

MEDAREX INC  
Form 424B5  
December 12, 2002  
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Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-52696

Prospectus Supplement to Prospectus dated December 22, 2000.

107,712 Shares

## **Medarex, Inc.**

Common Stock

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Medarex is offering 107,712 shares of its common stock all of which will be issued directly to Millennium Pharmaceuticals, Inc. in exchange for certain intellectual property rights.

The number of shares to be issued and delivered to Millennium was determined by dividing \$500,000 by \$4.642, the average of the opening and closing sales prices of our common stock for each of the five trading days commencing on November 29, 2002 and ending on December 5, 2002.

Our common stock is quoted on the Nasdaq National Market under the symbol MEDX. The last reported sale price for the common stock on December 11, 2002 was \$4.35 per share.

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*Investing in our common stock involves certain risks. See Risk Factors beginning on page S-9 of this prospectus supplement to read about important factors you should consider before investing in our common stock.*

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**Neither the Securities and Exchange Commission nor any other regulatory body 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.**

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The shares of common stock offered hereby are being issued directly to Millennium on the date hereof. No discounts, commissions, concessions or other compensation has been paid to any underwriter, broker, dealer or agent in connection with the offering.

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Prospectus Supplement dated December 12, 2002

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**FORWARD-LOOKING STATEMENTS**

This prospectus supplement includes or incorporates by reference forward-looking statements, including those identified by the words *believes*, *anticipates*, *expects* and similar expressions. Medarex has based these forward-looking statements on its current expectations and projections about future events. These forward-looking statements are subject to risks, uncertainties and assumptions, including among other things:

- uncertainties relating to the technological approach;
- 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 propriety 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.

Medarex undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in the prospectus supplement, the accompanying prospectus and in the incorporated documents might not occur.

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In this prospectus, the terms *Medarex*, *the Company*, *we*, *us*, and *our* refer to Medarex, Inc. and our wholly-owned subsidiaries. You should only rely on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. Medarex has not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. Medarex is not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate as of the date on the front cover of each such prospectus only. The business, financial condition, results of operations and prospects of Medarex may have changed since such dates.

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

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**THE COMPANY**

We are a biopharmaceutical company focused on the discovery and development of human antibody-based therapeutic products. Our UltiMAB Human Antibody Development System<sup>SM</sup> enables us to rapidly create and develop therapeutic products for a wide range of potential diseases, including cancer, inflammation, auto-immune disease and other life-threatening and debilitating diseases.

We believe that antibodies are proven candidates for therapeutic products. To date, the United States Food and Drug Administration, or FDA, has approved eleven antibody-based therapeutic products for sale in the United States. During the past three years, these products generated aggregate worldwide sales in excess of \$6 billion, with sales doubling from 1999 to 2001. We intend to participate in this market, and to this end, are developing an expanding pipeline of therapeutic antibody products developed through the use of our proprietary UltiMAB technology. Multiple therapeutic products generated using our technology are in various stages of human clinical trials, including several of which we are developing using our own resources and others where we have licensed our technology to our partners for their use in the development of their products. We and our partners also have a number of product candidates in preclinical development.

As of December 6, 2002, we have 42 partnerships with pharmaceutical and biotechnology companies to jointly develop and commercialize products or to otherwise acquire rights to use our proprietary technology in their development of new products, including industry leaders such as Amgen, Inc., Centocor, Inc. (a subsidiary of Johnson & Johnson), Eli Lilly & Company, Human Genome Sciences, Inc., Immunex Corporation, Novartis Pharma AG, Novo Nordisk A/S and Schering AG. Some of these are licensing partnerships, providing us with licensing fees, milestone payments and royalty payments; others are collaborative partnerships that provide for the sharing of product development costs, as well as any revenues, expenses and profits associated with products that might be sold commercially.

In addition to our UltiMAB Human Antibody Development System, we have considerable experience in preclinical and clinical development as well as in manufacturing antibodies for clinical trials. Our existing manufacturing facility in Annandale, New Jersey currently has the capacity to produce up to approximately 10 kilograms of monoclonal antibodies per year for clinical development purposes. We are implementing a strategy that contemplates increased developmental capacity, together with potential outside contract manufacturing for large-scale clinical production. We have assembled a team of experienced scientific, production, clinical and regulatory personnel to facilitate the discovery, development and commercialization of antibody-based products for us and for our partners. We intend to add sales and marketing and additional manufacturing capabilities as needed.

Our goal is to be a leader in the discovery and development of human antibody-based therapeutics for the treatment of cancer and other life-threatening and debilitating diseases. To this end, we have implemented a business strategy involving the expansion and diversification of our product pipeline and partnerships and an increase in our resources to develop, manufacture and commercialize products. We intend to capitalize on the value of our own human antibody products by developing them through late stage clinical trials and/or regulatory approval. We believe this will allow us to retain substantial commercial rights or profit sharing opportunities with regard to these products. In addition, we are enhancing and expanding our partnerships, which provides us the opportunity to participate in the development of substantially more product candidates than we could develop using only our own resources. We believe our business strategy will allow us to capitalize on our broad range of product development capabilities thereby maximizing the value of our business.

