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ANTARES PHARMA INC  
Form S-3/A  
May 22, 2003

As Filed with the Securities and Exchange Commission on May 22, 2003  
Registration No. 333-103958

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Securities and Exchange Commission  
Washington, D.C. 20549

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Pre-Effective Amendment No. 1  
to  
Form S-3  
Registration Statement  
Under  
The Securities Act of 1933

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Antares Pharma, Inc.  
(Exact Name of Registrant as Specified in its Charter)

|                                   |                        |
|-----------------------------------|------------------------|
| Minnesota                         | 41-1350192             |
| (State or Other Jurisdiction      | (I.R.S. Employer       |
| of Incorporation or Organization) | Identification Number) |

707 Eagleview Boulevard  
Suite 414  
Exton, PA 19341  
(610) 458-6200  
(Address, Including Zip Code, and Telephone Number,  
Including Area Code, of Registrant's Principal Executive Offices)

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Roger G. Harrison, Ph.D.  
Chief Executive Officer  
Antares Pharma, Inc.  
707 Eagleview Boulevard  
Suite 414  
Exton, PA 19341  
(610) 458-6200  
(Name, Address, Including Zip Code, and  
Telephone Number, Including Area Code, of Agent for Service)

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APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after this registration statement becomes effective.

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

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

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

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

CALCULATION OF REGISTRATION FEE

| TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED | AMOUNT TO BE REGISTERED (1) | PROPOSED MAXIMUM OFFERING PRICE PER SHARE (2) | PROPOSED MAXIMUM AGGREGATE OFFERING PRICE | AMOUNT OF REGISTRATION FEE (3) |
|--|-----------------------------|---|---|--------------------------------|
| Common Stock, par value \$.01 per share            | 705,241                     | \$0.73  | \$514,826                                 | \$42                           |

(1) Includes shares of common stock which may be offered pursuant to this registration statement, including shares issuable upon conversion of secured convertible debentures and exercise of warrants. The number of shares of common stock registered hereunder represents a good faith estimate by the Company of the number of shares of common stock issuable upon conversion of the debentures and exercise of the warrants. This registration statement shall also cover any additional shares of common stock which become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction which results in an increase in the number of the outstanding shares of common stock in accordance with Rule 416.

(2) This estimate is made pursuant to Rule 457(c) of the Securities Act of 1933, as amended, solely for purposes of determining the registration fee. The above calculation is based on the average of the high and low sales price of the Registrant's common stock on the Nasdaq SmallCap Market on Wednesday, May 21, 2003.

(3) The registrant previously registered 4,511,518 shares with its initial registration statement filed on March 21, 2003, and paid the corresponding registration fee of \$220 in accordance with Rule 157(c) (based on a \$0.53 per share offering price and a filing fee of \$92 per million). Accordingly, the registrant is paying the applicable fee of \$42 with this amendment to register the additional shares.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant files a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to such Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling securityholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.  
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SUBJECT TO COMPLETION, DATED MAY 22, 2003

PRELIMINARY PROSPECTUS

5,216,759 SHARES OF

ANTARES PHARMA, INC.

COMMON STOCK

This prospectus relates to the offering of 5,216,759 shares of our common stock which may be sold from time to time by the selling shareholders named in this prospectus.

The shares of our common stock are being registered to permit the selling shareholders to sell the shares from time to time in the public market. The shareholders may sell the shares in negotiated transactions or otherwise, at market prices prevailing at the time of sale or at negotiated prices. The timing and amount of any sale are within the sole discretion of the selling shareholders. In addition, the shares may be offered from time to time through ordinary brokerage transactions, directly to market makers of our shares or through any other means described in the section entitled "Plan of Distribution" beginning on page 21.

We will not receive any of the proceeds from the sale of the shares although we have paid the the expenses of preparing this prospectus and the related registration expenses. Our common stock is quoted on the Nasdaq SmallCap Market under the symbol "ANTR." The last reported sales price of our common stock on the Nasdaq SmallCap Market on May 21, 2003 was \$0.68 per share.

