

MEDAREX INC  
Form S-3/A  
November 16, 2004

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

As filed with the Securities and Exchange Commission on November 16, 2004

REGISTRATION NO. 333-117823

---

---

## SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

---

### AMENDMENT NO. 1 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 S-3/A

---

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

**\$150,000,000**

**MEDAREX, INC.**

**2.25% Convertible Senior Notes Due May 15, 2011  
Shares of Common Stock Issuable Upon Conversion of the Notes**

In May 2004, we issued and sold \$150,000,000 aggregate principal amount of our 2.25% Convertible Senior Notes, due May 15, 2011, in a private offering. This prospectus will be used by selling securityholders to resell the notes and the common stock issuable upon conversion of such notes at any time at market prices prevailing at the time of sale or at privately negotiated prices. 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.

The notes have the following provisions:

The holders of the notes may convert the notes into shares of our common stock at any time at a conversion price of approximately \$13.72 per share, which is equivalent to a conversion rate of 72.9129 shares per each \$1,000 principal amount of notes, subject to adjustment;

We will pay interest on the notes on May 15 and November 15 of each year commencing November 15, 2004;

The notes are senior unsecured obligations;

The notes will mature on May 15, 2011;

The notes are subject to redemption prior to maturity at any time on or after May 20, 2009 in accordance with the terms and conditions set forth herein under the sections entitled "Description of the Notes - Optional Redemption"; and

In the event of a Change of Control, as described in this prospectus, each holder of the notes may require us to repurchase some or all of the holder's notes at 100% of the principal amount of the notes plus accrued and unpaid interest. At our option, we may repurchase the notes for cash or common stock or a combination of cash, common stock or securities of a company that acquires us. See "Description of the Notes - Repurchase at Option of Holders Upon a Change of Control."

We do not intend to list the notes for trading on any national securities exchange or on the NASDAQ National Market.

Our common stock currently trades on the NASDAQ National Market under the symbol "MEDX." The last reported sale price on November 15, 2004 was \$9.51 per share.

---

**Investing in our securities involves risks. See "Risk Factors" on page 8 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 November 16, 2004**

---

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
SUMMARY CONSOLIDATED FINANCIAL DATA	5
RECENT DEVELOPMENTS	7
RISK FACTORS	8
FORWARD-LOOKING STATEMENTS	33
USE OF PROCEEDS	34
PRICE RANGE OF COMMON STOCK	34
DIVIDEND POLICY	35
RATIO OF EARNINGS TO FIXED CHARGES	35
CAPITALIZATION	36
BUSINESS	37
DESCRIPTION OF THE NOTES	39
DESCRIPTION OF CAPITAL STOCK	54
SELLING SECURITYHOLDERS	56
PLAN OF DISTRIBUTION	60
MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS	62
LEGAL MATTERS	70
EXPERTS	70
ADDITIONAL INFORMATION	70
INCORPORATION BY REFERENCE	70

**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 and development 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 diseases.

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

Currently, 20 antibody products derived from our UltiMAB human antibody development technology are in human clinical trials, or have had regulatory applications submitted for such trials. These antibodies are designed to treat a wide range of diseases, such as cancer (including various lymphomas), rheumatoid arthritis and other inflammatory, autoimmune and infectious diseases.

As of October 29, 2004, we have more than 45 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to enable other companies to use our proprietary technology in their development of new therapeutic products.

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®, and KM-Mouse® are registered trademarks of Medarex, Inc. UltiMAB® and Ultra-Potent Toxin and UPT are trademarks 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**

<b>Issuer</b>	Medarex, Inc.
<b>Securities Offered</b>	\$150,000,000 aggregate principal amount of 2.25% convertible senior notes due May 15, 2011.
<b>Maturity Date</b>	May 15, 2011, unless earlier redeemed, repurchased or converted.
<b>Interest</b>	2.25% per annum on the principal amount, payable semi-annually in arrears in cash on May 15 and November 15 of each year, commencing November 15, 2004. The first interest payment included interest from May 3, 2004, the date of issuance of the notes.
<b>Conversion</b>	<p>You may convert the notes at any time into shares of common stock at a conversion rate equal to 72.9129 shares of common stock per \$1,000 principal amount of notes, which is equivalent to a conversion price of approximately \$13.72 per share of common stock. The conversion rate is subject to adjustment in certain events.</p> <p>You may convert the notes at any time before the close of business on the maturity date, unless we have previously redeemed or repurchased the notes. Holders of notes called for redemption or repurchase will be entitled to convert the notes up to and including the business day prior to the date fixed for redemption or repurchase, as the case may be.</p>
<b>Ranking</b>	The notes are senior unsecured obligations and will rank equal in right of payment with our existing and future unsecured and unsubordinated indebtedness. The notes will be effectively subordinated to any future secured indebtedness to the extent of the value of the assets securing such indebtedness. The notes will be effectively subordinated to any future secured indebtedness to the extent of the value of the assets securing such indebtedness. The notes will also be "structurally subordinated" to the indebtedness and other liabilities of our existing subsidiaries and any future subsidiaries, including trade payables in existence on or after the date hereof. As of September 30, 2004, our subsidiaries had approximately \$3.3 million of indebtedness and other liabilities as to which the notes would have been "structurally subordinated," excluding intercompany liabilities. The indenture under which the notes were issued does not restrict us or any of our subsidiaries from incurring additional senior or other indebtedness and other liabilities, including secured indebtedness.
<b>Optional Redemption</b>	On or after May 20, 2009, we may redeem some or all of the notes at any time at the redemption prices specified in this prospectus, plus accrued and unpaid interest to the redemption date.