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**RECENT DEVELOPMENTS**

On December 9, 2002, we and our wholly owned subsidiary, Genpharm International, Inc., entered into an Assignment and License Agreement with Northwest Biotherapeutics, Inc., as well as a related Securities Purchase Agreement dated as of the same date, collectively referred to herein as the Northwest Agreements. Under the terms of the Northwest Agreements, we received certain intellectual property rights relating to the development and commercialization of three cancer-related disease targets, including Prostate Specific Membrane Antigen, or PSMA. We had previously entered into a Collaboration Agreement effective April 24, 2001 with Northwest covering the commercialization and development of these and other disease targets. As part of the current transaction, the three designated cancer targets were removed from inclusion in the original collaboration and we acquired all therapeutic rights to any antibodies created by Northwest against such designated targets. As consideration for these rights, we agreed to pay Northwest a total of \$3,000,000 of which \$1,000,000 has been paid in cash, \$1,000,000 has been paid through the issuance of 218,341 shares of our common stock and \$1,000,000 is payable, at our election, in cash, shares of our common stock, or any combination thereof on or before January 9, 2003. If we decide to make a payment to Northwest in shares of our common stock, the number of shares of our common stock to be issued will be determined by dividing \$1,000,000 (less any cash paid in connection with any installment) by the average of the opening and closing sales prices of our common stock for each of the trading days during the five-trading-day period immediately prior to the applicable date of issuance of such common stock as publicly reported by Nasdaq. In the event that, during the 30-day period following the applicable date of issuance of such common stock, Northwest sells all of the shares of our common stock delivered as payment for the preceding installment, and the proceeds of such sale are less than \$1,000,000 (less any cash paid in connection with any installment), we must pay the difference to Northwest in cash. In the event that, during any such 30-day period, Northwest does not sell all of the shares of our common stock delivered as payment of the preceding installment, then there will be no such adjustment.

In addition, under the terms of the Northwest Agreements, Northwest reacquired all development and commercialization rights to five potential cancer-related disease targets, including CXCR4, a potential antibody, anti-sense and small molecule target. Northwest also received certain licenses under our HuMAb Mouse technology to develop and sell antibody-based products against certain targets in return for fees, milestones and royalties. In return, Northwest will issue to us two million shares of its common stock, together with warrants to purchase a total of 800,000 shares of Northwest common stock. Following the issuance of such shares to us by Northwest, we will own approximately 14.7% of the outstanding common stock of Northwest. After six months, the warrants may be exercised at any time during the next 10 years at an exercise price based on the market value of Northwest common stock on the date of issuance. We also received a right of first negotiation in connection with any agreement to research, develop and/or commercialize antibody products against CXCR4.

On December 9, 2002, we entered into a royalty-free, worldwide, non-exclusive cross-license agreement with Millennium wherein each of Medarex and Millennium licensed to the other party certain patents relating to anti-PSMA antibodies. As part of the arrangement, we agreed to pay Millennium an upfront license fee of \$500,000, which is being paid through the issuance of the shares of our common stock being delivered to Millennium under this Prospectus Supplement. In addition, Millennium may receive an additional \$500,000 in cash, or at our election, in shares of our common stock or any combination thereof based upon certain contingencies. If we decide to make a payment in shares of our common stock, the number of shares of our common stock to be issued will be determined by dividing \$500,000 (less any cash paid in connection with any installment) by the average of the closing sales prices of our common stock for each of the trading days during the five-trading-day period ending two trading days immediately prior to the date of issuance of such common stock as publicly reported by Nasdaq. In the event that, during the 30-day period following the date of issuance of such common stock, Millennium sells all of the shares of our common stock delivered as payment, and the proceeds of such sale are less than \$500,000 (less any cash paid in connection with such payment), we must pay the difference to Millennium in cash. In the event such sales proceeds exceed \$500,000, Millennium must pay us 50% of any such excess in cash. In the event that, during any such 30-day period, Millennium does not sell all of the shares of our common stock delivered as payment of the preceding installment, then there will be no such adjustment.

All shares of our common stock issued to Northwest and Millennium will be fully registered and freely tradable; provided, however, that both Northwest and Millennium have agreed not to sell more than 50% of the total number of shares constituting a payment in any five-trading-day period.

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**THE OFFERING**

Common Stock Offered	107,712
Common Stock to be outstanding after the offering	76,783,002
Use of Proceeds	We will not receive any cash proceeds from the issuance of the shares of our common stock pursuant to this offering. We have received a royalty-free, worldwide, non-exclusive cross-license from Millennium for certain patents related to antibodies against PSMA.
Nasdaq National Market Symbol	MEDX

Unless otherwise stated herein, all information contained in this prospectus supplement relating to the number of outstanding shares of our common stock excludes:

9,946,999 shares of common stock issuable upon exercise of outstanding options having a weighted average exercise price of \$13.63 per share;

2,018,432 shares of common stock reserved for issuance under our existing stock option plans;

500,000 shares of common stock reserved for issuance under our new 2002 Employee Stock Purchase Plan;

6,067,961 shares of common stock reserved for issuance upon conversion of \$175,000,000 aggregate principal amount of our 4.50% Convertible Subordinated Notes due 2006; and

795,392 shares of common stock held in treasury.

In addition, the information contained in this prospectus supplement does not include shares of our common stock which we may be required to issue pursuant to certain contractual obligations and shares we may issue under a shelf registration statement on Form S-3 which we have filed under the Securities Act relating to the sale of up to \$304.25 million of our securities, all as more fully described herein under the section entitled Risk Factors.

