, the company 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. 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

- 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. 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, and our business, financial condition and results of operations may be materially harmed.

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

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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 recently announced that it is 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 monoclonal 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 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. These types of activities have been the subject of controversy and adverse publicity. Animal rights groups and various other organizations and individuals have attempted to stop genetic engineering activities and animal testing by lobbying for legislation and regulation in these areas.

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.

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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 have limited manufacturing capabilities.

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. 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 any of these companies 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 have no sales or marketing experience.

We currently have no sales, marketing or distribution capabilities. We may need to enter into arrangements with third parties to market and sell certain of our products. We may not be able to enter into marketing and sales arrangements with others on acceptable terms, if at all. To the extent that we enter into marketing and sales

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arrangements with other companies, our revenues, if any, will depend on the efforts of others. These efforts may not be successful. We may choose to market some of our products directly through a sales and marketing force. In order to do this, we will have to develop a sales and marketing staff and establish distribution capability. Developing a sales and marketing force would be expensive and time-consuming and could delay any product launch. If we choose to market any of our products directly but are unable to successfully implement a marketing and sales force, our business, financial condition and results of operations may be materially harmed.

We are, in part, dependent on our partners to support our business and to develop products generated using our human antibody technology.

We depend on our partners to support our business and to develop 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.

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, 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 may be harmed.

Our licensing partners generally have the right to terminate our partnerships at any time. 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

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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.

Our goals and/or strategy may conflict with those of our partners.

We may have goals and/or strategies that may conflict with those of our partners that could adversely affect our business. For example, our partners may pursue alternative technologies, including those of our competitors. Disputes may arise with respect to the ownership of rights to any technology or products developed with any partner. If our partners pursue alternative technologies or fail to develop or commercialize successfully any product candidate to which they have obtained rights from us, our business, financial condition and results of operations may be materially harmed.

We have a significant minority interest in two entities. There may be conflicts of interest between us and these entities.

We currently have an equity interest of approximately 31% in Genmab, which intends to develop and commercialize a portfolio of fully human antibodies generated through the use of our human antibody technology. In addition, we have an equity position in IDM of approximately 9%, which intends to develop and commercialize antibodies generated through the use of our technology. 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 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.

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, 2000, 2001 and 2002, our share of Genmab s losses were approximately $0.4 million, $7.3 million and $19.6 million, respectively. Genmab has publicly stated that it anticipates that it will incur substantial losses as it expands its research and product development efforts. As Genmab s losses continue to increase, the aggregate amount of such losses we must include in our consolidated financial statements will also increase.

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, Inc., Oxford GlycoSciences Plc, Seattle Genetics, Inc. and Tularik, Inc., and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. As these investments are the result of strategic alliances with our collaborative partners, we typically do not attempt to reduce or eliminate our market exposure of these types of strategic investments. Under

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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 have recorded impairment charges of approximately $40.5 million (of which approximately $31.0 million relates to Genmab) on our strategic investments. 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 and Eos. 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 year ended December 31, 2002, we have recorded impairment charges of approximately $2.4 million 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, Ph.D., our President and Chief Executive Officer, and Nils Lonberg, Ph.D., our Senior Vice President and Scientific Director. 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, marketing 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:

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

- apply for, obtain, protect and enforce patents.

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.

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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.

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property disputes are costly and time-consuming to pursue and their outcomes are uncertain.

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, either 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 owned by third parties that pertain to monoclonal antibodies against CTLA-4 and their uses. We are also aware of certain United States and foreign

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patents held by third parties relating to anti-CD4 antibodies, anti-EGFr antibodies, anti-PSMA antibodies, and anti-heparanase antibodies.

We are also aware of a United States patent owned by Genentech relating to the production of recombinant antibodies in host cells. We currently produce certain of our products and our partners products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in this patent, then we may need to obtain a license, should one be available. 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 which 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 which, 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 recombinant 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 are not the exclusive owner of the technology underlying our HuMAb-Mice. 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 and GenPharm a total of approximately $38.6 million during 1997 and 1998. This payment was 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 or if any of these entities breach the cross-license and settlement agreement.

We are not the exclusive owner of the technology underlying the KM Mouse. Effective September 4, 2002, we entered into a collaboration and license agreement with Kirin superceding the letter of intent entered into by us with Kirin in December 1999. Under this agreement, we and Kirin have exchanged certain cross-licenses for each other s technology for the development and commercialization of human antibody products made using the HuMAb Mouse, the Kirin mice (TC Mouse and HAC Mouse) and the KM Mouse. 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 may 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

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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 currently maintain liability insurance with specified coverage limits. 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. 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. As a result of these or other SAEs, we have received a small number of claims, of which five have 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. Any such claims against us, regardless of their merit, could result in significant awards against us which could materially harm our business, financial condition and results of operations.

We face intense competition and rapid technological change.