**Global Notes;**

**Book Entry System**

The notes may be issued only in fully registered form without interest coupons and in denominations of \$1,000 and greater multiples. The notes are evidenced by a global note deposited with the trustee for the notes, as custodian for The Depository Trust Company, or DTC. Beneficial interests in the global note will be shown on, and transfers of those beneficial interests can only be made through, records maintained by DTC and its participants. See "Description of the Notes Form, Denomination, Transfer, Exchange and Book-Entry Procedures."

**Repurchase at Holder's Option upon a Change in Control**

You may require us to repurchase your notes upon a change in control in cash, or, at our option, in our common stock or a combination of cash and common stock, at 100% of the principal amount of the notes to be repurchased plus accrued and unpaid interest to, but excluding, the repurchase date. If we pay the repurchase price in common stock, the common stock will be valued at 95% of the average closing sales price of the common stock on the NASDAQ National Market for the five consecutive trading days ending on the third trading day prior to the repurchase date.

**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.

**Events of Default**

The following are events of default under the indenture for the notes:

we fail to pay the principal of or any premium on any note when due;

we fail to pay any interest or any liquidated damages on any note when due, which failure continues for 30 days;

we fail to provide notice of a change in control;

we fail to perform any other covenant in the indenture and that failure continues for 60 days after written notice to us by the trustee or the holders of at least 25% in aggregate principal amount of outstanding notes;

any indebtedness under any bonds, debentures, notes or other evidences of indebtedness for money borrowed, or any guarantee thereof, by us or any of our significant subsidiaries, in an aggregate principal amount in excess of \$20 million is not paid when due either at its stated maturity or upon acceleration thereof, and such indebtedness is not discharged, or such acceleration is not rescinded or annulled, within a period of 30 days after notice as provided in the indenture; and

events of bankruptcy, insolvency or reorganization specified in the indenture.

**The NASDAQ National Market  
Symbol for Common Stock**

MEDX.

**Trading of Notes**

Prior to this offering, the notes have been eligible for trading on the PORTAL Market of the NASDAQ Stock Market, Inc. Notes sold by means of this prospectus are not expected to remain eligible for trading on the PORTAL Market. We do not intend to list the notes for trading on any national securities exchange or on the NASDAQ National Market.

**Governing Law**

The indenture and the notes will be governed by the laws of the State of New York.

**Risk Factors**

You should carefully consider all of the information contained or incorporated by reference in this prospectus prior to investing in the notes. In particular, we urge you to carefully consider the information set forth under "Risk Factors" beginning on page 8 of this prospectus for a discussion of risks and uncertainties relating to us, our business and an investment in the notes.



## SUMMARY CONSOLIDATED FINANCIAL DATA

The following table sets forth consolidated financial information for the periods indicated. The summary consolidated financial information for each of the years in the five-year period ended December 31, 2003 and at December 31 of each of those years has been derived from our audited consolidated financial statements. The financial information set forth below for the nine months ended September 30, 2003 and 2004 has been derived from unaudited consolidated financial information, which we believe presents fairly such consolidated information in conformity with U.S. generally accepted accounting principles and includes all adjustments, consisting only of normal recurring adjustments, that in the opinion of management are necessary for a fair presentation. Results for the nine months ended September 30, 2004 are not necessarily indicative of the results that may be expected for any other interim periods or for the year as a whole. You should read the summary consolidated financial information in conjunction with our consolidated financial statements and the notes thereto and the other financial information incorporated by reference in this prospectus.