BEFORE PURCHASING ANY OF THE SHARES COVERED BY THIS PROSPECTUS,  
YOU SHOULD CAREFULLY READ AND CONSIDER THE RISK FACTORS AND  
UNCERTAINTIES DISCUSSED IN THE SECTION ENTITLED "RISK FACTORS"  
BEGINNING ON PAGE 3. YOU SHOULD BE PREPARED TO ACCEPT ANY AND ALL  
OF THE RISKS ASSOCIATED WITH PURCHASING THE SHARES, INCLUDING A  
LOSS OF YOUR INVESTMENT.

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NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE  
SECURITIES REGULATORS HAS APPROVED OR DISAPPROVED OF THESE  
SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR  
COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL  
OFFENSE.

The date of this prospectus is \_\_\_\_\_, 2003

FORWARD LOOKING STATEMENTS

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This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of the securities laws. These forward-looking statements are subject to a number of risks and uncertainties, many of which are beyond our control. All statements other than statements of historical facts included or incorporated by reference in this prospectus regarding our strategy, future operations, financial position, estimated revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. When used in this prospectus, the words "will," "believe," "anticipate," "intend," "estimate," "expect," "project" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this prospectus. Neither we nor the selling shareholders undertake any obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Although we believe that our plans, intentions and expectations reflected in or suggested by the forward-looking statements that we make in this prospectus are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. The cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf.

### INCORPORATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference into this prospectus and refer you to the documents listed below:

- o our Quarterly Report on Form 10-Q for the period ended March 31, 2003, filed with the SEC on May 20, 2003;
- o our Current Report on Form 8-K, filed with the SEC on May 1, 2003;
- o our Current Report on Form 8-K, filed with the SEC on March 25, 2003;
- o our Annual Report on Form 10-K for the fiscal year ended December 31, 2002, filed with the SEC on March 21, 2003;
- o the description of our common stock contained in our registration statement on Form S-1/A, filed on August 15, 1996, including any amendment or report filed for the purpose of updating the description; and
- o any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this registration statement and prior to the filing of a post-effective amendment that indicates that all shares offered have been sold or which deregisters all shares then remaining unsold.

This prospectus is part of a registration statement on Form S-3 filed with the SEC under the Securities Act. This prospectus does not contain all of the information set forth in the registration statement. You should read the registration statement for further information about our company and the common stock.

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You may request, orally or in writing, a copy of these filings. We will provide the copies of these filings to you at no cost. Please direct your requests to:

Antares Pharma, Inc.  
707 Eagleview Boulevard  
Suite 414  
Exton, Pennsylvania 19341  
Attn: Lawrence Christian  
(610) 458-6200

You may also find information about us at our website:  
<http://www.antarespharma.com>. You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front page of those documents.

## RECENT DEVELOPMENTS REGARDING ISSUANCE OF SECURITIES

Because our common stock is listed on the Nasdaq SmallCap Market, we are subject to the NASD Nasdaq Marketplace Rules. Marketplace Rule 4350(i)(1)(D) requires that we obtain shareholder approval for any issuance of our common stock at a price below the market price where the amount of stock being issued exceeds 20% or more of the common stock or 20% or more of the voting power outstanding before the issuance. This registration statement is being filed to register, among other things, the shares of common stock issuable upon the conversion of convertible debentures and the exercise of warrants we recently issued. We held a special meeting of our shareholders on Thursday, May 8, 2003, at which we obtained shareholder approval for the issuance of the shares of our common stock upon conversion of the debentures and exercise of the warrants.

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### SUMMARY

#### Introduction

The following summary does not contain all of the information that may be important to you. You should read the entire prospectus, including the financial statements and other information incorporated by reference in this prospectus, before making an investment decision.

The terms "company," "Antares," "registrant," "we," "us," and "our" in this prospectus refer to Antares Pharma, Inc.

#### The Company and our Business

We were incorporated in Minnesota on January 31, 1979 under the name Derata Corporation. We changed our name to Medi-Ject Corporation on November 16, 1992. On January 31, 2001, we completed a business combination to acquire the three operating subsidiaries of Permaterc Holding AG, headquartered in Basel, Switzerland. Prior to the closing of the business combination, we did not have sufficient funds to continue our operations, and we had determined that it was necessary to, among other things, either raise more capital or merge with another biopharmaceutical company. Medi-Ject was a company focused on delivery of drugs across the skin using needle free technology, and Permaterc specialized in delivery of drugs across the skin using transdermal patch and gel technologies. Given that both groups were focused on delivery of drugs across the skin, but with a focus on different sectors, we believed that a business combination would be attractive to both pharmaceutical partners and to our shareholders.