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

We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapeutics. Some of these companies have commenced clinical trials of antibody products or have successfully commercialized antibody products. Many of these companies are addressing the same diseases and disease indications as we and our partners. Also, we compete with companies that offer antibody generation services to companies that have disease related target antigens. These competitors have specific expertise or technology related to 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 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 Abbott Laboratories, Inc., 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, IDEC Pharmaceuticals Corporation, Novartis, Genentech, Inc., Protein Design Labs, Inc. and Wyeth 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 isotypes 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, erythropoeitin, 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.

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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. These competitors, either alone or with their partners, may succeed in developing technologies or products that are more effective than ours.

We are subject to extensive and costly government regulation.

Product candidates employing our human antibody technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, 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 Services 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 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 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 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.

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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 to any foreign

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

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

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

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to FDA s current good manufacturing practice requirements. Application holders must obtain FDA approval for product and manufacturing 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

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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.

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 is 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.

If our license agreements violate the competition provisions of the Treaty of Rome, then some terms of our key agreements may be unenforceable.

Certain license agreements that we have entered into or may enter into will grant or may grant exclusive worldwide licenses of patents, patent applications and know-how, which are or may be arguably restrictive of competition under Article 81(1) of the Treaty of Rome. Article 81(1) prohibits agreements which restrict competition within the European Community and affect trade between member states. We determine on an agreement-by-agreement basis whether or not an exemption from the application of Article 81(1) applies to the agreement and, if it does not, whether to apply to the European Commission for an individual exemption from the application of Article 81(1). If an exemption is not applicable and we do not apply for, or are unsuccessful in obtaining, an exemption from the European Commission, provisions of any license agreement which are found to be restrictive of competition under Article 81(1), including those relating to the exclusivity of rights, may be unenforceable and we could lose the benefit of the rights granted under the provisions.

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.

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.

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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 December 31, 2002, we have 9,935,072 shares of common stock reserved for issuance pursuant to options which have been granted under our stock option plans having a weighted average exercise price of $13.64 per share. We have filed registration statements on Form S-8 covering those 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 are 761,552 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.

In addition, as of December 31, 2002, we have reserved 2,030,259 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 those shares. We have reserved 353,018 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 those shares. Shares issued under our plans, other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirement 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, 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 December 31, 2002, we had 6,067,961 shares of common stock reserved for issuance pursuant to the conversion of $175.0 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 million principal amount of notes, subject to adjustment.

Pursuant to our license agreement with Novartis, Novartis may purchase $2 million of our common stock at a price equal to 110% of the average of the closing sales prices of our common stock on Nasdaq, on the twenty consecutive days prior to the fifth anniversary (December 2003) of the agreement. Additionally, on the sixth anniversary (December 2004) of the agreement, Novartis may purchase $1 million of our common stock at a price equal to 110% of the average of the closing sales prices of such stock on the Nasdaq on the twenty consecutive days prior to such anniversary.

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

As of December 31, 2002, we have 76,929,984 shares of common stock outstanding, of which 2,017,860 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.

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In addition, we have filed a shelf registration statement on Form S-3 under the Securities Act relating to the sale of up to $303.25 million of any of the following securities:

- Debt Securities;
- Preferred Stock;
- Common Stock; or
- Warrants to Purchase Debt Securities, Preferred Stock or Common Stock.

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

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our outstanding 4.50% Convertible Subordinated Notes due 2006. As of December 31, 2002, $175.0 million aggregate principal amount of the notes was outstanding. We may pay the repurchase price in cash or, at our option, in common stock. Such repurchase right 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.

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 restated certificate of incorporation and by-laws and New Jersey law may discourage third parties from acquiring control of our company.

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

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

Item 2. Properties

We lease approximately 45,000 square feet of laboratory, clinical trial production and office space in Annandale, New Jersey. The term of the lease expires on September 30, 2008. We believe that this facility is well suited for clinical-grade production of monoclonal antibodies, since we have in place most utilities required for clinical-grade production of such antibodies, including a production unit designed to meet cGMP standards. This facility was renovated during the second quarter of 2002 and has a capacity to develop up to 15 new antibody projects per year. We believe that our existing 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.

In early 2001, we purchased a facility and adjacent land in Bloomsbury, New Jersey to expand our research and development capabilities. The Bloomsbury facility is situated on approximately 106 acres of land and currently contains space for approximately 165,000 square feet of laboratory and office space. The cost of the Bloomsbury facility including land and building was $9.2 million.

On November 3, 2000, we acquired the Milpitas, California facility for approximately $14.6 million. We had previously leased this facility. This space includes an animal facility to house our HuMAb-Mouse, research and development laboratories and administrative offices. This property currently contains approximately 60,000 square feet of laboratory and office space.

In July 2002, we entered into a lease for approximately 37,000 square feet of laboratory and office space in Sunnyvale, California. This facility replaces the South San Francisco facility of Corixa that was occupied by 30 employees we retained in connection with our acquisition of certain assets of Corixa.