**Table of Contents****SELECTED CONSOLIDATED FINANCIAL DATA**

The following table sets forth selected consolidated financial information for the periods indicated. The selected consolidated financial information for each of the years in the five-year period ended December 31, 2001 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, 2001 and 2002 has been derived from unaudited consolidated financial information, which we believe presents fairly such consolidated information in conformity with generally accepted accounting principles. You should read the selected consolidated financial information in conjunction with our consolidated financial statements and the notes thereto and the other financial information incorporated by reference herein.

	For the Year Ended December 31,					For the Nine Months Ended September 30,	
	1997	1998	1999	2000	2001	2001	2002
	(in thousands, except share and per share data) (Restated)					(unaudited)	(unaudited)
<b>Statement of Operations Data:</b>							
Revenues:							
Sales	\$ 221	\$ 1,349	\$ 1,079	\$ 264	\$ 191	\$ 879	\$ 176
Contract and license revenues	3,011	5,443	8,593	19,619	37,140	24,797	22,020
Sales, contract and license revenues from Genmab			252	2,574	4,973	2,913	11,288
Total revenues	3,232	6,792	9,924	22,457	42,304	28,589	33,484
Costs and expenses:							
Cost of sales	150	1,218	709	1,189	642	495	5,729
Research and development	14,100	23,122	19,929	33,942	38,626	23,714	56,517
General and administrative	3,644	5,065	8,036	18,142	19,344	11,801	17,022
Stock bonus to GenPharm employees	2,275						
Write-off of facility costs							11,294
Acquisition of in-process technology	40,316						16,312
Total costs and expenses	60,485	29,405	28,674	53,273	58,612	36,010	106,874
Operating loss	(57,254)	(22,613)	(18,750)	(30,816)	(16,308)	(7,421)	(73,390)
Equity in net loss of affiliate				(353)	(7,334)	(3,714)	(11,318)
Interest and investment income	1,903	1,956	1,205	21,158	24,728	18,885	14,290
Impairment loss on investment in Genmab							(30,971)
Impairment loss on investments in other corporate partners							(7,971)
Additional payments related to asset acquisition							(1,700)
Interest expense	(27)	(1,539)	(8)	(3)	(4,615)	(2,376)	(6,790)
Gain on disposition of Genmab stock					1,442		
Income (loss) before provision (benefit) for income taxes	(55,377)	(22,196)	(17,553)	(10,014)	(2,087)	5,374	(117,850)
Provision (benefit) for income taxes		341	(522)	(13,075)	600	450	75
Net income (loss)	\$ (55,377)	\$ (22,537)	\$ (17,031)	\$ 3,061	\$ (2,687)	4,924	(117,925)
Basic net income (loss) per share (1)	\$ (1.47)	\$ (0.44)	\$ (0.27)	\$ 0.04	\$ (0.04)	\$ 0.07	(\$ 1.58)



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

	<b>Common Stock Price*</b>	
	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2000</b>		
First Quarter	\$ 103.00	\$ 14.19
Second Quarter	\$ 44.44	\$ 16.63
Third Quarter	\$ 59.94	\$ 35.69
Fourth Quarter	\$ 75.00	\$ 30.06
<b>Year ended December 31, 2001</b>		
First Quarter	\$ 42.50	\$ 12.06
Second Quarter	\$ 32.25	\$ 11.75
Third Quarter	\$ 24.47	\$ 11.91
Fourth Quarter	\$ 25.05	\$ 14.25
<b>Year ended December 31, 2002</b>		
First Quarter	\$ 18.34	\$ 13.31
Second Quarter	\$ 16.83	\$ 6.71
Third Quarter	\$ 9.00	\$ 3.26
Fourth Quarter (through December 11)	\$ 5.35	\$ 2.55

\* All prices have been adjusted to reflect a two-for-one stock split as of September 27, 2000.

The number of shares of our common stock outstanding as of November 30, 2002 was 76,456,949. As of April 5, 2002, the record date for our last annual meeting of shareholders held on May 22, 2002, there were approximately 433 record holders of common stock (which includes individual holders) and approximately 23,650 beneficial shareholders of our common stock.

We currently expect to retain our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

**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 reclaim our earnings, if any, for the future operation and expansion of our business.



**Table of Contents****CAPITALIZATION**

The following table shows our total current assets, total assets, total current liabilities and capitalization at September 30, 2002 (i) on an actual basis, and (ii) on an as adjusted basis giving effect to our acquisition of certain intellectual property rights from Millennium as described herein under the section entitled Recent Developments. You should also refer to our consolidated financial statements and the related notes incorporated by reference herein.

	September 30, 2002	
	Actual	As Adjusted <sup>(1)</sup>
(Dollars in thousands) (Unaudited)		
Current assets:		
Cash and cash equivalents	\$ 69,077	\$ 69,077
Marketable securities	300,601	300,601
Prepaid expenses and other current assets	21,400	21,400
<b>Total current assets</b>	<b>391,078</b>	<b>391,078</b>
<b>Total assets</b>	<b>585,191</b>	<b>585,191</b>
Total current liabilities		
Deferred contract revenue long term	22,196	22,196
4.50% Convertible Subordinated Notes due 2006	1,316	1,316
Shareholders' equity	175,000	175,000
Preferred stock, \$1.00 par value, 2,000 shares authorized; none issued and outstanding		
Common stock, \$.01 par value; 200,000,000 shares authorized; 76,220,501 shares issued and 75,349,640 shares outstanding actual and 76,328,213 issued and 75,457,352 outstanding as adjusted <sup>(2)</sup>	762	763
Capital in excess of par value	625,271	625,770
Treasury stock, at cost, 870,861 shares	(2,190)	(2,190)
Deferred compensation	1,326	1,326
Accumulated other comprehensive income	5,497	5,497
Accumulated deficit	(243,987)	(244,487)
<b>Total shareholders' equity</b>	<b>386,679</b>	<b>386,679</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 585,191</b>	<b>\$ 585,191</b>

(1) The As Adjusted column reflects the issuance of a total of 107,712 shares of our common stock valued at \$500,000 representing the initial payment due to Millennium under the cross-license agreement. The As Adjusted column does not reflect any consideration to be paid based upon certain contingencies and does not reflect any adjustments related to possible cash payments or cash receipts arising from the sale proceeds by Millennium as described under the section herein entitled Recent Developments.