The business combination transaction with the Permaterc subsidiaries was accounted for as a reverse merger because upon the closing of the transaction, Permaterc owned in excess of 67% of the outstanding shares of our common stock. The historical financial statements of Permaterc thus became those of the company. Upon consummation of the transaction, the acquired Permaterc subsidiaries were renamed Antares Pharma AG, Antares Pharma IPL AG and Antares Pharma NV, and we changed our name to Antares Pharma, Inc. The following discussion of our business includes our operations following the transaction with Permaterc.

We develop, manufacture and market medical devices, called jet injectors, that allow people to self-inject drugs without using a needle. These jet injectors utilize a small spring-action device and attached disposable plastic syringes to hold the drug. A liquid drug is drawn up into the syringe through a small hole at the end. When the syringe is held against the body and the spring is released, a piston drives the fluid stream into the tissues beneath the skin. A person may re-arm the device and repeat the process or attach a new sterile syringe between injections. Recently we have developed a variation of our jet injector by adding a very small hidden needle to a

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pre-filled, single-use injector. With the Permateg combination, we are also involved in other methods of drug delivery, including transdermal patches and topical gel formulations.

We operate in the specialized drug delivery sector of the pharmaceutical industry. Companies in this sector generally bring technology and know-how in the area of drug

formulation (in our case, injection devices) to pharmaceutical manufacturers through licensing and development agreements. Our principal customers are pharmaceutical manufacturers. We have negotiated and executed licensing relationships in the growth hormone segment (needle-free devices in Europe and Asia), the hormone replacement segment (transdermal delivery of estradiol in South America) and topical hormone gels segment (several development programs in place worldwide). In addition, we continue to market needle-free devices for the home administration of insulin in the U.S. and international markets as we seek a distribution relationship with an insulin manufacturer.

Our principal executive office is located at 707 Eagleview Boulevard, Suite 414, Exton, Pennsylvania 19341, and our telephone number at that office is (610) 458-6200. We have wholly-owned subsidiaries in Switzerland (Antares Pharma AG and Antares Pharma IPL AG) and the Netherlands Antilles (Antares Pharma NV). Our United States research and manufacturing facility is located in Minneapolis, Minnesota.

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### RISK FACTORS

You should consider carefully the following information about risks, together with the other information contained in this prospectus and in the documents referred to below in "Where You Can Find More Information," before you decide whether to buy our common stock. Additional risks and uncertainties not known to us or that we now believe to be not material could also impair our business. If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline and you could lose all of your investment.

#### Risks Related to Our Business

As of May 22, 2003, we only have sufficient cash to continue operations for two weeks

Our cash position is currently only sufficient to fund working capital requirements for the next two to three weeks. From March 2003 through May 2003, our principal shareholder loaned us an aggregate of \$1,150,000 under five separate term notes, to help us meet our cash needs. However, there is no assurance that these loans will continue to be made. Therefore, we have no guaranteed access to additional capital. We expect our working capital needs over the next 12 months to approximate \$9.8 million. This amount consists of approximately \$3.3 million for research and development, \$500,000 for business development, \$300,000 for marketing and sales, \$400,000 for regulatory and quality assurance and \$5.3 million for general and administrative expenses, which is partially offset by approximately \$5.2 million of projected license fees and net product margins. As a result, we continue to seek funds through additional equity or debt offerings, equity investments by our strategic

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partners/customers and divestment of certain non-core technologies. There can be no assurance that sufficient additional equity or debt financing will be available. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail development of new drug technologies, further reduce operating costs through staff reductions or cease operations altogether. If for any reason we are unable to obtain additional financing we may not be able to continue as a going concern, which may result in material asset impairments, other material adverse changes in our business, results of operations or financial condition, or the loss by shareholders of all or a part of their investment in our company. Additionally, even if we are able to raise additional capital and continue our operations, if our Swiss subsidiaries do not generate sufficient cash flow on their own or the U.S. parent company is unable to provide funds to them, and these Swiss subsidiaries are therefore deemed technically insolvent, Swiss laws may require us to place the balance sheet of the Swiss subsidiaries into the Swiss courts. Such an action is often a precursor to a bankruptcy filing, and may be deemed an event of default under our debentures.

