

MEDAREX INC  
Form POS AM  
May 31, 2005

[QuickLinks](#) -- Click here to rapidly navigate through this document

As filed with the Securities and Exchange Commission on May 31, 2005

REGISTRATION NO. 333-108325

---

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

---

**POST-EFFECTIVE AMENDMENT NO. 3  
TO  
FORM S-3**

REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

---

**MEDAREX, INC.**

(Exact name of registrant as specified in its charter)

**New Jersey**  
(State or other jurisdiction of  
incorporation or organization)

**2836**  
(Primary standard industrial  
classification code number)

**22-2822175**  
(I.R.S. Employer Number)

---

**Medarex, Inc.**  
**707 State Road**  
**Princeton, NJ 08540**  
**(609) 430-2880**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Donald L. Drakeman**  
**President and Chief Executive Officer**  
**Medarex, Inc.**  
**707 State Road**  
**Princeton, NJ 08540**  
**(609) 430-2880**

---

**COPIES TO:**

**W. Bradford Middlekauff, Esq.**  
**Senior Vice President, General Counsel**  
**and Secretary**  
**Medarex, Inc.**  
**707 State Road**  
**Princeton, NJ 08540**  
**(609) 430-2880**

**Dwight A. Kinsey, Esq.**  
**Satterlee Stephens Burke & Burke LLP**  
**230 Park Avenue**  
**New York, NY 10169**  
**(212) 818-9200**

Edgar Filing: MEDAREX INC - Form POS AM

Approximate date of commencement of proposed sale to the public:  
From time to time after the effective date of the Registration Statement, as determined by the Registrant.

If the only securities registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.**

---

---

---

PROSPECTUS

## **MEDAREX, INC.**

### **18,603,263 Shares of Common Stock**

In July 2003, we issued and sold \$125,000,000 aggregate principal amount of our 4.25% Convertible Senior Notes, due August 15, 2010, in a private offering. In December 2004, we called for the full redemption of all such convertible senior notes under the terms described in such notes. Prior to the redemption date, all of the outstanding notes were converted into common stock in accordance with the terms of the notes, resulting in the issuance of 18,603,263 shares of our common stock. This prospectus relates to the sale of the shares of our common stock issued upon conversion of such notes. The selling securityholders may sell the notes or the common stock directly to purchasers or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions. We will not receive any proceeds from these resales.

Our common stock currently trades on the Nasdaq National Market under the symbol "MEDX." The last reported sale price on May 27, 2005 was \$7.86 per share.

---

**Investing in our securities involves risks. See Risk Factors" on page 3 of this prospectus.**

---

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

---

**The date of this prospectus is May 31, 2005**

---

YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN, OR INCORPORATED BY REFERENCE, INTO, THIS PROSPECTUS. WE HAVE NOT AUTHORIZED ANYONE TO PROVIDE YOU WITH DIFFERENT INFORMATION. THE SELLING SECURITYHOLDERS ARE NOT MAKING AN OFFER OF THE SECURITIES TO BE SOLD UNDER THIS PROSPECTUS IN ANY JURISDICTIONS WHERE THE OFFERS OR SALES ARE NOT PERMITTED. YOU SHOULD NOT ASSUME THAT THE INFORMATION CONTAINED IN THIS PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE ON THE FRONT COVER OF THIS PROSPECTUS, OR THAT THE INFORMATION CONTAINED IN ANY DOCUMENT INCORPORATED BY REFERENCE IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE OF THE DOCUMENT INCORPORATED BY REFERENCE. THE DELIVERY OF THIS PROSPECTUS DOES NOT, UNDER ANY CIRCUMSTANCES, MEAN THAT THERE HAS NOT BEEN A CHANGE IN OUR AFFAIRS SINCE THE DATE HEREOF. THIS PROSPECTUS WILL ONLY BE DISTRIBUTED IN PRINTED FORM BY HAND OR THROUGH THE MAILES.

TABLE OF CONTENTS

	<u>Page</u>
PROSPECTUS SUMMARY	1
RISK FACTORS	3
FORWARD-LOOKING STATEMENTS	26
USE OF PROCEEDS	26
PRICE RANGE OF COMMON STOCK	26
DIVIDEND POLICY	27
RATIO OF EARNINGS TO FIXED CHARGES	27
BUSINESS	28
DESCRIPTION OF CAPITAL STOCK	30
SELLING SECURITYHOLDERS	33
PLAN OF DISTRIBUTION	36
LEGAL MATTERS	38
EXPERTS	38
ADDITIONAL INFORMATION	38
INCORPORATION BY REFERENCE	38

**PROSPECTUS SUMMARY**

*This summary does not contain all the information that is important to you. You should read the entire prospectus, including the section entitled "Risk Factors," and the documents incorporated by reference in this prospectus, including the financial statements and related notes, identified under the section entitled "Incorporated by Reference" carefully before making an investment decision. When used in this prospectus, unless otherwise indicated, the terms "we," "our," and "us" refer to Medarex and its subsidiaries.*

**Medarex, Inc.**

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

Currently, 23 antibody product candidates derived from our UltiMAB human antibody development technology are in human clinical trials for the treatment of a wide range of diseases, such as cancer, rheumatoid arthritis and other inflammatory, autoimmune and infectious diseases. Eight of these products are in Phase II or Phase III clinical trials.

As of May 1, 2005, we had more than 50 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to enable other companies to use our proprietary technology in their development of new therapeutic products.

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

We are subject to a number of risks which could materially and adversely affect our business, results of operations and financial condition including, among other things, our history of operating losses and anticipation of future losses; uncertainties relating to our technology, product development, patent and proprietary rights, clinical trials, government regulation, obtaining regulatory approval, market acceptance of our products, health care reform and third-party reimbursement; our need for additional capital; our dependence on our key personnel and our research collaborators and scientific advisors; and the risk of product liability. These risks are described in more detail in the section herein entitled "Risk Factors."

---

We were incorporated in 1987. Our principal executive offices are located at 707 State Road, Princeton, New Jersey 08540. Our telephone number is (609) 430-2880. We maintain a worldwide website at [www.medarex.com](http://www.medarex.com). The reference to our worldwide web address does not constitute incorporation by reference of the information contained on our website. Our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and all amendments to those reports that we file with the Securities and Exchange Commission, or SEC, are currently available free of charge to the general public through our website at [www.medarex.com](http://www.medarex.com). These reports are accessible on our website at a reasonably practicable time after being filed with the SEC.

Medarex®, HuMAB-Mouse®, GenPharm® UltiMAB Human Antibody Development System®, UltiMAB® and KM-Mouse® are registered U.S. trademarks of Medarex, Inc. Ultra-Potent Toxin is a trademark of Medarex, Inc. All other company names, trademarks and service mark included herein are trademarks, registered trademarks, service marks or trade names of their respective owners.

**The Offering**

This prospectus relates to the sale by certain holders of 18,603,263 shares of our common stock issued upon conversion of all of our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010.

We will not receive any proceeds from the sale by the selling securityholders of the shares of common stock covered by this prospectus.

**The Common Stock**

The following is a brief summary of the terms of the common stock offered for resale by the selling securityholders by this prospectus. For a more complete description of the terms of our common stock, see "Description of Capital Stock" in this prospectus.

In January 2005, we issued 18,603,263 shares of our common stock to certain securityholders upon conversion of our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010.

Under the terms of registration rights agreement that we entered into in connection with the sale or issuance of the notes to the selling securityholders, we filed a shelf registration statement under the Securities Act of 1933 relating to the resale of the shares of common stock purchased by or issued to the selling securityholders. This prospectus constitutes a part of that registration statement. We filed the shelf registration statement to permit the resale of common stock, and investors who purchase shares of common stock from the selling securityholders in this offering will not be entitled to any registration rights under the registration rights agreement. In addition, under the registration rights agreement, the selling securityholders may be required to discontinue the sale or other disposition of the common stock pursuant to the shelf registration statement and to discontinue the use of this prospectus under certain circumstances specified in the registration rights agreement.