	For the Year Ended December 31,					For the Nine Months Ended September 30,	
	1999	2000	2001	2002	2003	2003	2004
	(in thousands, except per share data)					(unaudited)	
<b>Statement of Operations Data:</b>							
Revenues:							
Sales	\$ 1,079	\$ 264	\$ 191	\$ 176	\$ 25	\$ 25	\$
Contract and license revenues	8,593	19,619	37,140	24,552	5,833	4,593	4,807
Sales, contract and license revenues from Genmab	252	2,574	4,973	14,751	5,316	3,857	2,714
Total revenues	9,924	22,457	42,304	39,479	11,174	8,475	7,521
Costs and expenses:							
Cost of sales	709	1,189	642	8,327	3	3	
Research and development	19,929	33,942	38,626	82,626	95,459	72,018	93,695
General and administrative	8,036	18,142	19,344	22,852	21,727	16,204	16,985
Write-off of facility costs				11,294			
Acquisition of in-process technology				16,312	6,500		5,439
Total costs and expenses	28,674	53,273	58,612	141,411	123,689	88,225	116,119
Operating loss	(18,750)	(30,816)	(16,308)	(101,932)	(112,515)	(79,750)	(108,598)
Equity in net loss of affiliate		(353)	(7,334)	(50,625)	(14,997)	(11,593)	(14,478)
Interest and investment income	1,205	21,158	24,728	18,495	12,342	8,299	8,323
Impairment loss on investment in partners				(11,886)	(1,400)		
Additional payments related to asset acquisition				(2,425)	(31)	(86)	(245)
Interest expense	(8)	(3)	(4,615)	(9,065)	(11,777)	(8,013)	(10,090)
Gain on disposition of Genmab stock			1,442				
Net loss on extinguishment of debt							(4,241)
Income (loss) before provision (benefit) for income taxes	(17,553)	(10,014)	(2,087)	(157,438)	(128,378)	(91,143)	(129,329)
Provision (benefit) for income taxes	(522)	(13,075)	600	103	69	45	191
Income (loss) before cumulative effect of change in accounting principle	(17,031)	3,061	(2,687)	(157,541)	(128,447)	(91,188)	(129,520)
Cumulative effect of change in accounting principle					(830)	(830)	
Net income (loss)	\$ (17,031)	\$ 3,061	\$ (2,687)	\$ (157,541)	\$ (129,277)	\$ (92,018)	\$ (129,520)
Basic net income (loss) per share before cumulative effect of change in accounting principle	\$ (0.27)	\$ 0.04	\$ (0.04)	\$ (2.09)	\$ (1.64)	\$ (1.17)	\$ (1.62)
Basic net income (loss) per share cumulative effect of change in accounting principle					(0.01)	(0.01)	

Edgar Filing: MEDAREX INC - Form S-3/A

	For the Year Ended December 31,					For the Nine Months Ended September 30,								
Basic net income (loss) per share(1)	\$	(0.27)	\$	0.04	\$	(0.04)	\$	(2.09)	\$	(1.65)	\$	(1.18)	\$	(1.62)
Diluted net income (loss) per share before cumulative effect of change in accounting principle	\$	(0.27)	\$	0.04	\$	(0.04)	\$	(2.09)	\$	(1.64)	\$	(1.17)	\$	(1.62)
Diluted net income (loss) per share cumulative effect of change in accounting principle										(0.01)		(0.01)		
Diluted net income (loss) per share(1)	\$	(0.27)	\$	0.04	\$	(0.04)	\$	(2.09)	\$	(1.65)	\$	(1.18)	\$	(1.62)
Weighted average common shares outstanding(1)														
basic		63,840		71,532		73,937		75,231		78,314		78,046		79,981
diluted		63,840		73,232		73,937		75,231		78,314		78,046		79,981
Ratio (deficiency) of earnings available to cover fixed charges(2)								2.08						

Edgar Filing: MEDAREX INC - Form S-3/A

	December 31,					September 30,
	1999	2000	2001	2002	2003	2004
	(in thousands)					(unaudited)
<b>Balance Sheet Data:</b>						
Cash, cash equivalents and marketable securities	\$ 30,147	\$ 343,603	\$ 466,952	\$ 350,046	\$ 358,458	\$ 378,551
Working capital	22,382	329,807	447,326	339,480	350,437	360,815
Total assets	40,482	558,107	720,427	549,051	557,726	570,611
Long term obligations	23		175,000	175,000	300,000	296,986
Cash dividends declared per common share						
Accumulated deficit	(126,436)	(123,375)	(126,062)	(283,603)	(412,880)	(542,400)
Total shareholders' equity	22,299	485,289	482,562	352,143	234,011	159,414

(1) Computed on the basis described in note 2 to the consolidated financial statements.

(2) The ratio of earnings to fixed charges is computed by dividing "earnings," or loss from continuing operations before income taxes plus fixed charges, by fixed charges. Fixed charges consist of interest expense and that portion of rental payments under operating leases we believe to be representative of interest. "Earnings" were insufficient to cover fixed charges by \$17.6 million, \$9.7 million, \$106.8 million and \$113.4 million for the years ended December 31, 1999, 2000, 2002 and 2003, respectively, and \$79.6 million and \$114.9 million for the nine months ended September 30, 2003 and 2004, respectively.