We also lease approximately 20,000 square feet of office space in Princeton, New Jersey for our corporate headquarters and approximately 11,000 square feet in Clinton, New Jersey for our clinical operations group. The combined minimum annual lease commitments for our facilities in 2003 is approximately $3.7 million, and the aggregate future minimum lease commitments over the remainder of the lease terms are approximately $17.8 million.

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, 2002 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 listed on the Nasdaq National Market under the symbol MEDX. The following table sets forth the high and low sale prices per share of our common stock, as reported on the Nasdaq National Market, during the periods indicated.

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	Common Stock Price	
	High	Low
Year ended December 31, 2001		
First Quarter	$ 42.50	$ 12.06
Second Quarter	$ 32.25	$ 11.75
Third Quarter	$ 24.47	$ 11.91
Fourth Quarter	$ 25.05	$ 14.25
Year ended December 31, 2002		
First Quarter	$ 18.34	$ 13.31
Second Quarter	$ 16.83	$ 6.71
Third Quarter	$ 9.00	$ 3.26
Fourth Quarter	$ 5.35	$ 2.55

The number of shares of our common stock outstanding as of February 28, 2003 was 77,257,478. As of April 5, 2002, the record date for our last annual meeting of shareholders held on May 22, 2002, there were approximately 698 record holders of common stock (which includes individual holders) and approximately 23,678 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 to be held on May 28, 2003, which will be filed on or before April 30, 2003, and is incorporated herein by reference.

Item 6. Selected Consolidated Financial Data

	For the Year Ended December 31,				
	1998	1999	2000	2001	2002
Statement of Operations Data:	(Dollars in thousands, except per share data)				
Revenues:					
Sales	$ 1,349	$ 1,079	$ 264	$ 191	$ 176
Contract and license revenues	5,443	8,593	19,619	37,140	24,552
Sales, contract and license revenues from Genmab		252	2,574	4,973	14,751
Total revenues	6,792	9,924	22,457	42,304	39,479
Costs and expenses:					
Cost of sales	1,218	709	1,189	642	8,327

Research and development	23,122	19,929	33,942	38,626	82,626
General and administrative	5,065	8,036	18,142	19,344	22,852
Write-off of facility costs					11,294
Acquisition of in-process technology					16,312
Total costs and expenses	29,405	28,674	53,273	58,612	141,411
Operating loss	(22,613)	(18,750)	(30,816)	(16,308)	(101,932)
Equity in net loss of affiliate			(353)	(7,334)	(50,625)
Interest and dividend income	1,956	1,205	21,158	24,728	18,495
Impairment loss on investments in partners					(11,886)
Additional payments related to asset acquisition					(2,425)
Interest expense	(1,539)	(8)	(3)	(4,615)	(9,065)
Gain on disposition of Genmab stock				1,442	
Loss before provision (benefit) for income taxes	(22,196)	(17,553)	(10,014)	(2,087)	(157,438)
Provision (benefit) for income taxes	341	(522)	(13,075)	600	103
Net income (loss)	$ (22,537)	$ (17,031)	$ 3,061	$ (2,687)	$ (157,541)
Basic net income (loss) per share (1)	$ (0.44)	$ (0.27)	$ 0.04	$ (0.04)	$ (2.09)
Diluted net income (loss) per share (1)	$ (0.44)	$ (0.27)	$ 0.04	$ (0.04)	$ (2.09)
Weighted average common shares outstanding (1)					
basic	50,780	63,840	71,532	73,937	75,231
diluted	50,780	63,840	73,232	73,937	75,231

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	December 31,				
	1998	1999	2000	2001	2002
Balance Sheet Data:	(Dollars in thousands)				
Cash, cash equivalents and marketable securities	$ 34,664	$ 30,147	$ 343,603	$ 466,952	$ 350,046
Working capital	29,581	22,382	329,807	447,326	339,480
Total assets	42,235	40,482	558,107	720,427	549,051
Long term obligations	62	23		175,000	175,000
Cash dividends declared per common share					
Accumulated deficit	(109,405)	(126,436)	(123,375)	(126,062)	(283,603)
Total shareholders equity	35,229	22,299	485,289	482,562	352,143

(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

The following discussion should be read together with our consolidated financial statements and the accompanying notes included elsewhere in this Annual Report and contains trend analysis and other forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from those expressed or implied in these forward-looking statements as a result of various factors.

Overview

We are a biopharmaceutical company focused on the discovery and development of human antibody-based therapeutic products using our proprietary technology platform, the UltiMAb Human Antibody Development System[SM]. This unique combination of human antibody technologies enables us to rapidly create and develop high affinity, fully human antibodies to a wide range of diseases, including cancer, inflammation, auto-immune disease and other life-threatening and debilitating diseases.