(2) Unless otherwise stated herein, all information contained in this prospectus supplement relating to the number of outstanding shares of our common stock excludes:

9,946,999 shares of common stock issuable upon exercise of outstanding options having a weighted average exercise price of \$13.63 per share;

2,018,432 shares of common stock reserved for issuance under our existing stock option plans;

500,000 shares of common stock reserved for issuance under our new 2002 Employee Stock Purchase Plan;

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6,067,961 shares of common stock reserved for issuance upon conversion of \$175,000,000 aggregate principal amount of our 4.50% Convertible Subordinated Notes due 2006; and

795,392 shares of common stock held in treasury.

In addition, the information contained in this prospectus supplement does not include shares of our common stock which we may be required to issue pursuant to certain contractual obligations and shares we may issue under a shelf registration statement on Form S-3 we have filed under the Securities Act relating to the sale of up to \$304.25 million of our securities, all as more fully described herein under the section herein entitled Risk Factors.

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**RISK FACTORS**

This prospectus supplement contains forward-looking statements within the meaning of Sections 27A and 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations, beliefs, intentions, or strategies regarding the future. Forward-looking statements include, without limitation, statements in Risk Factors and elsewhere in this prospectus supplement 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 supplement are based on information available to us, as of the date hereof, and we do not assume any obligation to update any such forward-looking statements. Our actual results may differ materially from the results discussed in the forward-looking statements. Among the factors that could cause actual results to differ materially are the factors detailed in Risk Factors below. Accordingly, in addition to the other information in this prospectus supplement, the following factors should be considered carefully. References to our products, business, financial results or financial condition should be considered to refer to us and our subsidiaries unless the context otherwise requires.

**Dollars reported in thousands, except per share data.**

**Our product candidates are in early stages of development.**

Our human antibody technology is a new approach to the generation of antibody-based therapeutic products. Product candidates employing our human antibody technology are in early stages of development. Only a limited number of fully human antibody product candidates employing our human antibody technology have been generated pursuant to our collaborations. Investigational New Drug Applications, or INDs, have been submitted to the United States Food and Drug Administration, or FDA, for only a subset of these candidates, and clinical trials have not yet commenced for all of these candidates. Only one of these product candidates is currently in the Phase III clinical trial stage. In addition, we are not aware of any commercialized fully human monoclonal antibody therapeutic products that have been generated from any technologies similar to ours. Product candidates employing our human antibody technology may not advance beyond the early stages of product development or demonstrate clinical safety and effectiveness.

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

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

We have entered into corporate partnerships with a number of companies and are seeking additional alliances that will support the costs of developing our portfolio of antibody-based product candidates. The success of these products is dependent upon the efforts of our corporate partners in developing these products in the future. Neither we nor our corporate partners know if any of these products will be effective.

**Successful development of our products is uncertain.**

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

delays in product development, clinical testing or manufacturing;

unplanned expenditures in product development, clinical testing or manufacturing;

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failure in clinical trials or failure to receive regulatory approvals;

emergence of superior or equivalent products;

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

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

election by our collaborative partners not to pursue product development;

failure by our collaborative partners to develop products successfully; and

failure to achieve market acceptance.

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

Because we and our collaborative 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 collaborative partners. Further, due to our limited operating history, we have difficulty accurately forecasting our revenue. Our business and prospects should be considered in light of the heightened risks and unexpected expenses and problems we may face as a company in an early stage of development in a new and rapidly evolving industry. We have decided, in consultation with our partners, to discontinue our clinical development programs for MDX-33 and MDX-44, respectively. MDX-33 is a humanized antibody targeting CD64 that is designed for the treatment of idiopathic thrombocytopenia purpura, or ITP. MDX-44 is a humanized antibody targeting CD64 that has been studied in connection with atopic dermatitis.

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

We have incurred large operating losses and these losses may continue. In particular, as of September 30, 2002, we had an accumulated deficit of approximately \$243,987. 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;

investing in new technologies; and

expanding of our manufacturing and production capabilities.

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.

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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.**

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

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

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

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

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

- 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 trial due to the institutional review board responsible for overseeing the study at a particular study site; and

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- government or regulatory delays or clinical holds requiring suspension or termination of the trial.

Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our human antibody technology. The failure of clinical trials to demonstrate safety, effectiveness, potency and/or purity for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations will suffer.

**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 recently announced that it is moving several product categories currently regulated by the agency's Center for Biologics Evaluation and Research, or (CBER) to the agency's Center for Drug Evaluation and Research, or (CDER). These product categories include monoclonal antibodies as well as cytokines, growth factors, enzymes, interferons and certain proteins. The effect that this reorganization at the FDA will have on clinical trials and product approval outcomes or timing is uncertain, but could cause delays or other currently unforeseeable effects.