## RECENT DEVELOPMENTS

On November 7, 2004, we entered into a collaboration and co-promotion agreement and a related securities purchase agreement with Bristol-Myers Squibb Company, or BMS, pursuant to which we and BMS will each grant the other certain intellectual property licenses and product rights on a worldwide basis in order to enable us both to collaborate in research and development of therapeutic antibody-based products for the treatment of cancer and other diseases, and, in the event that further development work is successful, to commercialize any resulting products. In particular, the collaboration includes a grant by us to BMS of a license to commercialize MDX-010, a fully human antibody product developed using our UltiMAB Human Antibody Development System®, that is antagonistic to cytotoxic T-lymphocyte antigen 4 (CTLA-4). MDX-010 is currently under investigation for the treatment of a broad range of cancers and other diseases. The collaboration also includes the grant by us to BMS of a license to MDX-1379, a gp100 peptide vaccine, for use with MDX-010 for the treatment of metastatic melanoma. The FDA has granted Fast Track designation for MDX-010 in combination with MDX-1379 for the treatment of previously treated, unresectable Stage III and Stage IV metastatic melanoma, and we are currently conducting a Phase III clinical trial with MDX-010 and MDX-1379 combination therapy in Stage III and Stage IV metastatic melanoma patients at multiple sites within the United States.

As part of the collaboration, we and BMS have committed to an initial multi-year budget of approximately \$192 million to fund our development of MDX-010 as a potential treatment for a broad range of cancers. BMS will be responsible for 65% of all development costs related to clinical trials intended to support regulatory approval in both the United States and Europe, with the remaining 35% to be paid by us. The parties will share equally the costs of any clinical trials of products intended solely for regulatory approval in the United States, and BMS will be fully responsible for all development efforts that relate solely to regulatory approval in Europe and other parts of the world.

Under the terms of the collaboration, we could receive up to \$205 million from BMS if all regulatory milestones are met, plus up to an additional \$275 million in sales-related milestones. We will also have the option to co-promote any products in the United States, and, if we elect to exercise this option, we will receive 45%, subject to certain adjustments, of any profits from commercial sales. In the event we choose not to exercise our co-promotion rights, BMS will have exclusive commercial rights in the United States and will pay us royalties on commercial sales. Outside the United States, BMS will have exclusive commercial rights and will pay us royalties on commercial sales.

Pursuant to these agreements, BMS will make an initial cash payment to us of \$25 million. In addition, BMS will purchase a total of 2,879,223 unregistered shares of our common stock at a purchase price equal to \$8.6829 per share for an aggregate purchase price of \$25 million. These shares will be issued in a private placement pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. The purchase price represents a premium to the market price on the date the Agreement was signed. BMS has agreed to a two-year lock-up period with respect to any sales of such stock. We have no future obligation to register such stock.

The transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and is also subject to receipt of consent from the U.S. Public Health Service of the sublicense to BMS of our rights to MDX-1379, as well as other customary conditions.

Our wholly-owned subsidiary Celldex Therapeutics, Inc. has filed a registration statement with the Securities and Exchange Commission related to a proposed public offering of a portion of its common stock. As part of this transaction, we have assigned or licensed to Celldex certain intellectual property related to our vaccine technology, including the rights to MDX-1307, one of our product candidates for the treatment of cancer, as well as the IND associated with this product which became effective in February 2004. If the offering is completed, we anticipate that we will continue to hold approximately 75% of the outstanding shares of common stock of Celldex. We cannot assure you that this transaction will be consummated.

## RISK FACTORS

*An investment in our securities involves a number of risks. In deciding whether to invest, you should carefully consider the following factors, the information contained in this prospectus and the other information that we have referred you to. It is especially important to keep these risk factors in mind when you read forward-looking statements.*

### Risks Related to Medarex

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

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Active product candidates employing our human antibody technology are in the early and middle stages of clinical development. Based on public disclosures, regulatory applications, including Investigational New Drug Applications, or INDs, have been submitted to the FDA or comparable foreign authorities, for 20 product candidates derived from our UltiMab platform. To date, neither we nor our partners have any product candidates employing our human antibody technology that have been approved for sale by the FDA or comparable foreign authorities and/or commercialized. In addition, we are not aware of any commercialized fully human monoclonal antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond the early or middle stages of product development or demonstrate clinical safety and effectiveness.

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

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

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

delays in product development, clinical testing or manufacturing;

unplanned expenditures in product development, clinical testing or manufacturing;

failure in clinical trials or failure to receive regulatory approvals;

emergence of superior or equivalent products;

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

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

election by our partners not to pursue product development;

failure by our partners to develop products successfully; and

failure to achieve market acceptance.

## Edgar Filing: MEDAREX INC - Form S-3/A

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

effectiveness. In addition, we determined not to continue the development of one late-stage product candidate due to both a lack of effectiveness and unforeseen safety issues that arose in clinical testing. None of these products employed our core fully human antibody technology.

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

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

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

We have incurred large operating losses and we anticipate that these losses will continue for the foreseeable future. In particular, as of September 30, 2004, we had an accumulated deficit of approximately \$542.4 million. Our net losses were \$129.3 million and \$129.5 million for the year ended December 31, 2003 and the nine month period ended September 30, 2004, 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 new laboratory and manufacturing facilities and manufacturing of products;  
and

general and administrative costs relating to our operations.