**Risk Factors**

See the section herein entitled "Risk Factors" and other information included and incorporated by reference in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.

## RISK FACTORS

*You should carefully consider and evaluate all of the information in or incorporated by reference in this prospectus, including the risk factors listed below. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of the securities being offered by this prospectus.*

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

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Active product candidates employing our human antibody technology have not moved beyond clinical development. Based on public disclosures, regulatory applications, including INDs, have been submitted to the FDA or comparable foreign authorities, for 23 product candidates derived from our UltiMAb platform. To date, neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA or comparable foreign authorities and/or commercialized. In addition, we are not aware of any commercialized fully human monoclonal antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond clinical development or demonstrate clinical safety and effectiveness.

Our human antibody technology may not generate antibodies against all the antigens to which it is exposed in an efficient and timely manner, if at all. If our human antibody technology fails to generate antibody product candidates, or if we or our partners do not succeed in the development of products employing our antibody technology, those product candidates may not be approved or commercialized and our business, financial condition and results of operations may be materially harmed.

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

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

delays in product development, clinical testing or manufacturing;

unplanned expenditures in product development, clinical testing or manufacturing;

failure in clinical trials or failure to receive regulatory approvals;

emergence of superior or equivalent products;

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

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

election by our partners not to pursue product development;

failure by our partners to develop products successfully; and

failure to achieve market acceptance.

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

technology.



## Edgar Filing: MEDAREX INC - Form POS AM

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

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

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

We have incurred large operating losses and we anticipate that these losses will continue for the foreseeable future. In particular, as of March 31, 2005, we had an accumulated deficit of approximately \$646.3 million. Our net losses were \$186.5 million and \$46.9 million for the year ended December 31, 2004 and the three-month period ended March 31, 2005, respectively. Our losses have resulted principally from:

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

costs associated with the establishment of our laboratory and manufacturing facilities and manufacturing of products; and

general and administrative costs relating to our operations.

We intend to continue to make significant investments in:

research and development;

preclinical testing and clinical trials;

establishing new collaborations; and

new technologies.

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

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

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

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

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

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



## Edgar Filing: MEDAREX INC - Form POS AM

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

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

changes in regulatory requirements for clinical trials;

costs and expenses associated with preclinical testing and clinical trials;

the timing of regulatory approvals, if any;

sales and marketing expenses; and

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

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

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

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

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

the size and complexity of research and development programs;

the scope and results of preclinical testing and clinical trials;

the retention of existing and establishment of further partnerships, if any;

continued scientific progress in our research and development programs;

the time and expense involved in seeking regulatory approvals;

competing technological and market developments;

the time and expense of filing and prosecuting patent applications and enforcing patent claims; and

the cost of establishing manufacturing capabilities, conducting commercialization activities and arrangements and in-licensing products.

We believe our current sources of liquidity will be sufficient to meet our near term operating, debt service and capital requirements for at least the next 24 months. To the extent our 2.25% convertible senior notes due in 2011 are converted into shares of our common stock on or

## Edgar Filing: MEDAREX INC - Form POS AM

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

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

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

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

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

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

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

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

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

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

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

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

the need or desire to modify our manufacturing processes;

slower than expected rates of patient recruitment;



## Edgar Filing: MEDAREX INC - Form POS AM

modification of clinical trial protocols;

the inability to adequately observe patients after treatment;

changes in regulatory requirements for clinical trials;

the lack of effectiveness during the clinical trials;

unforeseen safety issues;

delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and

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

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

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

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

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

Results of our early clinical trials and those of our partners using our human antibody technology are based on a limited number of patients and may, upon review, be revised or negated by authorities

or by later stage clinical results. Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and effectiveness data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

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

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

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

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

cost-effectiveness;

alternative treatment methods;

reimbursement policies of government and third-party payors; and

marketing and distribution support for our product candidates.

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

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

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

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payors, the market for products employing our human antibody technology will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty



exists as to the reimbursement status of newly approved healthcare products. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products. Such studies may require us to dedicate a significant amount of resources. Our project candidates may not be considered cost-effective. Third-party payors may not reimburse sales of products employing our human antibody technology, or enable us or our partners to sell them at profitable prices.

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

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

Federal legislation, enacted in December 2003, has added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations may increase pressures to lower prices. While the new law specifically prohibits the U.S. government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the U.S. government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating *de facto* price controls on prescription drugs. In addition, the new law contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include some sorts of limitations on prescription drug prices. The new legislation also modified the methodology used for reimbursement of physician administered and certain other drugs already covered under Medicare Part B. This new methodology would likely apply to certain of our products if and when commercialized. Experience with new reimbursement methodology is limited, and could be subject to change in the future. Our results of operations could be materially harmed by the different features of the Medicare prescription drug coverage legislation, by the potential effect of such legislation on amounts that private insurers will pay for our products and by other healthcare reforms that may be enacted or adopted in the future.

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

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

In addition, in December 2003, federal legislation was enacted to change U.S. import laws and expand the ability to import lower priced versions of our and competing products from Canada, where there are government price controls. These changes to the import laws will not take effect unless and

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

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

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

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

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

We may also encounter problems with the following:

production yields;

quality control and assurance;

shortages of qualified personnel;

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

changes in FDA requirements;

production costs; and/or

development of advanced manufacturing techniques and process controls.

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. We are currently pursuing late-stage clinical and commercial supply agreements with cGMP-compliant third-party manufacturers with available capacity to meet our internal production timetables. We have entered into clinical supply agreements with Lonza Group Ltd. with respect to MDX-010 and MDX-060, and, together with our partner BMS, we are pursuing ongoing discussions with respect to terms of a commercial supply agreement for MDX-010. We do not currently have the capability to manufacture our products under development in large commercial quantities and have no experience in commercial-scale manufacturing. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin

producing antibodies under cGMP regulations. We cannot make assurances that we will be able to contract with such companies for clinical and/or commercial supply on acceptable terms or in a timely manner, if at all. Moreover, even if we are able to enter into clinical and/or commercial supply manufacturing arrangements with cGMP-compliant third-party manufacturers, we cannot assure you that such manufacturers will be able to produce products that are substantially equivalent to the product candidates that we have produced in our own facilities and used in our clinical trials. If such companies are not able to produce products that are substantially equivalent to our product candidates, the progress of our clinical trials and/or commercialization of our products may be delayed and our business, financial condition and results of operations may be materially harmed.

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

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

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

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

access proprietary antigens for the development of product candidates;

access skills and information that we do not possess;

fund our research and development activities;

manufacture products;

fund and conduct preclinical testing and clinical trials;

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

commercialize and market future products.

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

our partners have significant discretion whether to pursue planned activities;

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

## Edgar Filing: MEDAREX INC - Form POS AM

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

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

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

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

Our licensing partners generally have the right to terminate our partnerships at any time. Our ability to continue our current partnerships and to enter into additional partnerships is dependent in large part on our ability to successfully demonstrate that our UltiMAB technology is an attractive method of developing fully human antibody therapeutic products. Existing or potential partners may pursue alternative technologies, including those of our competitors, or enter into other transactions that could make a collaboration with us less attractive to them. For example, if an existing partner purchases or is purchased by a company that is one of our competitors, that company could be less willing to continue its collaboration with us. In addition, a company that has a strategy of purchasing companies rather than entering into partnership arrangements might have less incentive to enter into a collaboration agreement with us. Moreover, disputes may arise with respect to the ownership of rights to any technology or products developed with any current or future partner. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays or termination in the research, development or commercialization of product candidates. If we are not able to establish additional partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely:

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

significantly increase our need for capital; and/or

place additional strain on management's time.