Because of insufficient cash flows, we were also several days late in satisfying our U.S. operations payroll obligations for January 31, 2003. There can be no assurance that we will raise additional funds or receive sufficient monthly revenue payments to prevent this from occurring again.

If we default on the terms of the debentures we recently issued, the debenture holders will be able to foreclose on their lien on our assets for the amount of indebtedness we owe them

We currently have an aggregate of \$1,634,117 outstanding principal amount of our 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures. These debentures earn interest at a rate of 8% per annum and mature on March 31, 2004. Interest is payable quarterly, and the debenture holders have the option of receiving the interest payments in cash or in shares of our common stock or as an addition to principal. In the event these debentures are not converted prior to March 31, 2004, we will be required to repay the principal and any accrued but previously unpaid interest. We do not currently have the ability to repay the principal on these debentures, nor do we have any assurance that we will have adequate funds to

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repay them when they mature. We granted to the holders of the debentures a security interest in substantially all of our assets. Therefore, if we default on the terms of the debentures, the debenture holders will be able to take title to a substantial portion of our assets, up to the amount of indebtedness we owe them.

We have incurred significant losses to date, and for our last fiscal year we received an opinion from our accountants expressing substantial doubt about our ability to continue as a going concern

The report of our independent accountants in our Annual Report on Form 10-K for the fiscal year ended December 31, 2002, contains an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern as a result of recurring losses and negative cash flows from operations. We had negative working capital of (\$11,712), (\$4,188,234) and (\$7,827,625) at December 31, 2001 and 2002, and March 31, 2003, respectively. We incurred net losses of (\$5,260,387), (\$9,499,101), (\$11,608,765) and (\$3,017,451) in 2000, 2001 and 2002, and in the three months ended March 31, 2003, respectively. In



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addition, we have accumulated aggregate net losses from the inception of business through March 31, 2003, of (\$44,183,249).

The costs for research and product development of our drug delivery technologies along with marketing and selling expenses and general and administrative expenses have been the principal causes of our losses. We reported a net loss for the year ended December 31, 2002, and for the quarter ended March 31, 2003, as marketing and development costs related to bringing future generations of products to market continue. Long-term capital requirements will depend on numerous factors, including, but not limited to, the status of collaborative arrangements, the progress of research and development programs and the receipt of revenues from sales of products. Our ability to achieve and/or sustain profitable operations depends on a number of factors, many of which are beyond our control. These factors include, but are not limited to, the following:

- o the demand for our technologies from current and future biotechnology and pharmaceutical partners;
- o our ability to manufacture products efficiently and with the required quality;
- o our ability to increase manufacturing capacity to allow for new product introductions;
- o the level of product competition and of price competition;
- o our ability to develop additional commercial applications for our products;
- o our ability to obtain regulatory approvals;
- o our ability to control costs; and
- o general economic conditions.

We depend on a limited number of customers for the majority of our revenue, and the loss of any one of these customers could substantially reduce our revenue

During fiscal 2002, we derived approximately 79% of our revenue from the following two customers:

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- o Ferring Pharmaceutical NV (approximately 49%)
- o BioSante Pharmaceuticals, Inc. (approximately 30%)

The loss of either of these customers would cause revenues to decrease significantly, increase our continuing losses from operations and, ultimately, could require us to cease operating. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenues. We may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues. If that occurs, our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability or continue operations.

If we or our third-party manufacturer are unable to supply Ferring BV with our devices pursuant to our current license agreement with Ferring, Ferring would own a fully paid up license for certain of our intellectual property

Pursuant to our license agreement with Ferring BV, we licensed certain of our intellectual property related to our needle-free injection devices, including granting a license allowing Ferring to manufacture our devices on its own for use with its human growth hormone product. This license becomes effective if we are unable to continue to supply product to Ferring under our current supply agreement. In accordance with the license agreement, we entered

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into a manufacturing agreement with a third party to manufacture our devices for Ferring. If we or this third party are unable to meet our obligations to supply Ferring with our devices, Ferring would own a fully paid up license to manufacture our devices and to use and exploit our intellectual property in connection with Ferring's human growth hormone product. In such event, we would no longer receive royalty revenues from Ferring, and we would no longer be able to license such technology to other parties for use in the field of human growth hormone therapy.