We intend to continue to make significant investments in:

research and development;

preclinical testing and clinical trials;

establishing new collaborations; and

new technologies.

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

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

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

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

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

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

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

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

changes in regulatory requirements for clinical trials;

costs and expenses associated with preclinical testing and clinical trials;

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;



## Edgar Filing: MEDAREX INC - Form S-3/A

competing technological and market developments;

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

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

We believe our current sources of liquidity will be sufficient to meet our near term operating, debt service and capital requirements for at least the next 24 months. However, this 24-month period assumes the use of a significant portion of the proceeds we received from the sale of our convertible notes. To the extent our convertible notes are converted into shares of our common stock on or before their maturity dates, we will have use of that portion of the principal amount of the notes so converted to fund our on-going operations. In any event, we will 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 a significant amount of existing debt and debt service obligations, which, unless converted to shares of our common stock or redeemed, will mature in 2010 (approximately \$147.0 million) and 2011 (\$150.0 million), respectively. Our ability to make payments on our debt will depend on our future operating performance and ability to generate cash and may also depend on our ability to obtain additional debt or equity financing. Generally, during the last five years, our operating cash flows were negative and insufficient to cover our fixed charges. Our ability to generate sufficient operating cash flow to service our indebtedness, including the notes, and fund our operating requirements will depend on our ability, alone or with others, to successfully develop, manufacture, and obtain required regulatory approvals and market our product candidates, as well as other factors, including general economic, financial, competitive, legislative and regulatory conditions, some of which are beyond our control. If we are unable to generate sufficient operating cash flow to service our indebtedness and fund our operating requirements, we may need to obtain additional debt or equity financing to do so, which may not be available to us on satisfactory terms or at all. In addition, if new indebtedness is incurred, the risks relating to our ability to service our indebtedness that we face could intensify.

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

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

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

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

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

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

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

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

commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

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

slower than expected rates of patient recruitment;

the inability to adequately observe patients after treatment;

changes in regulatory requirements for clinical trials;

the lack of effectiveness during the clinical trials;

unforeseen safety issues;

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

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

Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our human antibody technology. In a number of instances, we have terminated the development of certain products in the early stages of human clinical testing due to a lack of effectiveness. None of these products employed our core fully human antibody technology. In addition, we have determined not to continue the development of one late-stage product candidate due to both a lack of effectiveness and unforeseen safety issues that arose in clinical testing. This product did not employ our core fully human antibody technology.

Generally, our clinical trials, including our melanoma trials, are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product is used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our products. The most common adverse events associated with our melanoma trials have consisted of flu-like symptoms such as fever, chills and nausea. These events were expected and generally responded to standard medical therapy. In addition, some patients have experienced anticipated drug-related autoimmune adverse events, such as dermatitis and colitis, ranging from mild in most cases to severe in a very small number of instances. Almost all of these adverse events responded to medical therapy. In a very small number of instances, fatalities have occurred during the course of these trials such fatalities may or may not be attributable to our product. We believe that these adverse events will not materially affect our ability to continue with clinical trials of this product as planned. We cannot assure you that additional safety issues will not arise with respect to our products in the future.

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

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

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

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

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

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

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

cost-effectiveness;

alternative treatment methods;

reimbursement policies of government and third-party payors; and

marketing and distribution support for our product candidates.

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

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

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

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

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

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

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

New federal legislation, enacted in December 2003, has added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations may increase pressures to lower prices. While the new law specifically prohibits the United States government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the United States government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating de facto price controls on prescription drugs. In addition, the new law contains triggers for Congressional consideration of cost containment measures for Medicare in 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 continues to rise due to the limited enforcement resources of the FDA and the U.S. Customs Service, and the pressure in the current political environment to permit the imports as a mechanism for expanding access to lower priced medicines.

In addition, in December 2003, federal legislation was enacted to change United States import laws and expand the ability to import lower priced versions of our and competing products from

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

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

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

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

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

We may also encounter problems with the following:

production yields;

quality control and assurance;

shortages of qualified personnel;

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

changes in FDA requirements;

production costs; and/or

development of advanced manufacturing techniques and process controls.

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

access proprietary antigens for the development of product candidates;

access skills and information that we do not possess;

fund our research and development activities;

manufacture products;

fund and conduct preclinical testing and clinical trials;

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

commercialize and market future products.

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

our partners have significant discretion whether to pursue planned activities;

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

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

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

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



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

Our licensing partners generally have the right to terminate our partnerships at any time. Our ability to continue our current partnerships and to enter into additional partnerships is dependent in large part on our ability to successfully demonstrate that our UltiMAb technology is an attractive method of developing fully human antibody therapeutic products. We have generated only a limited

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

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

significantly increase our need for capital; and/or

place additional strain on management's time.