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

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

Due to the size of our equity interest in Genmab, we are currently required to account for our interest in Genmab under the equity method of accounting, which provides that we must include a portion of Genmab's income and losses equal to our percentage equity interest in Genmab in our consolidated financial statements. For the years ended December 31, 2002, 2003 and 2004, our share of Genmab's losses were approximately \$19.6 million (excluding the \$31.0 million impairment charge discussed below), \$15.0 million and \$19.8 million, respectively. For the three-month period ended March 31, 2005, our share of Genmab's net loss was \$1.7 million. As such, the current value of our equity interest in Genmab as determined by the equity method of accounting is zero and, accordingly, recognition of our share of Genmab's net losses is now suspended indefinitely.

**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 Amgen, Inc., and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. As these investments are the result of strategic alliances with our collaborative partners, we typically do not attempt to reduce or eliminate our market exposure of these types of strategic investments. Under SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," these investments are designated as available-for-sale and are reported at fair value on our consolidated balance sheet. Unrealized holding gains and losses on available-for-sale

securities are generally excluded from earnings and reported within other comprehensive income which is a separate component of shareholders' equity. Under our accounting policy, marketable equity securities are generally considered to be impaired if their fair value is less than our cost basis in such securities for more than six months, or some other period in light of the particular facts and circumstances surrounding the investment. If a decline in the fair value of available-for-sale securities is considered to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. For the year ended December 31, 2002, we recorded impairment charges of approximately \$40.5 million (of which approximately \$31.0 million related to Genmab) on our strategic investments in publicly traded companies. During the year ended December 31, 2003, no impairment charges were recorded related to the value of our investments in publicly traded companies. For the year ended December 31, 2004, we recorded impairment charges of \$0.2 million on investments in partners whose securities are publicly traded. If we deem these investments to be further impaired at the end of any future reporting period, we may incur additional impairment charges on these investments.

In addition, we have investments in several of our partners whose securities are not publicly traded, such as IDM. The value of our investments in these companies are inherently more difficult to estimate than our investments in publicly traded companies. We estimate the value of these investments by using information acquired from industry trends, the management of these companies, financial statements, and other external sources. Specifically, our determination of any potential impairment of the value of privately held securities includes an analysis of the following for each company on a periodic basis: review of interim and year-end financial statements, cash position and overall rate of cash used to support operations, the progress and development of technology and product platform, the per share value of subsequent financing and potential strategic alternatives. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is considered to be other than temporary. For the years ended December 31, 2002, 2003 and 2004, we recorded impairment charges of approximately \$2.4 million, \$1.4 million and \$7.1 million, respectively, on our investments in privately-held companies. Approximately \$7.0 million of the 2004 impairment charge related to IDM. For the three month period ended March 31, 2005, we recorded an impairment charge of \$20.3 million which related entirely to IDM. Future adverse changes in market conditions or adverse changes in operating results of these companies may also require an impairment charge in the future.

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

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

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

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

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

Our success depends in part on our ability to:

apply for, obtain, protect and enforce patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

in-license certain technologies.

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

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

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

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

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

## Edgar Filing: MEDAREX INC - Form POS AM

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

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

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

Moreover, other parties could have blocking patent rights to products made using HuMAb-Mouse technology, such as antibodies, and their production and uses, for instance because of a proprietary position covering the antibody or the antibody's target. For example, we are aware of certain U.S. and European patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets and bispecific products, and the manufacture and use of such products. We are also aware of certain U.S. and foreign patents and patent applications held by third parties relating to anti-CD4 antibodies, such as HuMax-CD4, anti-CD30 antibodies, such as MDX-060, anti-CD20 antibodies, such as HuMax-CD20, anti-EGFr antibodies, such as HuMax-EGFr, anti-PSMA antibodies, such as MDX-070, anti-Type 1 IFN antibodies, such as MDX-1103, and antibody-antigen conjugates, such as MDX-1307/bHCG-VAC, as well as other antibody products under development by us.

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

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

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



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

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

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

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

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

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

have occurred during the course of these trials such fatalities may or may not be attributable to our product. Any of these events could result in a product liability claim. Any such claims against us, regardless of their merit, could result in significant awards against us, which could materially harm our business, financial condition and results of operations.

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

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

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

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

Some of our competitors have received regulatory approval or are developing or testing product candidates that compete directly with product candidates employing our antibody technology. Many of

these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development staffs than we or some of our partners do. In addition, many of these competitors have significantly greater experience than we do in:

developing products;

undertaking preclinical testing and clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing and marketing products.

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

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

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

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

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

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

impose additional costs on us or our partners;

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

adversely affect our receipt of revenues or royalties.



## Edgar Filing: MEDAREX INC - Form POS AM

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

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

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

warning letters;

fines;

import and/or export restrictions;

product recalls or seizures;

injunctions;

total or partial suspension of production;

civil penalties;

withdrawals of previously approved marketing applications or licenses;

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

criminal prosecutions.

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

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

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



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

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

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

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

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

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

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to FDA's current good manufacturing practice requirements. Application holders must obtain FDA approval for product, manufacturing, and labeling changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the

Veteran's Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

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

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



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

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

**Our stock price may be volatile.**

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

fluctuations in our operating results;

announcements of technological innovations or new commercial therapeutic products by us or our competitors;

published reports by securities analysts;

progress with clinical trials;

governmental regulation;

developments in patent or other proprietary rights;

developments in our relationship with collaborative partners;

public concern as to the safety and effectiveness of our products; and

general market conditions.

During the two-year period ended March 31, 2005, the sale prices of our common stock ranged between \$3.15 and \$11.55. The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these or other factors, including the sale or attempted sale of a large amount of our common stock into the market. Broad market fluctuations may also adversely affect the market price of our common stock.

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

At our annual meeting of shareholders held on May 19, 2005, our shareholders approved our 2005 Equity Incentive Plan, or the 2005 Plan, pursuant to which a total of 6,500,000 shares of our common stock were authorized for issuance. In addition, the 2005 Plan's share reserve will be increased by a maximum of 10,000,000 shares from the following sources: (1) shares authorized and remaining available for the future grants of awards under our prior equity incentive plans, or our Prior Plans, as of the date of the annual shareholders meeting, (2) shares subject to options outstanding under the Prior Plans as of the date of the annual shareholders meeting which expire or otherwise terminate without having been exercised and (3) shares withheld or reacquired by us on or after the date of the annual shareholders meeting in satisfaction of tax withholding obligations under the Prior Plans. As a result, the total number of shares that may be issued under the 2005 Plan, inclusive of shares previously issuable under our Prior Plans, is 16,500,000. As of April 29, 2005, we had 14,187,859 shares of common stock reserved for issuance pursuant to options and other stock based awards which had been



granted under our Prior Plans having a weighted average exercise price of \$7.94 per share and we had reserved 946,825 shares of common stock for issuance pursuant to future grants of options under our Prior Plans. We have filed registration statements on Form S-8 under the Securities Act covering all of the shares issuable under the Prior Plans and intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares issuable under the 2005 Plan. Shares issued pursuant to these plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

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

As of April 29, 2005, we had reserved 1,000,978 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 under the Securities Act covering all of those shares. All shares issued under this plan, other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

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

As of April 29, 2005, we had 10,936,935 shares of common stock reserved for the issuance pursuant to the conversion of the \$150.0 million aggregate principal amount of our outstanding 2.25% Convertible Senior Notes due May 15, 2011. Holders of these notes may convert their notes into shares of common stock at any time prior to maturity or redemption by us at a conversion rate of 72.9129 shares per each \$1,000 principal amount of the notes (\$13.72 per share), subject to adjustment.

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

As of April 29, 2005, we had 110,675,999 shares of common stock outstanding, of which 9,374,318 are restricted securities as that term is defined in Rule 144 under the Securities Act. Under certain circumstances, these restricted securities may be sold without registration pursuant to such rule. We are unable to predict the effect that sales made under Rule 144 or pursuant to any registration may have on the market price of our common stock. The sale of a significant number of additional securities, or even the possibility thereof, may lower the market price of our common stock.