We have limited manufacturing experience and may experience manufacturing difficulties related to the use of new materials and procedures, which could increase our production costs and, ultimately, decrease our profits

Our past assembly, testing and manufacturing experience for certain of our technologies has involved the assembly of products from machined stainless steel and composite components in limited quantities. Our planned future drug delivery technologies necessitate significant changes and additions to our manufacturing and assembly process to accommodate new components. These systems must be manufactured in compliance with regulatory requirements, in a timely manner and in sufficient quantities while maintaining quality and acceptable manufacturing costs. In the course of these changes and additions to our manufacturing and production methods, we may encounter difficulties, including problems involving yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment, component supplies and shortages of personnel, any of which could result in significant delays in production. Additionally, we recently entered into a manufacturing agreement under which a third party will assemble certain component parts of our MJ6B and MJ7 devices. There can be no assurance that this third party manufacturer will be able to meet these regulatory requirements or our own quality control standards. Therefore, there can be no assurance that we will be able to

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successfully produce and manufacture our drug delivery technology. Any failure to do so would negatively impact our business, financial condition and results of operations.

Our products have achieved only limited acceptance by patients and physicians, which continues to have a negative effect on our revenue

Our business ultimately depends on ultimate patient and physician acceptance of our needle-free injectors, gels and our other drug delivery technologies as an alternative to more traditional forms of drug delivery, including injections using a needle and transdermal patch products. To date, our device technologies have achieved only limited acceptance from such parties. Transdermal gels from other companies appear to be gaining increasing acceptance, but there is no guarantee that this will also be seen with our gel products when they are commercialized. If our drug delivery technologies are not accepted in the marketplace, we may be unable to successfully attract additional marketing partners or directly market and sell our products, which would limit our ability to generate revenues and to achieve and/or sustain profitability. The degree of acceptance of our drug delivery systems depends on a number of factors. These factors include, but are not limited to, the following:

- o demonstrated clinical efficacy, safety and enhanced patient compliance;
- o cost-effectiveness;
- o convenience and ease of use of injectors and transdermal gels;
- o advantages over alternative drug delivery systems or similar

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- o products from other companies; and marketing and distribution support.

Physicians may refuse to prescribe products incorporating our drug delivery technologies if they believe that the active ingredient is better administered to a patient using alternative drug delivery technologies, that the time required to explain use of the technologies to the patient would not be offset by advantages, or they believe that the delivery method will result in patient noncompliance. Factors such as patient perceptions that a gel is inconvenient to apply or that devices do not reproducibly deliver the drug may cause patients to reject our drug delivery technologies. Because only a limited number of products incorporating our drug delivery technologies are commercially available, we cannot yet fully assess the level of market acceptance of our drug delivery technologies.

If transdermal gels do not achieve market acceptance, we may be unable to achieve sufficient profits from this technology.

Because transdermal gels are a newer, less understood method of drug delivery, our potential consumers have little experience with manufacturing costs or pricing parameters. Our assumption of higher value may not be shared by the consumer. To date, transdermal gels have gained successful entry into only a limited number of markets. There can be no assurance that transdermal gels will ever gain sufficient market acceptance in those or other markets to achieve and/or sustain profitable operations.

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Our injectable depot gel technology may not achieve consumer acceptance and, as a result, may not result in revenues for our company.

Although the injectable depot gel research field is active, few products have reached the market. There is no data indicating that the specific depot gel formulations we are researching will be accepted. Regulatory compliance and approvals can take a substantial amount of time due to clinical evaluations that are required for this type of drug delivery method. There can be no assurance that injectable gels will ever obtain the necessary regulatory approvals or gain sufficient market acceptance to achieve and/or sustain profitable operations.

A recent FDA study questioned the safety of hormone replacement therapy for menopausal women, and our female hormone replacement therapy business may suffer as a result

In July 2002, the Federal Drug Administration halted a long-term study being conducted on oral female hormone replacement therapy (HRT) using a combination of estradiol and progestin because the study showed an increased risk of breast cancer, heart disease and blood clots in women taking HRT. The studies using estradiol alone were not halted. The halted study looked at only one brand of oral combined HRT, and there is no information on whether other brands with different levels of hormones would carry the same risks. In January 2003, the FDA announced that it would be requiring new warnings on the labels for HRT products, and it advised patients to consult with their doctors about whether to use continuous combined HRT and to limit the period of use to help manage post-menopausal vasomotor symptoms, not to manage osteoporosis or other possible longer-term indications. These results and recommendations have had an impact on the use of HRT, but we cannot predict whether sales will remain at this reduced level, or whether our own transdermal HRT contracts will continue as more information on the effects of HRT is released. Additionally, there is no

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information at this point regarding whether the transdermal gels and patches that we market for HRT will be shown to carry the same risks as those found in the study.