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

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

Due to the size of our interest in Genmab, we are currently required to account for our equity interest in Genmab under the equity method of accounting, which provides that we must include a portion of Genmab's income and losses equal to our percentage equity interest in Genmab in our consolidated financial statements. For the years ended December 31, 2001, 2002 and 2003, our share of Genmab's losses were approximately \$7.3 million, \$19.6 million and \$15.0 million, respectively. For the nine month period ended September 30, 2004, our share of Genmab's net loss was \$14.5 million.

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

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

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

investments in publicly traded companies. During the year ended December 31, 2003, no impairment charges were recorded related to the value of our investments in publicly traded companies. For the three and nine month periods ended September 30, 2004, we recorded impairment charges of \$0 and \$0.2 million, respectively, 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. Because these securities are not publicly traded, the value of our investments in these companies are inherently more difficult to estimate than our investments in publicly traded companies. We estimate the value of these investments by using information acquired from industry trends, the management of these companies, financial statements, and other external sources. 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 and 2003, we recorded impairment charges of approximately \$2.4 million and \$1.4 million, respectively, on our investments in privately-held companies. For the three and nine month periods ended September 30, 2004, we recorded impairment charges of \$0 and \$0.1 million, respectively, on investments in partners whose securities are privately held. 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 United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. While a number of patents have been issued in the United States and Europe relating to our human antibody technology, we may not be able to obtain patent protection in other countries. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued or enforceable. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide sufficient protection against competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

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

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

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

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

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

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

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

Moreover, other parties could have blocking patent rights to products made using HuMAb-Mouse technology, such as antibodies, and their production and uses, for instance because of a proprietary

position covering the antibody or the antibody's target. For example, we are aware of certain United States and European patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets and bispecific products, and the manufacture and use of such products. In particular, we are aware of certain United States and foreign patents and patent applications owned by third parties that pertain to monoclonal antibodies against CTLA-4, such as MDX-010, and their uses. We are also aware of certain United States and foreign patents and patent applications held by third parties relating to anti-CD4 antibodies, such as HuMax-CD4, anti-CD30 antibodies, such as MDX-060, anti-EGFr antibodies, such as HuMax-EGFr, and anti-PSMA antibodies, such as MDX-070, as well as other antibody products under development by us.

We are also aware of a United States patent owned by Genentech, Inc., relating to the production of recombinant antibodies in host cells. We currently produce certain of our products and our partners' products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in this patent, then we may need to obtain a license, should one be available. If we are unable to obtain a license on commercially reasonable terms, we may be restricted in our ability to make recombinant antibodies using Genentech's techniques. In addition to the Genentech patent, we are also aware of certain United States patents held by third parties relating to antibody expression in particular types of host cells, including CHO cells, which may be relevant to our current or future manufacturing techniques.

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

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

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

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 Brewery Co., Ltd., which provides for us to exchange certain cross-licenses for each other's technology for the development and commercialization of human antibody products made using the HuMAb-Mouse, the

KM-Mouse and certain other antibody-generating mice. Kirin has certain rights to distribute and use such mice throughout the world. Our business may suffer as a consequence of competition from Kirin or if the Collaboration and License Agreement were breached or terminated for any reason.

**We have had and may continue to face product liability claims related to the use or misuse of products employing our antibody technology.**

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

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

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

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

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

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, Inc. which enable them 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, Inc., Amgen, Biogen Idec, Novartis, Genentech, Inc., Protein Design Labs, Inc., Wyeth, Abbott and Corixa Corporation have generated therapeutic products that are currently on the market and that are derived from recombinant DNA that comprise human antibody components.

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

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

developing products;

undertaking preclinical testing and clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing and marketing products.

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

## Edgar Filing: MEDAREX INC - Form S-3/A

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

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

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

impose additional costs on us or our partners;

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

adversely affect our receipt of revenues or royalties.

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

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

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

warning letters;



finest;

import and/or export restrictions;

product recalls or seizures;

injunctions;

total or partial suspension of production;

civil penalties;

withdrawals of previously approved marketing applications or licenses;

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

criminal prosecutions.

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

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

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

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

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

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

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

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

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

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

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

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

Under current U.S. law and FDA policy, generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, may be approved through an abbreviated approval process. In general terms, the generic applicant references an approved innovator

product for which full clinical data demonstrating safety and effectiveness exist for the approved conditions of use. The generic applicant in turn need only demonstrate that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as the referenced innovator drug, and that the generic product is absorbed in the body at the same rate and to the same extent as the referenced innovator drug (this is known as bioequivalence). In addition, the generic application must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the referenced innovator drug.

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

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

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

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

**Our stock price may be volatile.**

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

fluctuations in our operating results;

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

published reports by securities analysts;

progress with clinical trials;

governmental regulation;

developments in patent or other proprietary rights;

developments in our relationship with collaborative partners;

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

general market conditions.

During the two-year period ended September 30, 2004, the sale prices of our common stock ranged between \$3.15 and \$11.13. The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these or other factors, including the sale or attempted sale of a large amount of our common stock into the market. Broad market fluctuations may also adversely affect the market price of our common stock.