Through our 1997 acquisition of GenPharm International, Inc. and our collaboration with Kirin Brewery Co. Ltd., we expanded our business to include both our HuMAb-Mouse® and Kirin s TC Mouse technologies. In December 2000 we unveiled the KM-Mouse, a unique crossbred mouse developed in partnership with Kirin, as the newest addition to our UltiMAb Human Antibody Development System. With the UltiMAb[SM] platform, we have assembled a unique family of human antibody technologies for creating the entire spectrum of high-affinity, fully human antibodies. We intend to leverage our product development capabilities with those of our partners, while also gaining access to novel therapeutic targets and complementary development, sales and marketing infrastructures. As of March 1, 2003, we have over 40 partnerships with pharmaceutical and biotechnology companies, including industry leaders such as Amgen, Inc., Centocor, Inc. (a subsidiary of Johnson & Johnson), Eli Lilly & Company, Human Genome Sciences, Inc., Abbott Laboratories, Inc., Novartis Pharma AG, Novo Nordisk A/S, and Schering AG, to jointly develop and commercialize products or enable other companies to use our proprietary technology in their development and commercialization of new therapeutic products. 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.

Our licensing partners typically obtain licenses to one or more of our antibody generating technologies which we expect will allow these partners to develop and commercialize antibody-based products using our technology. We could receive license fees, milestones and royalties in connection with each of these products. Under these licenses, there is usually an initial period during which our partners may elect to enter into a research license for antibodies to a particular designated target. Subsequently, our partners may elect to obtain a commercial license for monoclonal antibodies to a particular target.

We are also pursuing an Applied Genomics strategy in order to gain access to new target antigens as they are identified, while also sharing the risks and rewards of the related antibody development and commercialization. To this end, we have established a number of collaborative partnerships with leading

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companies in the fields of genomics and proteomics to jointly develop and commercialize human antibody products. Typically, our partner will provide a target antigen, and we will generate antibodies against that antigen using our UltiMAb Human Antibody Development System. We and our partners 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.

Revenue Our revenue is principally derived through licensing our human antibody technology to pharmaceutical and biotechnology companies. The terms of these agreements typically include potential license fees and a series of potential milestone payments commencing upon 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 royalties on product sales. Additional revenue is earned from the sales to and, in some cases, manufacturing of antibodies for corporate partners and from government grants.

Research and Development Expenses Research and development expenses consist primarily of compensation expense, facilities, preclinical and clinical trials and supply expense relating to antibody product development and to the breeding, caring for and continued development of each of the HuMAb-Mouse and KM-Mouse, as well as to the performance of contract services for our collaborative partners.

General and Administrative Expenses General and administrative expenses consist primarily of compensation, facility, travel, legal fees and other expenses relating to our general management, financial, administrative and business development activities.

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 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

Historically, a significant portion of our revenue has been recognized pursuant to collaboration and license agreements with our partners. Revenue related to collaborative research with our partners is recognized as earned based upon the performance requirements of each agreement. Deferred revenue may result when we do not expend the required level of effort during a specific period in comparison to funds received under the respective agreements or when funds received are refundable under certain circumstances. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements and when collectibility of such milestone payment is assured. Non-refundable upfront payments received in connection with our collaborative partnerships are deferred and recognized as revenue on a straight-line basis over the period we are obligated to perform services related to each of the respective agreements.

Investments

All 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

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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 period in light of the facts and circumstances surrounding the investments.

In addition, in connection with our collaborative partnering business, we make strategic investments in the securities of companies that are privately held. These securities are carried at original investment cost. Because these securities are not listed on a financial exchange, 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 operating results of underlying investments that may not be reflected in an investment s current carrying value may also require an impairment charge in the future.

Valuation of Long-Lived and Intangible Assets

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

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

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

Acquired In-Process Technology

In-Process Technology expense 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

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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. A valuation for our acquisition of assets from Corixa Corporation was completed by an independent third-party.

Results of Operations

Years Ended December 31, 2000, 2001 and 2002

Revenues for 2000, 2001 and 2002 were principally derived from our contract and licensing activities. Total revenue for 2000 of $22.5 million included contract and license revenues of $6.0 million from Kirin, $6.0 million from IDM and $4.0 million from Scil Biomedicals. Total revenue for 2001 of $42.3 million increased by $19.8 million, or 88% over 2000. The increase relates principally to an increase of $14.3 million of contract and license revenues from IDM and an increase of $2.4 million of sales, contract and license revenues from Genmab. Total revenue for 2002 of $39.5 million decreased by $2.8 million, a 7% decrease compared to 2001. The decrease relates principally to a decrease of contract and license revenues of $6.0 million from Kirin and $5.6 million from IDM partially offset by an increase of $9.8 million of sales, contract and license revenues from Genmab. As a result of Genmab s announced decision to wind down its anti-CD4 program for rheumatoid arthritis, we anticipate that sales of MDX-CD4 (and corresponding cost of sales) will be significantly lower in the future. In addition, we expect contract and license revenues to be lower in the future as a result of the completion in September 2002 of the revenue recognition associated with the transfer of technology to IDM in July 2000.