We rely on third parties to supply components for our products, and any failure to retain relationships with these third parties could negatively impact our ability to manufacture our products

Certain of our technologies contain a number of customized components manufactured by various third parties. Regulatory requirements applicable to medical device and transdermal patch manufacturing can make substitution of suppliers costly and time-consuming. In the event that we could not obtain adequate quantities of these customized components from our suppliers, there can be no assurance that we would be able to access alternative sources of such components within a reasonable period of time, on acceptable terms or at all. The unavailability of adequate quantities, the inability to develop alternative sources, a reduction or interruption in supply or a significant increase in the price of components could have a material adverse effect on our ability to manufacture and market our products.

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We may be unable to successfully expand into new areas of drug delivery technology, which could substantially reduce our revenue and negatively impact our business as a whole

We intend to continue to enhance our current technologies. Even if enhanced technologies appear promising during various stages of development, we may not be able to develop commercial applications for them because

- o the potential technologies may fail clinical studies;
- o we may not find a pharmaceutical company to adopt the technologies;
- o it may be difficult to apply the technologies on a commercial scale;
- o the technologies may not be economical to market; or
- o we may not receive necessary regulatory approvals for the potential technologies.

We have not yet completed research and development work or obtained regulatory approval for any technologies for use with any drugs other than insulin, human growth hormone and estradiol. There can be no assurance that any newly developed technologies will ultimately be successful or that unforeseen difficulties will not occur in research and development, clinical testing, regulatory submissions and approval, product manufacturing and commercial scale up, marketing, or product distribution related to any such improved technologies or new uses. Any such occurrence could materially delay the commercialization of such improved technologies or new uses or prevent their market introduction entirely.

As health insurance companies and other third-party payors increasingly challenge the products and services for which they will provide coverage, our individual consumers may be unable to afford to use our products, which could substantially reduce our revenues

Our injector device products are currently sold in the European Community (EC) and in the United States for use with human growth hormone or insulin. In the case of human growth hormone, our products are provided to users at no cost by the drug manufacturer. In the United States the injector products are only available for use with insulin.

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Although it is impossible for us to identify the amount of sales of our products that our customers will submit for payment to third-party insurers, at least some of these sales may be dependent in part on the availability of adequate reimbursement from these third-party healthcare payors. Currently, insurance companies and other third-party payors reimburse the cost of certain technologies on a case-by-case basis and may refuse reimbursement if they do not perceive benefits to the technologies' use in a particular case. Third-party payors are increasingly challenging the pricing of medical products and services, and there can be no assurance that such third-party payors will not in the future increasingly reject claims for coverage of the cost of certain of our technologies. Insurance and third party payor practice vary from country to country, and changes in practices could negatively affect our business if the cost burden for our technologies were shifted more to the patient. Therefore, there can be no assurance that adequate levels of reimbursement will be available to enable us to achieve or maintain market acceptance of our technologies or maintain price levels sufficient to realize profitable operations. There is also a possibility of increased government control or influence over a broad range of healthcare

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expenditures in the future. Any such trend could negatively impact the market for our drug delivery technologies.

The loss of any existing licensing agreements or the failure to enter into new licensing agreements could substantially affect our revenue

Our business plans require us to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use and marketing of drug delivery technologies with specific drug therapies. Under these arrangements, the partner company is to assist us in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. Our licensees will also be responsible for distribution and marketing of the technologies for these drug therapies either worldwide or in specific territories. We are currently a party to a number of such agreements, all of which are currently in varying stages of development. Although none of our collaborative agreements have been terminated for failure to meet milestones, we may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product) and thus, would not receive the fees expected from such arrangements. Moreover, there can be no assurance that we will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of our drug delivery technologies. In such event, our business, results of operations and financial condition could be adversely affected, and our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability. As a result of our collaborative agreements, we are dependent upon the development, data collection and marketing efforts of our licensees. The amount and timing of resources such licensees devote to these efforts are not within our control, and such licensees could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales

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of our drug delivery technology.