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

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

debt securities;

preferred stock;

common stock; or

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

We have also filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of up to 18,601,190 shares of our common stock which were issued upon the conversion of our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010 in connection with the provisional redemption of such notes in January 2005. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144. We also have filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of up to 3,272,091 shares of our common stock which were issued on the conversion of all of our \$21.986 million 4.25% Convertible Senior Notes due August 15, 2010, in connection with the provisional redemption of such notes in January 2005. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to the resale limitations of Rule 144. In connection therewith, we have agreed to use our best efforts to keep these registration statements continuously effective until the earliest of (i) the sale of all outstanding registrable securities registered under the registration statements; (ii) the expiration of the period referred to in Rule 144(k) of the Securities Act with respect to the notes held by non-affiliates of us; (iii) all the registrable securities have ceased to be outstanding (whether as a result of repurchase or otherwise); and (iv) two years after the respective effective dates of these registration statements.

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

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

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

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our outstanding 2.25% Convertible Senior Notes due May 11, 2011. As of April 29, 2005, \$150.0 million aggregate principal amount of these notes was outstanding. In each instance, we may pay the repurchase price in cash or, at our option, in common stock. These change of control events include, without limitation, (i) the acquisition by any third party of at least 50% of our common stock; or (ii) our merger or consolidation with or into any other person, any merger or consolidation of another person into us or our sale or other disposal of all or substantially all of our assets, except in certain limited circumstances provided in the indentures relating to the notes. Such repurchase rights may be triggered at a time at which we do not have sufficient funds available to pay the repurchase price in cash or determine that payment in cash is otherwise inadvisable. In such event, the issuance of a significant number of additional shares of common stock in payment of the repurchase price may lower the market price of our common stock.

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

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

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

a classified board of directors;

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

advance notice requirements for shareholder proposals and nominations;

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

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

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

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

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

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

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

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

**FORWARD-LOOKING STATEMENTS**

This prospectus, including the documents that we incorporate by reference, 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 "Summary Medarex, Inc.," "Risk Factors," "Business," and elsewhere in this offering circular 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; 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 offering circular 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 the section entitled "Risk Factors" above. Accordingly, in addition to the other information in this offering circular, such 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.

**USE OF PROCEEDS**

The selling securityholders will receive all of the proceeds from the sale under this prospectus of the notes and the common stock issuable upon conversion of the notes. We will not receive any proceeds from these sales.

**PRICE RANGE OF COMMON STOCK**

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

	<b>Common Stock Price</b>	
	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2003</b>		
First Quarter	\$ 4.36	\$ 2.69
Second Quarter	\$ 7.35	\$ 3.15
Third Quarter	\$ 7.67	\$ 4.48
Fourth Quarter	\$ 7.56	\$ 5.78
<b>Year ended December 31, 2004</b>		
First Quarter	\$ 9.93	\$ 6.28
Second Quarter	\$ 11.13	\$ 6.51
Third Quarter	\$ 8.41	\$ 4.37
Fourth Quarter	\$ 11.55	\$ 7.06
<b>Year ended December 31, 2005</b>		
First Quarter	\$ 10.87	\$ 6.88
Second Quarter (through May 27, 2005)	\$ 8.23	\$ 6.65

The last reported sale price of our common stock on the Nasdaq National Market on May 27, 2005 was \$7.86. As of such date, there were approximately 600 stockholders of record of our common stock.

**DIVIDEND POLICY**

We have never declared or paid cash dividends. We do not anticipate declaring or paying cash dividends in the foreseeable future. Instead, we will retain our earnings, if any, for the future operation and expansion of our business.

**RATIO OF EARNINGS TO FIXED CHARGES**

Ratios of earnings to fixed charges are computed by dividing earnings by fixed charges. For purposes of computing this ratio of earnings to fixed charges, earnings consist of pre-tax loss from continuing operations adjusted by adding fixed charges. Fixed charge consist of interest expense, amortization of financing costs and estimated interest component of rental expense on operating leases.

	Year ended December 31,					Three Months Ended March 31 2005
	2000	2001	2002	2003	2004	
Ratio of earnings to fixed charges						2.08

Earnings were insufficient to cover fixed charges by \$9.7 million, \$106.8 million, \$113.4 million, \$166.7 million and \$42.5 million for the years ended December 31, 2000, 2002, 2003 and 2004, and the three months ended March 31, 2005, respectively.

## BUSINESS

We are a biopharmaceutical company focused on the discovery, development and potential commercialization of fully human antibody-based therapeutic products. We believe that our UltiMab Human Antibody Development System enables us to rapidly create and develop therapeutic products for a wide range of diseases, including cancer, inflammation and autoimmune disorders and other life-threatening and debilitating diseases.

Currently, 23 antibody product candidates generated from our UltiMab Human Antibody Development System are in human clinical trials(1). Eight of these products are in Phase II or Phase III clinical trials. These 23 product candidates are designed to treat a wide range of diseases, such as cancer, rheumatoid arthritis and other inflammatory, autoimmune and infectious diseases. The most advanced of these products is MDX-010 (Phase III, Phase II and Phase I clinical trials), which we are developing jointly with Bristol-Myers Squibb Company, or BMS, for the treatment of metastatic melanoma and other cancers. Five of these antibody products are fully owned by Medarex and its affiliates: MDX-060 for lymphomas (Phase II clinical trial), MDX-070 for prostate cancer (Phase II clinical trial), MDX-214 for cancer (Phase I/II clinical trial), and MDX-1307 for genitourinary and breast cancers (Phase I clinical trial) and MDX-1100 for ulcerative colitis (Phase I clinical trial). We are developing MDX-066 (Phase I clinical trial) jointly with The Massachusetts Biologic Laboratories of the University of Massachusetts Medical School, or MBL, for the treatment of *Clostridium difficile* associated diarrhea. Another antibody, MDX-018 (Phase I/II clinical trial), is being jointly developed with Genmab A/S for autoimmune disease, and three additional antibodies are being developed separately by Genmab: HuMax -CD4 (Phase III and Phase II clinical trials) for T-cell lymphomas, HuMax-EGFr (Phase I/II clinical trial) for head and neck cancer and HuMax-CD20 (Phase I/II clinical trial) for lymphomas. Genmab and Amgen, Inc. are developing AMG 714 (Phase II clinical trial) for rheumatoid arthritis. Additionally, other licensing partners, including Novartis Pharma AG, Eli Lilly and Company, and Centocor, Inc. (a subsidiary of Johnson & Johnson), are developing a total of ten antibody products, for inflammatory and/or autoimmune diseases and cancer, that are currently in clinical trials. Human Genome Sciences, Inc. has also announced the initiation of a Phase I trial of one anticancer antibody product developed pursuant to a licensing agreement with our partner Kirin Brewery Co., Ltd. We and our partners also have a number of UltiMab® product candidates in preclinical development.

In November 2004, we announced a worldwide collaboration with BMS to develop and commercialize MDX-010, an antibody product targeting the CTLA-4 receptor, that was developed by us using our UltiMab Human Antibody Development System. The BMS collaboration also includes MDX-1379, an investigational gp100 melanoma peptide vaccine, which will be developed for potential use in combination with MDX-010 in melanoma. MDX-010 in combination with the MDX-1379 tumor vaccine is currently in Phase III clinical development for the treatment of metastatic melanoma under a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, and has been granted Fast Track status by the FDA for the treatment of high risk Stage II, Stage III and Stage IV melanoma. We received an initial cash payment from BMS of \$50.0 million, of which \$25.0 million was for the purchase of our common stock at a small premium to the market price at the time we entered into the collaboration. We and BMS have agreed to jointly continue the investigation and the development of MDX-010 in additional tumor types and have jointly committed to an initial multi-year budget of approximately \$192.0 million to fund such development. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the U.S. and Europe, with the remaining 35% of the development costs to be paid by us. The parties will share equally the costs of any clinical trials of products intended solely for regulatory approval in the U.S., and BMS will be fully responsible for all development costs that relate solely to regulatory approval in Europe and other parts of the world. Under the terms of the collaboration, we could receive up to an additional \$205.0 million pursuant to the collaboration if all regulatory



milestones are met, and up to \$275.0 million in sales-related milestones. We will have an option to co-promote and share profits with BMS in the U.S. based on a 45:55 percentage split. BMS will receive an exclusive license to MDX-010 outside of the U.S. and pay us royalties on commercial sales.