Our cost of sales of $1.2 million in 2000 was due to higher production of MDX-CD4 that was sold to Genmab. Cost of sales were $0.6 million in 2001, a decrease of $0.6 million, or a 46% decrease compared to 2000 despite comparable sales. The decrease primarily reflects a lower unit production cost of MDX-CD4. Cost of sales were $8.3 million in 2002, an increase of $7.7 million, or 1,197% over 2001. The increase primarily reflects the production cost of MDX-CD4 that was sold to Genmab in 2002.

Research and development expenses are largely comprised of (i) personnel costs, (ii) those expenses related to facilities for our clinical research, development and clinical trial manufacturing efforts, (iii) third party research costs, (iv) supply costs and (v) license and technology access fees. Our total research and development costs from inception to date are $242.2 million. We have incurred research and development expenses for our products in development of $33.9 million, $38.6 million and $82.6 million for the years ended December 31, 2000, 2001 and 2002, respectively. Research and development expenses in 2001 were $38.6 million, an increase of $4.7 million, or 14% over 2000. Research and development expenses in 2002 were $82.6 million an increase of $44.0 million, or 114% over 2001. The increases relate primarily to costs associated with the following:

- Personnel costs in 2001 were $14.3 million, an increase of $5.1 million or 55% over 2000. Personnel costs in 2002 were $28.3 million, an increase of $14.0 million or 98% over 2001. The increase in staff is to support higher levels of product development and clinical trial manufacturing activities, the continued development of our UltiMAb system, as well as the performance of contract services for our collaborative partners and clinical activities. Included in the increase are 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 in clinical trials.

- Facility costs in 2001 were $8.0 million, an increase of $4.3 million or 99% over 2000. Facility costs in 2002 were $16.0 million, an increase of $8.0 million or 100% over 2001. The increase in facility costs primarily relates to the substantial investments made in our three research and development facilities during 2001 and 2002. As a result, depreciation, utilities, maintenance, property taxes and related expenses increased for each of the years ended December 31, 2001 and 2002, 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 reduced rate.

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- Research supply costs in 2001 were $7.1 million, an increase of $4.0 million or 127% over 2000. Research supply costs in 2002 were $14.7 million, and increase of $7.6 million or 106% over 2001. Included in these costs are materials and small equipment associated with the development of our products. We expect these costs to increase as we continue to expand our research and product development activities.

- Outside funding of research in 2001 was a credit of $1.2 million, a decrease of $8.3 million, or a 117% decrease compared to 2000. Outside funding of research in 2002 was $4.4 million, an increase of $5.6 million or 470% over 2001. During 2000, we made a $5.0 million upfront payment to Eos Biotechnology, under our binding letter of intent. The 2001 decrease was principally due to the April 2001 refund of this $5.0 million fee by Eos as part of a restructuring of that collaboration and this resulted in a credit balance in outside funding of research in 2001. Excluding the 2001 refund, the 2002 and 2001 periods were comparable. Outside funding of research expenses include funds paid to certain partners for research services. We expect outside funding of research expenses, including funds paid to certain partners for research services, to increase in the future.

- License and technology access fees in 2001 were $2.2 million, an increase of $2.1 million or 3,382% over 2000. License and technology access fees in 2002 were $7.2 million, an increase of $5.0 million or 234% over 2001. These costs represent fees paid to partner and research organizations in connection with our collaboration and license agreements. Included in the 2002 cost are payments to Northwest Biotherapeutics, Tularik and Millennium Pharmaceuticals. We expect license fees, including funds paid to certain partners, to increase in the future.

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

General and administrative expenses in 2001 were $19.3 million, an increase of $1.2 million, or 7% as compared to general and administrative expenses of $18.1 million in 2000. The increase is primarily attributable to an increase in personnel costs, as well as higher legal and travel costs incurred in connection with the expansion of our business activities. The increase was partially offset by lower consulting and shareholder relation expenses. General and administrative expenses in 2002 were $22.9 million, an increase of $3.5 million, or 18% over 2001. The 2002 increase is primarily attributable to higher personnel costs of $0.7 million, depreciation expense of $0.7 million, insurance expense of $0.5 million and legal fees of $0.5 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 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. We are in negotiation with third party manufacturers for clinical and commercial supply agreements. As of March 1, 2003, we had not entered into any such supply agreements. 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. Furthermore, we have expanded our existing clinical manufacturing capacity in our Annandale, New Jersey facility, which we expect will meet all near-term production demands.

Acquisition of in-process technology relates to our acquisition of certain assets of Corixa in May 2002. The total cost of the acquisition (including transaction costs), discussed more fully under the section herein entitled

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Liquidity and Capital Resources, was $21.4 million. Based upon an independent third party valuation, $16.3 million of this amount was charged to operations as acquisition of in-process technology in 2002.