The failure of any of our third-party licensees to develop, obtain regulatory approvals for, market, distribute and sell our products could substantially reduce our revenue

Pharmaceutical company partners help us develop, obtain regulatory approvals for, manufacture and sell our products. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of the products as planned, our revenues and gross profits may not reach expectations or may decline. We may not be able to control the timing and other aspects of the development of products because pharmaceutical company partners may have priorities that differ from ours. Therefore, commercialization of products under development may be delayed unexpectedly. We do not intend to have a direct marketing channel to consumers for our drug delivery technologies except through current distributor agreements in the United States for our insulin delivery device. Therefore, the success of the marketing organizations of the pharmaceutical company partners, as well as the level of priority assigned to

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the marketing of the products by these entities, which may differ from our priorities, will determine the success of the products incorporating our technologies. Competition in this market could also force us to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability.

We face increasing competition, and our business could suffer if we are unable to effectively compete with our competitor's technology

Additional competitors in the needle-free injector market, some with greater resources and experience than us, may enter the market, as there is an increasing recognition of a need for less invasive methods of injecting drugs. Similarly, several companies are competing in the transdermal gel market. Our success depends, in part, upon maintaining a competitive position in the development of products and technologies in a rapidly evolving field. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical company partners may choose to adopt the drug delivery technologies of our competitors. Drug delivery companies that compete with our technologies include Bioject Medical Technologies, Inc., Equidyne Corporation, Bentley Pharmaceuticals, Inc., Cellegy Pharmaceuticals, Inc., Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc. and Novavax, Inc., along with other companies. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do, and, therefore, represent significant competition.

In general, injection is used only with drugs for which other drug delivery methods are not possible, in particular with biopharmaceutical proteins (drugs derived from living organisms, such as insulin and human growth hormone) that cannot currently be delivered orally, transdermally (through the skin) or pulmonarily (through the lungs). Transdermal patches and gels are also used for drugs that cannot be delivered orally or where oral delivery has other limitations (such as high first pass drug metabolism). Many companies, both large and small, are engaged in research and development efforts on less invasive methods of delivering drugs that cannot be taken orally. The successful

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development and commercial introduction of such a non-injection technique would likely have a material adverse effect on our business, financial condition, results of operations and general prospects.

Competitors may succeed in developing competing technologies or obtaining governmental approval for products before we do. Competitors' products may gain market acceptance more rapidly than our products, or may be priced more favorably than our products. Developments by competitors may render our products, or potential products, noncompetitive or obsolete.

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If we are unable to raise additional capital to continue operating, we may be unable to realize the value we have attributed to our goodwill, patents and intellectual property

Currently, our most valuable assets on our balance sheet are our goodwill from the acquisition of Mediject of \$1,095,355, patents and intellectual property of \$2,181,148 related to our devices and transdermal gels. We have valued these assets in accordance with generally accepted accounting principles. If we are not able to raise additional capital to continue our operations, we may be unable to continue licensing these patents, and would not receive any additional revenue from them. Additionally, we may be required to sell our patents and intellectual property to a third party. In such event, the purchase price we receive for our patents and intellectual property may be substantially lower than the value we have attributed to them in our financial statements.

We have applied for, and have received, several patents, and we may be unable to protect our intellectual property, which would negatively affect our ability to compete

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

Currently, we have been granted 25 patents in the United States and 30 patents in other countries. We have also made application for a total of 90 patents, both in the United States and other countries. Any patent applications we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain patents that may have an adverse effect on our ability to conduct business or are able to circumvent our patents. Further, we may not have the necessary financial resources to enforce our patents.

To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with employees, consultants and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information.

Others may bring infringement claims against us, which could be time-consuming and expensive to defend

Third parties may claim that the manufacture, use or sale of our drug delivery technologies infringe their patent rights. If such claims are asserted,

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we may have to seek licenses, defend infringement actions or challenge the validity of those patents in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, United States or foreign patents that pose a risk of potential infringement claims.