In September 2004, we entered into a series of agreements with Pfizer, Inc. The first agreement amended our existing collaborative research and license and royalty agreements with Pfizer to provide for the discovery and development of up to 50 antibody products over ten years. Under this amendment, we have the potential to receive research funding, license fees and milestone payments (if certain development milestones are met), as well as royalties on any commercial sales of the products. The second and third agreements were a sublicense from us to Pfizer and a cross-license of certain patents and patent applications, in each case, solely relating to our respective anti-CTLA-4 antibody programs. Under these licenses, we have the potential to receive milestones and royalty payments based upon commercial sales of any Pfizer anti-CTLA-4 antibody product. In contrast, we have no future payment obligations to Pfizer in connection with any anti-CTLA-4 product we may develop. The fourth agreement was a stock purchase agreement also related to the anti-CTLA-4 programs. Pursuant to certain of these agreements, Pfizer made a total initial cash payment to us of \$110.0 million, of which \$30.0 million was for the purchase of our common stock at a small premium to market price at the time we entered into the collaboration.

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

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

## DESCRIPTION OF CAPITAL STOCK

The following is a description of our capital stock.

### General

Our restated certificate of incorporation authorizes the issuance of up to 200,000,000 shares of common stock, \$.01 par value per share, and authorizes the issuance of up to 2,000,000 shares of preferred stock, \$1.00 par value per share, the rights and preferences of which may be established from time to time by the Board of Directors. As of April 29, 2005, 110,792,172 shares of common stock were issued and 110,675,999 shares of common stock were outstanding and no shares of preferred stock were issued and outstanding.

### Common Stock

Each share of common stock entitles the holder thereof to one vote on all matters submitted to a vote of the shareholders. Since the holders of common stock do not have cumulative voting rights, holders of more than 50% of the outstanding shares can elect all of our directors and holders of the remaining shares by themselves cannot elect any directors. The holders of common stock do not have preemptive rights or rights to convert their common stock into other securities. Holders of common stock are entitled to receive ratably such dividends as may be declared by the Board of Directors out of funds legally available therefor. In the event of our liquidation, dissolution or winding up, holders of common stock have the right to a ratable portion of the assets remaining after payment of liabilities. All shares of common stock outstanding and to be outstanding upon completion of this offering are and will be fully paid and non-assessable.

### Preferred Stock

Our authorized preferred stock consists of 2,000,000 shares, par value \$1.00 per share. Our restated certificate of incorporation grants the Board of Directors the authority to issue by resolution shares of preferred stock in one or more series and to fix the number of shares constituting any such series, the voting powers, if any, designations, preferences and relative, participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including the rate or rates at which, and the other terms and conditions on which, dividends shall be payable; whether and on what terms the shares constituting any series shall be redeemable, subject to sinking fund provisions, or convertible or exchangeable; and the liquidation preferences, if any, of such series, without any further vote or action by the stockholders. For example, the Board of Directors is authorized to issue a series of preferred stock that would have the right to vote, separately or with any other series of preferred stock, on any proposed amendment to our restated certificate of incorporation, or any other proposed corporate action, including business combinations and other transactions. In connection with our shareholders rights plan, our Board of Directors has designated 250,000 shares of preferred stock as Series A Junior Participating Preferred Stock.

The authorization of undesignated preferred stock makes it possible for the Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company. The amendment of any of these provisions would require approval by holders of at least  $66\frac{2}{3}\%$  of the outstanding common stock.

### Registration Rights

We entered into a registration rights agreement with the initial purchasers of the notes, a copy of which has been incorporated by reference as an exhibit to the registration statement of which this

prospectus is a part. In the registration rights agreement we have agreed, for the benefit of the holders of the notes and the holders of the shares of common stock issued upon the conversion of the notes, referred to as the registrable securities, that we will, at our expense:

use our best efforts to cause the registration statement, of which this prospectus is a part, to be declared effective under the Securities Act; and

use our best efforts to keep continuously effective the registration statement until the earliest of (i) the sale of all outstanding registrable securities registered under the registration statement; (ii) the expiration of the period referred to in Rule 144(k) of the Securities Act with respect to the notes held by non-affiliates of us; (iii) all the registrable securities have ceased to be outstanding (whether as a result of redemption, repurchase, cancellation, conversion or otherwise); and (iv) two years after the effective date of the registration statement.

We are permitted to suspend the use of this prospectus in connection with the sale of registrable securities during prescribed periods of time for reasons relating to pending corporate developments, public filings with the SEC and other events. The periods during which we can suspend the use of this prospectus may not, however, exceed a total of 30 days in any 90-day period or a total of 90 days in any 12-month period. We will provide to each holder of registrable securities copies of this prospectus, notify each holder when the registration statement has become effective, notify each holder of any suspension of the use of this prospectus and take certain other actions required to permit public resales of the registrable securities.

A holder who elects to sell any registrable securities pursuant to the registration statement:

will be required to be named as a selling securityholder in this prospectus;

may be required to deliver a prospectus to purchasers;

may be subject to certain civil liability provisions under the Securities Act in connection with those sales; and

will be bound by the provisions of the registration rights agreement that apply to a holder making such an election, including certain indemnification provisions.

No holder of registrable securities will be entitled:

to be named as a selling security holder in the shelf registration statement as of the date the registration statement is declared effective; or

to use this prospectus for offers and resales of registrable securities at any time, unless such holder has returned a completed and signed notice and questionnaire to us by the deadline for response set forth in the notice and questionnaire.

Holders of registrable securities will, however, have at least 28 calendar days from the date on which the notice and questionnaire is first mailed to return a completed and signed notice and questionnaire to us. If we are required to send out a supplemental notice and questionnaire because of comments we receive from the SEC, holders of registrable securities may have less than 28 calendar days from the date on which the supplemental notice and questionnaire is first mailed to return a completed and signed supplemental notice and questionnaire to us.

Beneficial owners of registrable securities who have not returned a notice and questionnaire by the questionnaire deadline described above may receive another notice and questionnaire from us upon request. Following our receipt of a completed and signed notice and questionnaire, we will include the registrable securities covered thereby in the shelf registration statement.

This summary of certain provisions of the registration rights agreement is not complete and is subject to, and qualified in its entirety by reference to, all of the provisions of the registration rights agreement.

### **Shareholder Rights Plan**

We have 250,000 shares of Series A Junior Participating Preferred Stock authorized and reserved for issuance in connection with our shareholder rights plan set forth in our Rights Agreement dated May 23, 2001 with Continental Stock Transfer & Trust Company, as rights agent. Each outstanding share of our common stock has one preferred stock purchase right. The rights expire on July 6, 2011 unless exchanged or redeemed prior to that date. Our Board of Directors may extend the expiration date.

Generally, if any person or group acquires 20% or more of our common stock, the rights holders will be entitled to receive, upon exercise of a preferred stock purchase right, the number of shares of common stock that, at that time, have a market value equal to twice the purchase price of the right. The shares of preferred stock acquired upon exercise of a purchase right are not redeemable and are entitled to preferential quarterly dividends. They are also entitled to preferential rights in the event of liquidation. Finally, if any business combination occurs in which our common shares are exchanged for shares of another company, each preferred share will be entitled to receive 1,000 times the amount received per common share of Medarex.