Equity in net loss of affiliate of $0.4 million in 2000 reflects our share of Genmab s loss for the year ended December 31, 2000. Equity in net loss of affiliate in 2001 was $7.3 million, an increase of $6.9 million over 2000. The increased loss reflects our share of Genmab s loss for the full year. This loss is primarily the result of Genmab s increased activity in research and development and expansion of its business. Genmab is an affiliated company and is accounted for using the equity method (see Note 12 to the Consolidated Financial Statements). Equity in net loss of affiliate in 2002 was $50.6 million, an increase of $43.3 million or 590% over 2001. Included in the 2002 equity in net loss of affiliate is in an impairment loss on our investment in Genmab of $31.0 million resulting from an approximate 60% decrease in the market value of Genmab 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 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. 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 this investment 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 Genmab s expanded research and development efforts. We expect Genmab s net loss to increase in 2003 due to their stated intention to make additional investments in research and development costs to develop its product pipeline. The recognition of our equity in Genmab s net losses reduces the carrying value (basis) of our investment in Genmab.

Interest and dividend income in 2001 was $24.7 million, an increase of $3.6 million, or 17% as compared to 2000 interest and dividend income of $21.2 million. The increase reflects interest earned on higher average cash balances as the result of proceeds received from the June 26, 2001 public offering of our 4.50% convertible subordinated notes due in 2006. Interest and dividend income in 2002 was $18.5 million, a decrease of $6.2 million, or a 25% decrease compared to 2001. The decrease reflects lower interest income due to lower average cash balances in 2002 as we funded our operations and capital expenditures from our cash reserves. We anticipate lower investment income in the future as we continue to liquidate our investments to fund our operations and capital expenditures.

Impairment loss on investments in partners of $11.9 million during 2002 represents a write-down of the value of our investments in certain of our partners (both publicly and privately held). During 2002, the decline in the value of these investments was determined to be other than temporary. If we deem these investments to be further impaired at the end of any future period, we may incur additional impairment charges on these investments.

Additional payments related to asset acquisition of $2.4 million during 2002 represents additional payments to Northwest Biotherapeutics, Millennium Pharmaceuticals and Corixa Corporation. Pursuant to the terms of these agreements, under certain circumstances we were 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 in 2001 was $4.6 million, an increase of $4.6 million over 2000. This increase reflects accrued interest for approximately six months on the 4.50% convertible subordinated notes issued on June 26, 2001 and due in 2006. Interest expense in 2002 was $9.1 million, an increase of $4.5 million, or 96% over 2001. This increase reflects a full year of interest expense incurred on our 4.50% convertible subordinate notes. Interest is payable on January 1 and July 1 of each year.

Our benefit for income taxes for the year ended December 31, 2000 of $13.1 million was partially due to our recording of an increased basis of Genmab s assets from its initial public offering in October 2000. It consisted

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of $20.3 million of deferred tax benefit and $0.9 million from the sale of New Jersey state NOLs, offset, in part, by provisions for federal and state taxes and by current and deferred foreign withholding tax expense. The deferred tax benefit related to deferred tax assets for which no valuation allowance was necessary because an equivalent amount of deferred tax liability was established, related to an unrealized gain included in comprehensive income. The tax benefit is principally derived from our portion of the increase in the book value of the assets of Genmab resulting from the proceeds Genmab received upon completion of its initial public offering in October 2000. The current federal and state tax provisions for the year ended December 31, 2000 resulted from revenue that is deferred for financial reporting purposes but not for tax reporting purposes, and from limitation of the available federal NOLs. After tax deductions related to exercises of stock options, no current federal or state taxes were payable at December 31, 2000. Applicable accounting rules require recognition of tax benefits associated with these deductions through adjustment to additional paid-in capital rather than through current tax expense. Our tax expense for the year ended December 31, 2001 of $0.6 million was the result of deferred foreign tax assets reversing in 2001. The $0.1 million of tax expense for the year ended December 31, 2002 relates to the New Jersey alternative minimum tax assessment which became effective in 2002.

We do not believe that inflation has had a material impact on our results of operations.

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 note issue. 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 2000, 2001 and 2002, we received net proceeds of $570.7 million from sales of our equity and debt securities.

At December 31, 2001 and 2002, we had $467.0 million and $350.0 million, respectively, in cash, cash equivalents and marketable securities. We 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. Operating activities consumed $14.4 million, $7.7 million, and $64.0 million of cash for the years ended December 31, 2000, 2001 and 2002, respectively. The increase in cash used in operating activities in 2002 relates primarily to the significant increase in research and development and manufacturing (i.e. cost of goods sold) expense. In 2002, total research and development expense of $82.6 million increased by $44.0 million as compared to 2001. The increase in research and development expense results from higher personnel costs, those expenses related to facilities for our clinical research, development and manufacturing efforts, third party research costs, research supply costs and license and technology access fees. To a lesser extent, the increase in cash used in operations also results from higher general and administrative costs, attributable mainly to higher personnel costs. Partially offsetting the use of cash for these operating expenses were depreciation and amortization, non-cash compensation and license fees paid in stock. Lastly, the increase in cash used in operations also resulted from reduced investment income and an increase in interest paid to our convertible note holders.