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

Even if clinical trials demonstrate the safety, effectiveness, potency and purity of products developed by us or our corporate 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 tablets or capsule delivery. The degree of market acceptance of any product candidates employing our technology will depend on a number of factors, including:

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

cost-effectiveness;

alternative treatment methods;

reimbursement policies of government and third-party payors; and

marketing and distribution support for our product candidates.

In addition, many of our activities involve genetic engineering in animals and animal testing. These types of activities have been the subject of controversy and adverse publicity. Animal rights groups and various other organizations and individuals have attempted to stop genetic engineering activities and animal testing by lobbying for legislation and regulation in these areas.

If products employing our technology do not achieve significant market acceptance, our business will suffer.

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**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 provide 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 corporate 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 employing our human antibody technology. These variations could harm our ability and the ability of our corporate partners to sell products employing our human antibody technology in commercially acceptable quantities at profitable prices.

**We have limited manufacturing capabilities.**

Before approving a new drug or biologic product, 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 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;
- changes in FDA requirements;
- production costs; and
- development of advanced manufacturing techniques and process controls.

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin producing antibodies under cGMP regulations. We cannot make assurances that we will be able to contract with any of these companies on acceptable terms or in a timely manner, if at all.

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

### **We have no sales or marketing experience.**

We currently have no sales, marketing or distribution capabilities. We may need to enter into arrangements with third parties to market and sell certain of our products. We may not be able to enter into marketing and sales arrangements with others on acceptable terms, if at all. To the extent that we enter into marketing and sales arrangements with other companies, our revenues, if any, will depend on the efforts of others. These efforts may not be successful. We may choose to market some of our products directly through a sales and marketing force. In order to do this, we will have to develop a sales and marketing staff and establish distribution capability. Developing a sales and marketing force would be expensive and time-consuming and could delay any product launch. If we choose to market any of our products directly but are unable to successfully implement a marketing and sales force, our business and operating results will be harmed.

### **We are, in part, dependent on our collaborative and licensing partners to support our business and to develop products employing our human antibody technology.**

We depend on our collaborative and licensing partners to support our business and to develop products employing our antibody technology. We currently, or in the future may, rely on our collaborative and licensing 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
- commercialize and market future products.

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

- our collaborative and licensing partners have significant discretion whether to pursue planned activities;
- we cannot control the quantity and nature of the resources our collaborative and licensing partners may devote to product candidates;
- our collaborators may not develop products employing our antibody technology as expected; and
- business combinations or significant changes in a collaborative and licensing 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 collaborators, our business will suffer.



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

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

Our partners generally have the right to terminate our partnerships at any time. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays or termination in the research, development or commercialization of product candidates. If we are not able to establish additional collaboration or licensing partnerships on terms that are favorable to us or if a significant number of our existing corporate 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
- place additional strain on management's time.

Any of the above may harm our business.

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

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

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

We currently have an equity interest of approximately 31% in Genmab, which intends to develop and commercialize a portfolio of fully human antibodies derived from our human antibody technology. In addition, we have an equity position in IDM of approximately 6%. In the event that we exercise certain warrants held by us to purchase convertible or redeemable bonds of IDM and such bonds are converted or redeemed, our equity position in IDM would be approximately 29%, based on the shares currently outstanding. These warrants are exercisable between September 2002 and September 2010, and such bonds may be converted or redeemed within six months of such exercise. Each of IDM and Genmab intends to develop and commercialize a portfolio of antibody-based products.

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, 1999, 2000 and 2001, our share of Genmab's losses were \$0, \$353 and \$7,334 respectively. For the nine-month period ended September 30, 2002, our share of Genmab's net loss was \$11,318. Genmab has publicly stated that it anticipates that it will incur substantial losses as it expands its research and product development efforts. As Genmab's losses continue to increase, the aggregate amount of such losses we must include in our consolidated financial statements will also increase.

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**Our strategic investments in our corporate partners whose securities are publicly traded expose us to equity price risk and, in addition, investments in our corporate 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 collaborative partners, including Genmab, Northwest, Oxford GlycoSciences Plc, Seattle Genetics, Inc. and Tularik, Inc., and as part of our business strategy, we may choose to make additional similar investments in public companies in the future. As these investments are the result of strategic alliances with our collaborative partners, we typically do not attempt to reduce or eliminate our market exposure of these types of strategic investments. Under 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. Through September 30, 2002, we have recorded impairment charges of approximately \$38,942 (of which approximately \$30,971 relates to Genmab) on our strategic investments. If we deem these investments to be further impaired at the end of any future reporting period, we may incur additional impairment charges on these investments.

In addition, we have investments in several of our corporate partners whose securities are not publicly traded such as IDM. Because these securities are not publicly traded, we value these investments by using information acquired from industry trends, the management of these companies, financial statements, and other external sources. Based on the information acquired through these sources, we record an investment impairment charge when we believe an investment has experienced a decline in value that is considered to be other than temporary. 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, our President and Chief Executive Officer, and Nils Lonberg, Ph.D., Senior Vice President and Scientific Director. For us to pursue product development, marketing and commercialization plans, we will need to hire additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. We may not be able to attract and retain personnel on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. If we are not able to attract and retain qualified personnel, our business will suffer.

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

Our success depends in part on our ability to:

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

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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. 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 for our human antibody technology 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 corporate partners may be prevented from pursuing product development, manufacturing or commercialization. Such a result would harm our business.