If we are acquired in a business combination, the purchase rights holders will be entitled to acquire, for the purchase price, the number of shares of common stock of the acquiring corporation that, at the time, have a market value equal to twice the purchase price of the right. Our Board of Directors has the right to redeem the purchase rights in certain circumstances for \$.001 per share, subject to adjustment.

The rights plan is designed to protect our shareholders in the event of unsolicited offers to acquire us and other coercive takeover tactics, which, in the Board's opinion, would impair its ability to represent our shareholders' interests. The rights plan may make an unsolicited takeover more difficult or less likely to occur or may prevent a takeover, even though a takeover may offer our shareholders the opportunity to sell their stock at a price above the prevailing market rate and may be favored by a majority of our shareholders.

### **Certain Special Charter and By-Law Provisions**

Our restated certificate of incorporation and by-laws contain certain provisions that may delay, defer or prevent a change in control. Specifically, the Board of Directors is classified. Directors are elected for three year terms with only one class of board members elected each year. In addition, the by-laws provide that special meetings of shareholders may be called only by the President, the Chairman of the Board of Directors or the Board of Directors.

Furthermore, our restated certificate of incorporation, as amended, incorporates all of the provisions of the New Jersey Shareholders Protection Act (the "New Jersey Act"), which provides that resident New Jersey corporations may not engage in certain Business Combinations with any Interested Stockholder (as such terms are defined therein) for a period of five years following the date that such Interested Stockholder became the owner, directly or indirectly, of 10% or more of the voting power of our company, unless (i) such transaction is approved by our Board of Directors prior to the acquisition date, or (ii) the holders of two-thirds (66<sup>2</sup>/<sub>3</sub>%) of our voting stock, excluding the shares of the Interested Stockholder, approve such transaction. The New Jersey Act also precludes the purchase by us (except as hereinafter noted) at a premium over market of any of our voting stock from an Interested Stockholder who has owned such securities for less than five years. Notwithstanding the foregoing, such a purchase would be permitted if the same offer were made to all other holders of the

same kind of securities, or the transaction were approved by the holders of 66<sup>2</sup>/<sub>3</sub>% of our outstanding voting stock excluding the shares of any Interested Stockholder, or the Board of Directors approved such a transaction prior to such Interested Stockholder's acquisition date. Our restated certificate of incorporation, as amended, does not provide for any additional anti-takeover protections other than those set forth in the New Jersey Act.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004.

#### **SELLING SECURITYHOLDERS**

The 4.25% Convertible Senior Notes were originally issued by Medarex and sold by the initial purchasers of the notes in a transaction exempt from the registration requirements of the Securities Act to persons reasonably believed by the initial purchasers to be qualified institutional buyers in reliance on Rule 144A under the Securities Act. The shares of common stock issued upon conversion of the notes were issued pursuant to an exception from the registration requirements of the Securities Act. Selling securityholders, including their transferees, pledgees or donees or their successors, may from time to time offer and sell pursuant to this prospectus any or all of the shares of common stock issued upon conversion of the notes.

The following table sets forth information as of May 27, 2005, with respect to the selling securityholders and the numbers of shares of common stock beneficially owned by each selling securityholder that may be offered pursuant to this prospectus. The information is based on information provided by or on behalf of the selling securityholders. The selling securityholders may offer all, some or none of the common stock. Because the selling securityholders may offer all or some portion of the common stock, we cannot estimate the amount of the common stock that will be held by the selling securityholders upon termination of any of these sales. In addition, the selling securityholders identified below may have sold, transferred or otherwise disposed of all or a portion of their common stock since the date on which they provided the information regarding their stock in transactions exempt from the registration requirements of the Securities Act.

## Edgar Filing: MEDAREX INC - Form POS AM

Based upon information provided by the selling securityholders, none of the selling securityholders nor any of their affiliates, officers, directors or principal equity holders has held any position or office or has had any material relationship with us within the past three years.

Name	Shares of Common Stock Beneficially Owned(1)	Percentage of Outstanding Common Stock Beneficially Owned Prior to the Offering(2)	Shares of Common Stock Being Offered(3)	Common Stock Beneficially Owned After the Offering	Percentage of Common Stock Beneficially Owned After the Offering(2)
Polaris Vega Fund L.P.	297,652	*	297,652	*	*
Sunrise Partners L.P.	818,543	*	818,543	*	*
Alta Partners Holding LDC	744,130	*	744,130	*	*
LLT Limited	26,044	*	26,044	*	*
UBS OConnor LLC OConnor Global Convertible Arbitrage Master Limited	595,304	*	595,304	*	*
DBAG London	74,413	*	74,413	*	*
Silverback Master, Ltd.	1,339,434	*	1,339,434	*	*
Forest Fulcrum Fund L.P.	60,721	*	60,721	*	*
Associated Electric & Gas Insurance Service Limited	29,765	*	29,765	*	*
Citadel Equity Fund Ltd.	520,891	*	520,891	*	*
Citadel Jackson Investment Fund Ltd.	500,000	*	500,000	*	*
Barclays Global Investors Diversified Alpha Plus Funds	22,323	*	22,323	*	*
Forest Multi-Strategy Master Fund SPC	83,342	*	83,342	*	*
Zurich Institutional Benchmarks Master Fund, Ltd.	37,206	*	37,206	*	*
Forest Global Convertible Fund, Ltd., Class A-5	298,247	*	298,247	*	*
Lyxor/Forest Fund Ltd.	148,826	*	148,826	*	*
Relay 11 Holdings Co.	18,603	*	18,603	*	*
RBC Alternative Assets L.P.	4,911	*	4,911	*	*
Sphinx Convertible Arbitrage SPC	11,161	*	11,161	*	*
Univest Convertible Arbitrage Fund, Ltd.	16,370	*	16,370	*	*
Xavex Convertible Arbitrage 4 Fund	16,370	*	16,370	*	*
Salomon Brothers Asset Management, Inc.	4,289,168	3.9%	4,289,168	*	*
Hourglass Master Fund, Ltd.	1,201,770	1.1%	1,201,770	*	*
ZCM Asset Holding Co., Inc.	212,077	*	212,077	*	*
Radcliffe Spc, Ltd. (For and on behalf of the Class A Crossover Segregated Portfolio)	1,637,087	*	1,637,087	*	*
Aristeia International Ltd.	1,007,255	*	1,007,255	*	*
Aristeia Trading LLC	220,560	*	220,560	*	*
MLQA Convertible Securities Arbitrage Ltd.	744,130	*	744,130	*	*
Goldman Sachs & Co.(4)	732,850	*	3,721	729,129	*
Excelsior Master Fund L.P.	148,826	*	148,826	*	*
JP Morgan Securities, Inc.	297,652	*	297,652	*	*
UBS AG London	1,934,739	1.7%	1,934,739	*	*
Marathon Global Convertible Muster Fund, Ltd.	446,478	*	446,478	*	*

\*

Edgar Filing: MEDAREX INC - Form POS AM

Less than one percent.

(1)

Amounts indicated may be in excess of the total amount registered due to sales or transfers exempt from the registration requirements of the Securities Act since the date upon which the selling securityholders provided to us the information regarding their common stock.

(2)

Calculated based on Rule 13d-3(d)(i) under the Securities Exchange Act of 1934, as amended, using 110,675,999 shares outstanding as April 30, 2005. In calculating this amount, we treated as outstanding the number of shares of common stock issuable upon conversion of all of the

## Edgar Filing: MEDAREX INC - Form POS AM

convertible notes held by a particular holder. However, we did not assume the conversion of the convertible notes held by any other holder.

- (3) Unless otherwise noted, represents shares of common stock issued upon conversion of all of our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010.
- (4) Includes 729,129 shares of common stock held separate from conversion of our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010.

Selling securityholders who are registered broker-dealers or affiliates of registered broker-dealers may be deemed to be "underwriters" within the meaning of the Securities Act. To our knowledge, no selling securityholder who is a registered broker-dealer or an affiliate of a registered broker-dealer received any securities as underwriting compensation.