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

As of October 29, 2004, we had 14,306,831 shares of common stock reserved for issuance pursuant to options and other stock based awards which had been granted under our stock option plans having a weighted average exercise price of \$7.84 per share and we had reserved 1,052,154 shares of common stock for issuance pursuant to future grants of options under our stock option plans. We have filed registration statements on Form S-8 covering all of these shares, other than 500,000 shares of common stock reserved for issuance under our 2004 New Employee Stock Option Plan. We intend to file a registration statement covering these shares prior to the grant of any options under this plan. Except for these unregistered shares, shares issued pursuant to these plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

In addition, as of that date, there were 233,269 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 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 October 29, 2004, we had reserved 1,095,447 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 covering 95,447 of those shares. The remaining 1,000,000 shares have not yet been registered but we intend to file a registration statement covering these shares prior to issuance under this plan. Upon the effectiveness of such registration statement, all shares issued under this plan, other than shares issued to affiliates, will be freely tradable on the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

The exercise of all or a portion of the outstanding options may result in a significant increase in the number of shares of our common stock that will be subject to trading on the NASDAQ National Market 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 October 29, 2004, we had 21,875,353 shares of common stock reserved for issuance pursuant to the conversion of the approximately \$147.0 million aggregate principal amount of our outstanding 4.25% Convertible Senior Notes due August 15, 2010. Holders of these notes may convert their notes

into shares of common stock at any time prior to maturity or their redemption by us at a conversion rate of 148.8261 shares per each \$1,000 principal amount of the notes (\$6.72 per share), subject to adjustment.

As of October 29, 2004, 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 October 29, 2004, we had 85,451,840 shares of common stock outstanding, of which 6,278,355 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 stockholders. These shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitations of Rule 144.

In addition, we have filed a shelf registration statement on Form S-3 under the Securities Act relating to the sale of up to \$290.31 million of any of the following securities:

debt securities;

preferred stock;

common stock; or

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

We have also filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of our \$125.0 million 4.25% Convertible Senior Notes due August 15, 2010, and up to 18,601,190 shares of our common stock which may be issued upon the conversion of the notes. These notes and shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitation of Rule 144. We also have filed a registration statement on Form S-3 under the Securities Act that relates to the sale by certain selling securityholders of our \$21.986 million 4.25% Convertible Senior Notes due August 15, 2010, and up to 3,271,727 shares of our common stock which may be issued upon the conversion of the notes. The notes and shares of common stock are freely tradable without restriction or further registration under the Securities Act except for shares held by our affiliates, which will be subject to resale limitation of Rule 144. In connection therewith, we have agreed to use our best efforts to keep these registration statements continuously effective until the earliest of (i) the sale of all outstanding registrable securities registered under the registration statements; (ii) the expiration of the period referred to in Rule 144(k) of the Securities Act with respect to the notes held by non-affiliates of us; (iii) all the registrable securities have ceased to be outstanding (whether as a result of redemption, repurchase, cancellation, conversion or otherwise); and (iv) two years after the respective effective dates of these registration statements.

We have filed a registration statement on Form S-4 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.

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

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our outstanding 4.25% Convertible Senior Notes due August 15, 2010. As of October 29, 2004, approximately \$147.0 million aggregate principal amount of these notes was outstanding. Upon such change of control event, we are also required to offer to repurchase all of our outstanding 2.25% Convertible Senior Notes due May 11, 2011. As of October 29, 2004, \$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, 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 by-laws include:

a classified board of directors;

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

advance notice requirements for shareholder proposals and nominations;

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

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

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

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

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

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

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. For example, effective January 1, 2003, we changed our method of accounting for asset retirement obligations in accordance with Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations* (SFAS No. 143). Previously, we were not required to recognize amounts related to asset retirement obligations. Under SFAS No. 143, we now recognize asset retirement obligations in the period in which they are incurred if a reasonable estimate of a fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. The adoption of SFAS No. 143 resulted in an increase in net property, buildings and equipment of approximately \$1.4 million, recognition of an asset retirement obligation liability of approximately \$2.2 million and a cumulative effect of a change in accounting principle of approximately \$0.8 million or \$0.01 per share.

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

**Risks Related to the Offering**

**We may not be able to make required payments on our indebtedness, including the notes.**

Our ability to make payments on our debt, including the notes, 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.

**The notes are unsecured, and future indebtedness could effectively rank senior to the notes.**

The notes are unsecured and will rank equal in right of payment with our existing and future unsecured and unsubordinated indebtedness. The notes will be effectively subordinated to any future secured indebtedness to the extent of the value of the assets that secure the indebtedness. The notes will also be "structurally subordinated" to all indebtedness and other liabilities of our existing and future subsidiaries, including trade payables in existence currently or in the future. In the event of our bankruptcy, liquidation or reorganization or upon acceleration of the notes, payment on the notes could be less, ratably, than on any secured indebtedness. We may not have sufficient assets remaining after payment to our secured creditors and creditors of our existing and future subsidiaries to pay amounts due on any or all of the notes then outstanding.