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

If we become involved in any 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 collaborative 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 permitted 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 monoclonal antibodies. These patents do not cover all human antibodies.

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

Moreover, other parties could have blocking patent rights to products made using HuMAb-Mouse technology, such as antibodies, and their production and uses, either because of a proprietary position covering the antibody or the antibody's target. For example, we are aware of certain United States and European patents held by third parties relating to particular targets for their human monoclonal antibodies, to human monoclonal antibodies against various targets and bi-specific products, and the manufacture and use of such products. In particular, we are aware of certain United States and foreign

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patents owned by a third party that pertain to monoclonal antibodies against CTLA-4 and their uses. We are also aware of certain United States and foreign patents held by third parties relating to particular anti-CD4 antibodies, anti-EGFr antibodies, and anti-heparanase antibodies.

We are also aware of a United States patent owned by Genentech relating to the production of recombinant antibodies in host cells. We currently produce certain of our products and our partners' products using recombinant antibodies from host cells and may choose to produce additional products in this manner. If any of our antibody products are produced in the manner claimed in this patent, then we may need to obtain a license, should one be available. If we are unable to obtain a license on commercially reasonable terms, we may be impaired from making 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 which may be relevant to our future manufacturing techniques.

If our antibody products (or those antibody products of our partners using our human antibody technology) or their commercial use or production meet all of the requirements of any of the claims of the aforementioned patents, or patents which may issue from the aforementioned patent applications, then we or our partners may need a license to one or more of these patents. Further, we are aware of a number of other third party patent applications which, if granted, with claims as currently drafted, may cover our and our partners' current or planned activities. We 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 have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that our products and/or actions in developing or selling its recombinant human antibody products will not infringe such patents.

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

We are not the exclusive owner of the technology underlying our HuMAb-Mice. In March 1997, prior to our acquisition of GenPharm International, Inc., GenPharm entered into a cross-license and settlement agreement with Abgenix, Inc., Cell Genesys, Inc., Xenotech, L.P. and Japan Tobacco, Inc., pursuant to which Abgenix and these entities paid us and GenPharm a total of approximately \$38,600 million during 1997 and 1998. This payment was in exchange for a non-exclusive license to certain patents, patent applications, third-party licenses and inventions pertaining to the development and use of certain transgenic rodents, including mice, that produce fully human antibodies that are integral to our products and business. These patents, licenses and inventions form the basis of our HuMAb-Mouse technology. Our business may suffer from the competition of these entities or if any of these entities breach the cross-license and settlement agreement.

We are not the exclusive owner of the technology underlying the KM Mouse. Effective September 4, 2002, we entered into a collaboration and license agreement with Kirin superseding the letter of intent entered into by us with Kirin in December 1999. Under this agreement, we and Kirin have exchanged certain cross-licenses for each other's technology for the development and commercialization of human antibody products made using the HuMAb Mouse, the Kirin mice (TC Mouse and HAC Mouse) and the KM Mouse. Kirin has certain rights to distribute and use such mice throughout the world. Our business may suffer as a consequence of competition from Kirin or if the license agreement were breached or terminated for any reason.

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

The administration of drugs to humans, in clinical trials or after commercialization, may expose us to product liability claims. Consumers, healthcare producers or persons selling products based on our technology may be able to bring claims against us based on the use of our products in clinical trials and the sale of products based on our technology. Product liability claims may be expensive to defend and may result in large judgments against us. We currently maintain liability insurance with specified coverage limits. Although we believe these coverage limits are adequate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms. In November 1998, we voluntarily suspended clinical trials for one of our products after some patients experienced serious adverse events, or SAEs. As a result of these or other SAEs, we have received a small number of claims, of which five have resulted in lawsuits being filed. Four of these lawsuits have been settled for insubstantial amounts. The remaining lawsuit is in a preliminary stage and we cannot assure you that it too will be settled or that it will be settled for an insubstantial amount. In addition, we cannot assure you that additional claims will not be filed against us relating to these SAEs. Any such claims against us, regardless of their merit, could result in significant awards against us which could 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 development activities currently face competition from several competitors and from other technologies. The actual products being developed by our collaborators or by us 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 which are actively engaged in research and development in areas related to antibody therapy. 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 corporate partners. Also, we compete with companies that offer antibody generation services to companies that have antigens. These competitors have specific expertise or technology related to antibody development. We compete directly with Abgenix, with respect to the generation of fully human antibodies from transgenic mice. In addition, we have entered into agreements with each of Kirin and Genmab, respectively, which grant these companies licenses to our proprietary technology platform, enabling them to compete with us in offering antibody generation and development services in certain markets. Xenerex Biosciences and XTL Biopharmaceutical, Ltd. have developed technology that, according to Xenerex and XTL, will allow them to generate fully human monoclonal antibodies. 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 synthetic antibodies comprising human antibody sequence. For example, phage and yeast display technology is being used by companies, such as Abbott Laboratories, Inc., Cambridge Antibody Technology Group plc, or CAT, Dyax Corp., Genetastic, Inc. and MorphoSys AG to develop therapeutic products comprising human antibody sequences. Companies such as Johnson & Johnson, Medimmune, Inc., Immunex, IDEC Pharmaceuticals Corporation, Novartis, Genentech, Inc., Protein Design Labs, Inc. and Wyeth have generated therapeutic products derived from recombinant DNA that comprise human antibody components that are currently being marketed.