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 develop, on a proprietary or co-developed basis, multiple product candidates. We also expect facility costs to increase in 2003 as a result of our 2002 capital expansion and renovations. We also expect our general and administrative costs to increase as we expand our administrative and business development activities. Our operating expenditures will only be partially offset by revenues from our partners for license fees, milestone payments, and, to a lesser extent, development and manufacturing services as well as interest and dividend income received on our investments. Going forward, we anticipate lower investment income due to lower average cash balances, resulting primarily from the funding of future operations, as well as planned capital expenditures out of our cash reserves.

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Cash Provided by Investing Activities. Net cash provided by investing activities was $93.9 million in 2002 compared to net cash used in investing activities of $209.0 million in 2001. The increase in net cash provided by investing activities was primarily the result of the following factors:

- Capital expenditures of $55.0 million and $43.7 million for the years 2001 and 2002, respectively. The decrease in capital spending in 2002 was primarily related to the completion of the renovation of our existing Bloomsbury, New Jersey facility, which was first opened in May 2001;

- Net purchases of securities for the year ended December 31, 2001 of $168.0 million was primarily a result of the proceeds received from our convertible note offering in June 2001 (see discussion below);

- Net sales of securities for the year ended December 31, 2002 of $136.7 million was primarily to fund 2002 operations and capital expenditures.

In November 2000, we purchased our Milpitas, California facility for approximately $14.6 million. We previously leased this facility. This property currently contains approximately 60,000 square feet of laboratory and office space. As of December 31, 2002, we had cumulatively expended approximately $23.0 million on renovating and expanding this facility.

In January 2001, we purchased a facility and adjacent land in Bloomsbury, New Jersey for approximately $9.2 million. The Bloomsbury 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 currently are using approximately 75,000 square feet as laboratory and office space. As of December 31, 2002, we had cumulatively expended approximately $46.0 million on renovating this facility.

In July 2002, we entered into a lease for approximately 37,000 square feet of laboratory and office space in Sunnyvale, California. This space replaced the Corixa facility in South San Francisco that was occupied by 30 employees retained in connection with our acquisition of certain assets of Corixa, discussed more fully below. During 2002, we expended approximately $4.4 million on leasehold improvements for this space.

We anticipate 2003 capital expenditures will be approximately $15.0 million primarily for scientific equipment, lab automation, and final payments for the Milpitas and Sunnyvale improvements.

Cash Provided by Financing Activities. During 2002, net cash provided by financing activities was $0.7 million primarily from proceeds received from common stock issuances related to our equity compensation plans. During 2001, net cash provided by financing activities was $169.5 million primarily from the proceeds received from our June 2001 issuance of $175 million of convertible subordinated notes. The notes bear interest at an annual rate of 4.50% payable on January 1 and July 1 of each year. The cost of issuance of the notes of approximately $5.9 million has been deferred and is being amortized over the five year term of the notes. Such amortization is included in interest expense on our Consolidated Statements of Operations for the years ended December 31, 2001 and 2002. The notes are subordinated to all existing and future senior indebtedness. We may redeem any or all of the notes at any time at specified redemption prices (plus possible make whole payments as defined in the indenture), plus accrued and unpaid interest to the redemption date. The notes will mature on July 1, 2006 unless earlier converted, redeemed at our option or redeemed at the option of the noteholder upon a fundamental change as described in the indenture for the notes. In addition, neither we nor any of our subsidiaries are restricted under the indenture from paying dividends, incurring debt, or issuing or repurchasing our securities. During 2000, net cash provided by financing activities was $400.4 million, primarily as the result of the proceeds

received from the sale of our common stock in a March 2000 follow-on public offering.

In May 2002, we adopted an Employee Stock Purchase Plan, or ESPP, authorizing the issuance of 500,000 shares of our common stock pursuant to purchase rights granted to eligible employees. The ESPP provides a means by which employees purchase our common stock through payroll deductions of up to 10% of their base compensation. At the end of each six month purchase period during the calendar year, we use 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) at July 1, 2002 or (ii) at the end of each six month purchase period. The purchase periods end on June 30 and December 31 of each year. Generally, all employees, including executive officers, who work at least 20 hours per week and five months per year may participate in the ESPP. Employees who are deemed to own greater than 5% of the combined voting power of all classes of our stock are not eligible for participation in the ESPP. As of December 31, 2002, 146,982 shares have been issued under the ESPP resulting in proceeds to us of approximately $0.5 million.

Net Operating Loss Carryforwards. As of December 31, 2002, we had federal net operating loss (NOL) carryforwards of approximately $217.1 million. These NOL carryforwards will expire in the years 2003 2022 (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, 2002 the amount of NOL subject to the limitation was $43.9 million and the amount not subject to limitation was $173.2 million.

Other Liquidity Matters. In connection with our merger with Essex Medical Products, or Essex, in 1987, we committed to pay to 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, 2002. 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 SEC.