The indenture governing the notes does not prohibit or limit us or our subsidiaries from incurring additional indebtedness and other liabilities, from pledging assets to secure such indebtedness and liabilities or from providing guarantees of indebtedness under the indenture. The incurrence of additional indebtedness, and in particular the granting of a security interest to secure the indebtedness, could adversely affect our ability to pay our obligations on the notes. We anticipate that from time to time we will incur additional indebtedness in the future, some or all of which may be secured indebtedness.

**The notes are not protected by restrictive covenants.**

The indenture governing the notes does not contain any financial or operating covenants or restrictions on the payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries. The indenture contains no covenants or other provisions to afford protection to holders of the notes in the event of a fundamental change involving Medarex except to the extent described under "Description of the Notes Repurchase at Option of Holders Upon a Change in Control."



**We may be unable to repurchase the notes upon a repurchase event.**

You may require us to repurchase all or any portion of your notes upon a repurchase event. We may not have sufficient cash funds to repurchase the notes upon a repurchase event. We may elect, subject to certain conditions, to pay the repurchase price in common stock or a combination of cash and common stock. Although there are currently no restrictions on our ability to pay the repurchase price, future debt agreements may prohibit us from repaying the repurchase price in either cash or common stock. If we are prohibited from repurchasing the notes, we could seek consent from our lenders to repurchase the notes. If we are unable to obtain their consent, we could attempt to refinance the notes. If we were unable to obtain a consent or refinance, we would be prohibited from repurchasing the notes. If we were unable to repurchase the notes upon a repurchase event, it would result in an event of default under the indenture. An event of default under the indenture could result in a further event of default under our other then-existing debt. In addition, the occurrence of the repurchase event may be an event of default under our other debt.

**Because it is unlikely that an active trading market for the notes will develop, you may not be able to sell your notes. You should therefore be prepared to hold the notes until maturity unless you convert them into shares of common stock.**

On May 3, 2004, we issued the notes to the initial purchasers in a private placement. We do not intend to list the notes on any national securities exchange or on the NASDAQ National Market. The notes constitute a new issue of securities for which there is no established trading market. Because the notes will not be listed on NASDAQ or a national securities exchange, it is unlikely that an active trading market for the notes will develop. If an active market for the notes fails to develop or be sustained, the trading price of the notes could fall. If an active trading market were to develop, the notes could trade at prices that may be lower than the initial offering price of the notes. Whether or not the notes will trade at lower prices depends on many factors, including:

prevailing interest rates and the markets for similar securities;

general economic conditions; and

our financial condition, historic financial performance and future prospects.

If a trading market does not develop, you may be required to hold the notes to maturity unless you convert them into shares of common stock.

**FORWARD-LOOKING STATEMENTS**

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Exchange Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations, beliefs, intentions, or strategies regarding the future. Statements preceded by, followed by or that otherwise include the words "believes", "expects", "anticipates", "intends", "estimates", "plans", "forecasts", "is likely to", "projected" and similar expressions or future conditional verbs such as "will", "should", "would", "may", and "could" are generally forward-looking in nature and not historical facts. Forward-looking statements include, without limitation, statements in "Summary Medarex, Inc.," "Recent Developments," "Risk Factors," "Business," and elsewhere in this prospectus (inclusive of the documents incorporated herein by reference) regarding, among other things, uncertainties relating to our technology; history of operating losses and anticipation of future losses; uncertainty of product development; need for additional capital and uncertainty of change; uncertainty of patent and proprietary rights; management of growth, and risks of acquiring new technologies; uncertainties related to clinical trials; government regulation and uncertainty of obtaining regulatory approval; dependence on key personnel; dependence on research collaborators and scientific advisors; uncertainty of health care reform measures and third-party reimbursement and risk of product liability. All forward-looking statements included in this prospectus 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 above in the section entitled "Risk Factors." Accordingly, in addition to the other information in this prospectus, the above risk 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, 2002</b>		
First Quarter	\$ 18.46	\$ 13.31
Second Quarter	\$ 16.83	\$ 6.71
Third Quarter	\$ 9.00	\$ 3.26
Fourth Quarter	\$ 5.35	\$ 2.55
<b>Year ended December 31, 2003</b>		
First Quarter	\$ 4.36	\$ 2.69
Second Quarter	\$ 7.35	\$ 3.15
Third Quarter	\$ 7.67	\$ 4.48
Fourth Quarter	\$ 7.56	\$ 5.78
<b>Year ended December 31, 2004</b>		
First Quarter	\$ 9.93	\$ 6.28
Second Quarter	\$ 11.13	\$ 6.51
Third Quarter	\$ 7.84	\$ 4.73
Fourth Quarter (through November 15, 2004)	\$ 9.85	\$ 7.19

The last reported sale price of our common stock on the NASDAQ National Market on November 15, 2004 was \$9.51. 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 dividin