Other technologies can also be applied to the treatment of the diseases that we or our corporate 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

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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 conventional 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 corporate partners, have substantially greater financial resources and larger research and development staffs than we or some of our corporate 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 corporate partners do. If we or our corporate partners commence commercial product sales, we or our corporate partners will be competing against companies with greater marketing and manufacturing capabilities, areas in which we and certain of our corporate partners have limited or no experience.

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

**If our operating losses are greater than anticipated, 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:

- 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 corporate partnerships, if any;
- continued scientific progress in our research and development programs;
- the time and expense involved in seeking regulatory approvals;
- competing technological and market developments;
- the time and expense of filing and prosecuting patent applications and enforcing patent claims; and
- the cost of establishing manufacturing capabilities, conducting commercialization activities and arrangements and in-licensing products.

We may be unable to raise sufficient funds to complete development of any of our product candidates or to continue operations. As a result, we may face delay, reduction or elimination of research and development programs or preclinical or clinical trials, in which case our business will suffer.

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

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

- adversely affect the successful commercialization of any drugs that we or our corporate partners develop;
- impose additional costs on us or our corporate partners;
- diminish any competitive advantages that we or our corporate 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 corporate partners or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things:

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

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- 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 corporate partners to file INDs with the FDA and to direct the regulatory approval process for products employing our human antibody technology. Our corporate 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 corporate 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 may be 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 may commence only when a BLA or NDA is approved.

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our products in the United States or in any foreign jurisdiction. None of our product candidates has been determined to be safe and effective, and we have not submitted an NDA, or BLA, to the FDA or to any foreign 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 FDA) denied approval to the product candidate altogether or denied a commercially important indicated use; the product candidate was not economical for us to manufacture; and/or the product candidate was not cost effective in light of alternative therapies. We cannot guarantee that we will ever be able to produce commercially successful products.

### **If we or our manufacturing partners do not obtain and maintain current Good Manufacturing Practices, we will not be able to commercialize our product candidates.**

We will depend on our own manufacturing facilities and on those of our corporate partners and other third parties to manufacture products employing our human antibody technology. Before commercializing a new drug, manufacturers must demonstrate compliance with the applicable cGMP regulations which include quality control and quality assurance requirements as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products employing 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



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able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements, may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and/or civil or criminal sanctions.

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

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

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

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of 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 FDA to modify or withdraw a product approval.

### **Our operations involve hazardous materials and are subject to environmental controls and regulations.**

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

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

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

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relating to the exclusivity of rights, may be unenforceable and we could lose the benefit of the rights granted under the provisions.

### **Our stock price may be volatile.**

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

- fluctuations in our operating results;
- announcements of technological innovations or new commercial therapeutic products by us or our competitors;
- published reports by securities analysts;
- progress with clinical trials;
- governmental regulation;
- developments in patent or other proprietary rights;
- developments in our relationship with collaborative partners;
- public concern as to the safety and effectiveness of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these or other factors, including the sale or attempted sale of a large amount of our common stock into the market. Broad market fluctuations may also adversely affect the market price of our common stock.

### **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 November 30, 2002, we have 9,946,999 shares of common stock reserved for issuance pursuant to options, which have been granted under our stock option plans having a weighted average exercise price of \$13.63 per share. In addition, as of that date, we have reserved 2,018,432 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 the shares issuable under our stock option plans. Additionally, as of November 30, 2002, there are 761,552 shares reserved for issuance pursuant to a deferred compensation plan. The shares reserved for the deferred compensation plan will be issued in various amounts over various periods of time during the next five years. We have filed a registration statement on Form S-8 covering those shares. Shares issued under our plans, other than shares issued to affiliates, will be freely tradable in the open market. Shares held by affiliates may be sold pursuant to the requirements of Rule 144.

We have reserved 500,000 shares of common stock for issuance pursuant to our 2002 Employee Stock Purchase Plan. We have filed a registration statement on Form S-8 covering those shares. Shares issued under 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 and warrants may result in a significant increase in the number of shares of our common stock that will be subject to trading on Nasdaq and the issuance and sale of the shares of our common stock upon the exercise thereof may have an adverse effect on the price of our common stock.

As of November 30, 2002, we had 6,067,961 shares of common stock reserved for issuance pursuant to the conversion of \$175,000 aggregate principal amount of our 4.50% Convertible Subordinated Notes due 2006. Holders of these notes may convert their notes into shares of common

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stock at any time prior to maturity or their redemption by us at a conversion rate of 34.6789 shares per each \$1,000 principal amount of notes, subject to adjustment.

Pursuant to our license agreement with Novartis, Novartis may purchase \$2,000 of our common stock at a price equal to one hundred and ten percent of the average of the closing sales prices of our common stock on Nasdaq, on the twenty consecutive days prior to the fifth anniversary (December 2003) of the agreement. Additionally, on the sixth anniversary of the agreement, Novartis may purchase \$1,000 of our common stock at a price equal to one hundred and ten percent of the average of the closing sales prices of such stock on the Nasdaq on the twenty consecutive days prior to such anniversary.

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

As of November 30, 2002, we have 76,456,949 shares of common stock outstanding, of which 2,158,215 are restricted securities as that term is defined in Rule 144 under the Securities Act. Under certain circumstances, these restricted securities may be sold without registration pursuant to such rule. We are unable to predict the effect that sales made under Rule 144 or pursuant to any registration may have on the market price of our common stock. The sale of a significant number of additional securities, or even the possibility thereof, may lower the market price of our common stock.