In July 2000, we entered into an Agreement with IDM whereby we licensed to IDM certain of our technologies in exchange for equity units in IDM. As a result of this transaction, we realized a gain from the transfer of technology of approximately $40.5 million (based upon an independent valuation). In accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, during the years ended December 31, 2000, 2001 and 2002, we recognized non-cash revenue of $5.9 million, $20.3 million and $14.3 million, respectively. As of December 31, 2002, there is no additional revenue to recognize regarding this transaction.

On May 23, 2002, we 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 subsidiary of Corixa Corporation (collectively referred to as Corixa). Under the terms of the Asset Purchase Agreement, 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. In addition, we retained approximately 30 Corixa employees related to such product candidates and programs and agreed to temporarily, sublease approximately 30,000 square feet of laboratory and office space at Corixa s South San Francisco facility for six months. This sublease terminated in November 2002.

Under the terms of the Asset Purchase Agreement, we acquired the Corixa 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 our election, in shares of common stock. As of December 31, 2002, a total of 3,086,075 shares of common stock with a fair value of $19.25 million were issued to Corixa along with cash of $1.75 million as payment for the $21.0 million purchase price. In the event that, during any month during the six-month period following the closing of the transaction, Corixa sold all of the shares of the common stock delivered as payment for the preceding monthly installment and the proceeds of such sale were less that $3.5 million, we were obligated to pay the difference to Corixa in cash. During 2002, we expensed approximately $2.3 million representing the net cash shortfall experienced by Corixa. Such amounts are included in Additional payments related to asset acquisition in our consolidated statement of operations for the year ended December 31, 2002.

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We 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.

As part of this transaction, Corixa may receive up to an additional $6.0 million in future consideration in cash or, at our election, in shares of common stock, based upon certain contingencies.

Our material contractual obligations under lease, debt and research funding agreements for the next five years, and thereafter, as of December 31, 2002 are as follows:

	Payments Due by Period				
	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years	Total
			(in thousands)		
Contractual Obligations (1)					
Convertible notes	$	$	$ 175,000(2)	$	$ 175,000
Research funding	3,600	6,000	6,000	3,000	18,600
Operating leases and other	3,748	6,580	4,730	2,772	17,830
Total contractual cash obligations	$ 7,348	$ 12,580	$ 185,730	$ 5,772	$ 211,430

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 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.

Future Liquidity Resources. Our current sources of liquidity are 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 $175.0 million required to meet our repayment obligations with respect to our convertible notes due on July 1, 2006. In the event our convertible notes are converted into shares of our common stock on or before July 1, 2006, we will have use of the $175.0 million 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, lines 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.

Recently Issued Accounting Pronouncements

In June 2001, the FASB issued Statement No. 143, *Accounting for Asset Retirement Obligations*, which is effective for fiscal year beginning after June 15, 2002. Statement No. 143 requires legal obligations associated with the retirement of long-lived assets to be recognized at their fair value at the time the obligations are incurred. Upon initial recognition of a liability, that cost should be capitalized as part of the related long-lived asset and allocated to expense over the useful life of the asset. The Company will adopt Statement No. 143 on January 1, 2003, and, based on certain circumstances, does not believe the impact of adoption of Statement No. 143 will have a material impact on the Company s financial position or results of operations.

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In June 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Statement 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).* Statement No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF 94-3, a liability for an exit cost was required to be recognized at the date of an entity s commitment to an exit plan. Statement No. 146 is effective for exit or disposal activities that are initiated by us after December 31, 2002.

On December 31, 2002, the FASB issued Statement No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. Statement No. 148 amends FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition to Statement No. 123 s fair value method of accounting for stock-based employee compensation for an entity that voluntarily changed to the fair value based method of accounting for stock-based employee compensation. Statement No. 148 also required prominent disclosure of the effects of an entity s accounting policy with respect to stock-based employee compensation on reported net income and earning per share in annual and interim financial statements. We intend to continue to follow the disclosure-only provisions of FASB Statement No. 123 and, accordingly, will continue to apply Accounting Principles Board Opinion No. 25 and its related interpretations in accounting for its plans. The adoption of Statement No. 148 will have no impact on our results of operations, financial position or cash flows.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

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

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

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Item 8. Consolidated Financial Statements and Supplementary Data

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Report of Independent 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, 2001 and 2002, and the related consolidated statements of operations, shareholders equity and cash flows for each of the three years in the period ended December 31, 2002. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of Genmab A/S as of December 31, 2001 and for each of the two years in the period ended December 31, 2001, (a corporation in which the Company has a 31% interest), have been audited by other auditors whose report dated February 10, 2002 has been furnished to us; insofar as our opinion on the consolidated financial statements relates to the amounts included for Genmab A/S, it is based solely on their report.

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, 2001 and 2002, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

MetroPark, New Jersey

March 7, 2003

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MEDAREX, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31,	
	2001	2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,269	$ 61,812
Marketable securities	435,683	288,234
Prepaid expenses and other current assets	24,860	10,143
Total current assets		