Information concerning other selling securityholders will be set forth in prospectus supplements from time to time, if required. Information concerning the securityholders may change from time to time, and any changed information will be set forth in supplements to this prospectus and/or statements to the registration statement of which this prospectus is a part, if and when necessary. In addition, the conversion price, and therefore the number of shares of common stock issuable upon conversion of the notes, is subject to adjustment under certain circumstances. Accordingly, the aggregate principal amount of notes and the number of shares of common stock into which the notes are convertible may increase or decrease.



**PLAN OF DISTRIBUTION**

The selling securityholders and their successors, which term includes their transferees, pledgees or donees or their successors may sell the common stock directly to purchasers or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling securityholders of the purchasers. These discounts, concessions or commissions as to any particular underwriter, broker-dealer or agent may be in excess of those customary in the types of transactions involved.

The common stock may be sold in one or more transactions at:

- fixed prices,
- prevailing market prices at the time of sale,
- prices related to the prevailing market prices,
- varying prices determined at the time of sale, or
- negotiated prices.

These sales may be effected in transactions:

- for the common stock, on any national securities exchange or quotation service on which our common stock may be listed or quoted at the time of sale, including the Nasdaq National Market,
- in the over-the-counter market,
- otherwise than on such exchanges or services or in the over-the-counter market,
- through the writing and exercise of options, whether the options are listed on an options exchange or otherwise, or
- through the settlement of short sales.

These transactions may include block transactions or crosses. Crosses are transactions in which the same broker acts as agent on both sides of the trade.

In connection with the sale of the common stock or otherwise, the selling securityholders may enter into hedging transactions with broker-dealers or other financial institutions. The broker-dealers or financial institutions may in turn engage in short sales of the common stock in the course of hedging the positions they assume with selling securityholders. The selling securityholders may also sell the common stock short and deliver these securities to close out such short positions, or loan or pledge the notes or the underlying common stock to broker-dealers that in turn may sell these securities.

The aggregate proceeds to the selling securityholders from the sale of the common stock offered by them hereby will be the purchase price thereof less discounts and commissions, if any. Each of the selling securityholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

Our outstanding common stock is listed for trading on the Nasdaq National Market under the symbol "MEDX".

## Edgar Filing: MEDAREX INC - Form POS AM

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers.

The selling securityholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock may be deemed to be "underwriters" within the meaning of Section 2(11) of

the Securities Act. Profits on the sale of the common stock by selling securityholders and any discounts, commissions or concessions received by any broker-dealers or agents might be deemed to be underwriting discounts and commissions under the Securities Act. Selling securityholders who are deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act. To the extent the selling securityholders may be deemed to be "underwriters," they may be subject to statutory liabilities, including, but not limited to, Sections 11, 12 and 17 of the Securities Act.

The selling securityholders and any other person participating in a distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder. Regulation M of the Exchange Act may limit the timing of purchases and sales of any of the securities by the selling securityholders and any other person. In addition, Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making activities with respect to the particular securities being distributed for a period of up to five business days before the distribution. The selling securityholders have acknowledged that they understand their obligations to comply with the provisions of the Exchange Act and the rules thereunder relating to stock manipulation, particularly Regulation M, and have agreed that they will not engage in any transaction in violation of such provisions.

To our knowledge, there are currently no plans, arrangements or understandings between any selling securityholder and any underwriter, broker-dealer or agent regarding the sale of the common stock by the selling securityholders.

A selling securityholder may decide not to sell any common stock described in this prospectus. We cannot assure you that any selling securityholder will use this prospectus to sell any or all of the common stock. Any securities covered by this prospectus which qualify for sale pursuant to Rule 144 or Rule 144A of the Securities Act may be sold under Rule 144 or Rule 144A rather than pursuant to this prospectus. In addition, a selling securityholder may transfer, devise or gift the common stock by other means not described in this prospectus.

With respect to a particular offering of the common stock, to the extent required, an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement of which this prospectus is a part will be prepared and will set forth the following information:

the common stock to be offered and sold,

the names of the selling securityholders,

the respective purchase prices and public offering prices and other material terms of the offering,

the names of any participating agents, broker-dealers or underwriters, and

any applicable commissions, discounts, concessions and other items constituting compensation from the selling securityholders.

We entered into the registration rights agreement for the benefit of holders of the common stock covered by this prospectus under applicable federal and state securities laws under certain circumstances and at certain times. The registration rights agreement provides that the selling securityholders and Medarex will indemnify each other and their respective directors, officers and controlling persons against specific liabilities in connection with the offer and sale of the common stock, including liabilities under the Securities Act, or will be entitled to contribution in connection with those liabilities. We will pay all of our expenses and specified expenses incurred by the selling securityholders incidental to the registration, offering and sale of the common stock to the public, but

each selling securityholder will be responsible for payment of any and all commissions, concessions, fees and discounts of underwriters, broker-dealers and agents.

This prospectus will only be delivered in printed form by hand or through the mails.

#### **LEGAL MATTERS**

Certain legal matters in connection with the shares of common stock offered hereby will be passed upon for us by Satterlee Stephens Burke & Burke LLP, New York, New York. Dwight A. Kinsey, Esq., a partner of Satterlee Stephens Burke & Burke LLP, owns 6,000 shares of our common stock. Mr. Kinsey also holds options to purchase 40,000 shares of our common stock which he received for services rendered as our Assistant Secretary. No other partner or associate of the law firm owns shares or holds options to purchase any of our shares having a fair market value either individually or in the aggregate in excess of \$50,000.

#### **EXPERTS**

The consolidated financial statements of Medarex, Inc. appearing in Medarex, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2004, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon included therein and incorporated herein by reference, which is based in part on the report of PricewaterhouseCoopers, independent registered public accounting firm. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

#### **ADDITIONAL INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or SEC, under the Exchange Act. The Exchange Act file number for our SEC filings is 0-19312. You may read and copy any document we file at the public reference facilities maintained by the SEC at 450 Fifth Street N.W., Judiciary Plaza, Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. We file information electronically with the SEC. Our SEC filings are available from the SEC's Internet site at [www.sec.gov](http://www.sec.gov), which contains reports, proxy and information statements and other information regarding issuers that file electronically. Our common stock is listed on the Nasdaq National Market System under the symbol "MEDX." You may read and copy our SEC filings and other information at the office of the Nasdaq Operations, 1735 K Street N.W., Washington, D.C. 20006. Copies of certain information filed by us with the SEC are also available on our website at [www.medarex.com](http://www.medarex.com). This website is not part of this prospectus.

#### **INCORPORATION BY REFERENCE**

We are "incorporating by reference" specified documents that we file with the SEC, which means:

Incorporated documents are considered part of this prospectus;

We are disclosing important information to you by referring you to those documents; and

Information that we file in the future with the SEC automatically will update and supersede earlier information in or incorporated by reference in this prospectus.

We incorporate by reference the documents listed below and any documents that we file in the future with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this

## Edgar Filing: MEDAREX INC - Form POS AM

prospectus and before the completion of the offering of the notes (other than current reports furnished under Item 9 or Item 12 of Form 8-K):

Our Current Report on Form 8-K filed with the SEC on May 20, 2005 (File No. 0-19312);

Our Current Report on Form 8-K filed with the SEC on May 9, 2005 (File No. 0-19312);

Our Current Report on Form 8-K filed with the SEC on March 18, 2005 (File No. 0-19312);

Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2005 filed with the SEC on May 10, 2005 (File No. 0-19312);

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, filed with the SEC on March 16, 2005 (File No. 0-19312); and

The information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, from our Proxy Statement for our 2005 Annual Meeting of Shareholders, filed with the SEC on April 8, 2005 (File No. 0-19312).