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

In addition, we have filed a shelf registration statement on Form S-3 under the Securities Act relating to the sale of up to \$304.25 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 a significant amount of debt and may have insufficient cash to satisfy our debt service obligations. In addition, the amount of our debt could impede our operations and flexibility.**

We have a significant amount of convertible debt and debt service obligations, which, unless converted to shares of our common stock, will mature in 2006. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we have could adversely affect us in a number of ways, including by:

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

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

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

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

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

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

Upon the occurrence of certain change of control events of our company, we are required to offer to repurchase all of our outstanding 4.50% Convertible Subordinated Notes due 2006. As of September 30, 2002, \$175,000 aggregate principal amount of the notes was outstanding. We may pay the repurchase price in cash or, at our option, in common stock. Such repurchase right may be triggered at a time at which we do not have sufficient funds available to pay the repurchase price in cash or determine that payment in cash is otherwise inadvisable. In such event, the issuance of a significant number of additional shares of common stock in payment of the repurchase price may lower the market price of our common stock.

**Our restated certificate of incorporation, by-laws, stockholder rights plan and New Jersey law contain provisions that could delay or prevent an acquisition of our company.**

In May 2001, our board of directors adopted a stockholder rights plan. The stockholder rights plan provides for a dividend of one preferred share purchase right on each outstanding share of our common stock. Each right entitles stockholders to buy 1/1000<sup>th</sup> 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 stockholder rights plan and certain provisions of our restated certificate of incorporation and amended and restated by-laws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. This could limit the price that certain investors might be willing to pay in the future for our common stock.

The provisions of our restated certificate of incorporation and by-laws include:

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

We are also afforded the protections of the New Jersey Shareholders Protection Act. This New Jersey statute contains provisions that impose restrictions on shareholder action to acquire control of our company. The effect of the provisions of our restated certificate of incorporation and by-laws and New Jersey law may discourage third parties from acquiring control of our company.

**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.

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**USE OF PROCEEDS**

We will not receive any cash proceeds from the issuance of the shares of our common stock pursuant to this offering. For a more detailed description of this transaction see the section herein entitled "Recent Developments."

**PLAN OF DISTRIBUTION**

The shares of common stock offered hereby are being issued directly to Millennium on the date of this prospectus supplement. No underwriters, agents, brokers or dealers were involved in the distribution of the shares of common stock offered hereby. No discounts, commissions, concessions or other compensation was paid to any underwriter, agent, broker or dealer in connection with the offering.

**LEGAL MATTERS**

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

**WHERE YOU CAN FIND MORE INFORMATION**

A registration statement on Form S-3 (File No. 333-52696) with respect to the shares offered hereby (together with any amendments, exhibits and schedules thereto) has been filed with the SEC under the Securities Act. This prospectus supplement does not contain all of the information contained in such registration statement on Form S-3, certain portions of which have been omitted pursuant to the rules and regulation of the SEC. For further information with respect to us and the shares offered hereby, reference is made to the registration statement on Form S-3. Statements contained in this prospectus supplement regarding the contents of any contract or any other documents are not necessarily complete and, in each instance, reference is hereby made to the copy of such contract or document filed as an exhibit to the registration statement on Form S-3. The registration statement may be inspected without charge at the SEC's principal office in Washington D.C., and copies of all or any part thereof may be obtained from the public reference facilities maintained by the SEC at 450 Fifth Street, NW, Judiciary Plaza, Washington D.C., 20549, upon payment of prescribed fees.

We also file annual, quarterly and special reports, proxy statements and other information with the SEC under the Exchange Act. The Exchange Act file number for our SEC filings is 0-19312. You may read and copy any document we file at the public reference facilities maintained by the SEC at 450 Fifth Street, NW, Judiciary Plaza, Washington D.C., 20549:

You may obtain information on the operation of the public reference room in Washington, D.C. by calling the SEC at 1-800-SEC-0330. We file information electronically with the SEC. Our SEC filings are available from the SEC's Internet site at <http://www.sec.gov>, which contains reports, proxy and information statements and other information regarding issuers that file electronically. Our common stock is listed on the Nasdaq National Market under the symbol "MEDX." You may read and copy our SEC filings and other information at the offices of Nasdaq Operations, 1735 K Street, N.W., Washington, D.C. 20006.

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**INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference the documents we file with it, which means that we can disclose important information to you by referring you to those documents. The information in the documents incorporated by reference is considered to be part of this prospectus supplement, and information in the documents that we file later with the SEC will automatically update and supersede information in this prospectus supplement. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Section 13(a), 13(c), 14 and 15(d) of the Exchange Act:

- Annual Report on Form 10-K for the year ended December 31, 2001
- Quarterly Report on Form 10-Q for the three months ended March 31, 2002
- Quarterly Report on Form 10-Q for the six months ended June 30, 2002
- Quarterly Report on Form 10-Q for the nine months ended September 30, 2002
- Current Report on Form 8-K filed on May 3, 2002
- Current Report on Form 8-K filed on September 18, 2002
- Current Report on Form 8-K filed on September 25, 2002

All documents filed by Medarex with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date hereof and prior to the termination of the offering of the common stock shall hereby be deemed to be incorporated by reference into this prospectus supplement and to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein or in the accompanying prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement or the accompanying prospectus.

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

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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

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**107,712 Shares**

**Medarex, Inc.**

**Common Stock**

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**PROSPECTUS SUPPLEMENT**

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