You should rely only upon the information provided in this document or incorporated in this document by reference. We have not authorized anyone to provide you with different information. You should not assume that the information in this document, including any information incorporated by reference, is accurate as of any date other than the date indicated on the front cover of this document or the date of the document incorporated by reference, as applicable.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address:

Medarex, Inc.  
707 State Road  
Princeton, New Jersey 08540  
(609) 430-2880  
ATTN: Secretary

Exhibits to the filings will not be sent, however, unless such exhibits have specifically been incorporated by reference in this document.

We will furnish our stockholders with annual reports that contain audited financial statements and quarterly reports for the first three quarters of each year that contain unaudited interim financial information.

**PART II****Information Not Required in Prospectus****Item 14. Other Expenses of Issuance and Distribution**

Expenses in connection with the issuance and distribution of the securities being registered, other than the underwriting discounts and commissions, are set forth in the following table. All amounts except the Securities and Exchange Commission registration fee are estimated.

	<b>Expenses</b>
Registration Fee Securities and Exchange Commission	\$ 11,500
Transfer Agent and Trustee's Fees and Expenses	15,000
Accounting Fees and Expenses	25,000
Legal Fees and Expenses	75,000
Blue Sky Fees and Expenses	5,000
Printing and Engraving	25,000
Miscellaneous	2,500
<b>TOTAL</b>	<b>\$ 159,000</b>

The Registrant will bear all of the expenses of the registration of the securities being offered.

**Item 15. Indemnification of Directors and Officers**

The Restated Certificate of Incorporation and the Registrant's Amended and Restated By-Laws provide for the indemnification of its Officers and Directors under certain circumstances and are incorporated herein by reference.

Section 14A:3-5 of The New Jersey Business Corporation Act (the "NJBCA") empowers a New Jersey corporation to indemnify any person who is or was a director, officer, employee or agent of the indemnifying corporation or of any constituent corporation absorbed by the indemnifying corporation in a consolidation or merger and any person who is or was a director, officer, trustee, employee or agent of any other enterprise, serving as such at the request of the indemnifying corporation, or of any such constituent corporation, or legal representative of any such director, officer, trustee, employee or agent (a "corporate agent"), against his expenses and liabilities incurred in connection with any proceeding involving the corporate agent, other than a proceeding by or in the right of the corporation, if (a) such corporate agent acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and (b) with respect to any criminal proceeding, such corporate agent had no reason to believe that his conduct was unlawful. In addition, a corporation may indemnify such corporate agent against his expenses in connection with any proceeding by or in the right of the corporation to procure a judgment in its favor which involves such corporate agent by reason of his having been such corporate agent, if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation. However, in such proceeding no indemnification shall be provided in respect of any claim, issue or matter as to which such corporate agent shall have been adjudged to be liable to the corporation, unless and only to the extent that the Superior Court of the State of New Jersey or the court in which such proceeding was brought shall determine upon application that despite the adjudication of liability, but in view of all circumstances of the case, such corporate agent is fairly and reasonably entitled to indemnity for such expenses as the Superior Court or such other court shall deem proper.

Under the NJBCA a corporation shall indemnify a corporate agent against expenses to the extent that such corporate agent has been successful on the merits or otherwise in any proceeding referred to above or in defense of any claim, issue or matter therein.

The indemnification and advancement of expenses provided by or granted pursuant to the NJBCA shall not exclude any other rights, including the right to be indemnified against liabilities and expenses incurred in proceedings by or in the right of the corporation, to which a corporate agent may be entitled under a certificate of incorporation, by-law, agreement, vote of shareholders, or otherwise; provided that no indemnification shall be made to or on behalf of a corporate agent if a judgment or other final adjudication adverse to the corporate agent establishes that his acts or omissions (a) were in breach of his duty of loyalty to the corporation or its shareholders, (b) were not in good faith or involved a knowing violation of law or (c) resulted in receipt by the corporate agent of an improper personal benefit.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Act") may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in that Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The Registrant maintains a standard form of officers' and directors' liability insurance policy which provides coverage to the officers and directors of the Registrant for certain liabilities, including certain liabilities which may arise out of this Registration Statement.

**Item 16. Exhibits and Financial Statement Schedules**

(a)

**Exhibits**

II-2

---

## Edgar Filing: MEDAREX INC - Form POS AM

The following exhibits are filed as part of this Registration Statement:

- <sup>1</sup>4.1 Indenture dated as of July 23, 2003 between the Registrant and the Wilmington Trust Company, including therein the form of the notes.
  - <sup>1</sup>4.2 Registration Rights Agreement dated July 23, 2003 among the Registrant and Goldman, Sachs & Co., UBS Financial Services, Inc., and J.P. Morgan Securities, Inc.
  - <sup>1</sup>4.3 Pledge Agreement dated as of July 23, 2003 between the Registrant and the Wilmington Trust Company, as securities intermediary.
  - <sup>2</sup>5.1 Opinion of Satterlee Stephens Burke & Burke LLP re: legality of securities being registered.
  - <sup>2</sup>10.1 Employment Agreement between the Registrant and Donald L. Drakeman dated January 5, 2004.
  - 12.1 Statement of Computation of Ratio of Earnings to Fixed Charges
  - 23.1 Consent of Ernst & Young LLP
  - 23.2 Consent of PricewaterhouseCoopers
  - <sup>2</sup>23.3 Consent of Satterlee Stephens Burke & Burke LLP (included in their opinion filed as Exhibit 5.1.)
  - <sup>2</sup>24.1 Power of Attorney
  - <sup>2</sup>25.1 Statement of Eligibility and Qualification on Form T-1 under the Trust Indenture Act of 1939, as amended.
- 

<sup>1</sup> Filed as an exhibit to the Registrant's Current Report on Form 8-K dated July 28, 2003.

<sup>2</sup> Previously filed.

**(b)**

### **Financial Statement Schedules**

All schedules are omitted because of the absence of the conditions under which they are required, or because the information called for is included in the financial statements or notes thereto.

### **Item 17. Undertakings**

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sale are being made, a post-effective amendment to this Registration Statement:

(i) to include any prospectus required by Section 10(a) (3) of Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424 (b) under the Securities Act of 1933 if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and



## Edgar Filing: MEDAREX INC - Form POS AM

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

Provided, however, that paragraph (1) (i) and (1) (ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the Registrant pursuant to Section 13 or Section 15 (d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new Registration Statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13 (a) or Section 15 (d) of the Securities Exchange Act (and, where applicable, each filing of any employee benefit plan's annual report pursuant to Section 15 (d) of the Securities Exchange Act) that is incorporated by reference in the Registration Statement shall be deemed to be a new Registration Statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(5) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305 (b) (2) of the Act.



Power of Attorney previously filed

II-5

---

**INDEX TO EXHIBITS**

- 12.1 Statement Re: Computation of Ratio of Earning to Fixed Changes.
  - 23.1 Consent of Ernst & Young LLP.
  - 23.2 Consent of PricewaterhouseCoopers.
-

QuickLinks

[MEDAREX, INC.](#)

[18,603,263 Shares of Common Stock](#)

[TABLE OF CONTENTS](#)

[PROSPECTUS SUMMARY](#)

[Medarex, Inc.](#)

[The Offering](#)

[RISK FACTORS](#)

[FORWARD-LOOKING STATEMENTS](#)

[USE OF PROCEEDS](#)

[PRICE RANGE OF COMMON STOCK](#)

[DIVIDEND POLICY](#)

[RATIO OF EARNINGS TO FIXED CHARGES](#)

[BUSINESS](#)

[DESCRIPTION OF CAPITAL STOCK](#)

[SELLING SECURITYHOLDERS](#)

[PLAN OF DISTRIBUTION](#)

[LEGAL MATTERS](#)

[EXPERTS](#)

[ADDITIONAL INFORMATION](#)

[INCORPORATION BY REFERENCE](#)

[PART II Information Not Required in Prospectus](#)

[SIGNATURES](#)

[INDEX TO EXHIBITS](#)