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Additionally, the drugs to which our drug delivery technologies are applied are generally the property of the pharmaceutical companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical companies or third parties. If those patents or other forms of protection expire, become ineffective or are subject to the control of third parties, sales of the drugs by the collaborating pharmaceutical company may be restricted or may cease. Our revenues, in that event, may decline.

We may incur significant costs seeking approval for our products, which could delay the realization of revenue and, ultimately, decrease our revenues from such products

The design, development, testing, manufacturing and marketing of pharmaceutical compounds, medical nutrition and diagnostic products and medical devices are subject to regulation by governmental authorities, including the FDA and comparable regulatory authorities in other countries. The approval process is generally lengthy, expensive and subject to unanticipated delays. Currently, we, along with our partners, are actively pursuing marketing approval for a number of products from regulatory authorities in other countries and anticipate seeking regulatory approval from the FDA for products developed pursuant to our agreement with BioSante. Our revenue and profit will depend, in part, on the successful introduction and marketing of some or all of such products by our partners or us. There can be no assurance as to when or whether such approvals from regulatory authorities will be received.

Applicants for FDA approval often must submit extensive clinical data and supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new drug application also may cause delays or rejection of an approval. Even if the FDA approves a product, the approval may limit the uses or "indications" for which a product may be marketed, or may require further studies. The FDA also can withdraw product clearances and approvals for failure to comply with regulatory requirements or if unforeseen problems follow initial marketing.

In other jurisdictions, we, and the pharmaceutical companies with whom we are developing technologies, must obtain required regulatory approvals from regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market the products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues would be reduced. We may not be able to obtain all necessary regulatory approvals. We may be required to incur significant costs in obtaining or maintaining regulatory approvals.

Our business could be harmed if we fail to comply with regulatory requirements



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and, as a result, are subject to sanctions

If we, or pharmaceutical companies with whom we are developing technologies, fail to comply with applicable regulatory requirements, the pharmaceutical companies, and we, may be subject to sanctions, including the following:

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- o warning letters;
- o fines;
- o product seizures or recalls;
- o injunctions;
- o refusals to permit products to be imported into or exported out of the applicable regulatory jurisdiction;
- o total or partial suspension of production;
- o withdrawals of previously approved marketing applications; or
- o criminal prosecutions.

Our revenues may be limited if the marketing claims asserted about our products are not approved

Once a drug product is approved by the FDA, the Division of Drug Marketing, Advertising and Communication, the FDA's marketing surveillance department within the Center for Drugs, must approve marketing claims asserted by our pharmaceutical company partners. If a pharmaceutical company partner fails to obtain from the Division of Drug Marketing acceptable marketing claims for a product incorporating our drug technologies, our revenues from that product may be limited. Marketing claims are the basis for a product's labeling, advertising and promotion. The claims the pharmaceutical company partners are asserting about our drug delivery technologies, or the drug product itself, may not be approved by the Division of Drug Marketing.

Product liability claims related to participation in clinical trials or the use or misuse of our products could prove to be costly to defend and could harm our business reputation

The testing, manufacturing and marketing of products utilizing our drug delivery technologies may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical companies with whom we are developing drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses that may have been suffered. A successful product liability claim against us, if not covered by, or if in excess of the product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations. As the result either of adverse claim experience or of medical device or insurance industry trends, we may in the future have difficulty in obtaining product liability insurance or be forced to pay very high premiums, and there can be no assurance that insurance coverage will continue to be available on commercially reasonable terms or at all.

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Our business may suffer if we lose certain key officers or employees

The success of our business is materially dependent upon the continued services of certain of our key officers and employees. The loss of such key personnel could have a material adverse effect on our business, operating results or financial condition. There can be no assurance that we will be successful in retaining key personnel.

We are involved in many international markets, and this subjects us to additional business risks

We have offices and a research facility in Basel, Switzerland, and we also license and distribute our products in the European Community and the United States. These geographic localities provide economically and politically stable environments in which to operate. However, in the future, we intend to introduce products through partnerships in other countries. As we expand our geographic market, we will face additional ongoing complexity to our business and may encounter the following additional risks:

- o increased complexity and costs of managing international operations;
- o protectionist laws and business practices that favor local companies;
- o dependence on local vendors;
- o multiple, conflicting and changing governmental laws and regulations;
- o difficulties in enforcing our legal rights;
- o reduced or limited protections of intellectual property rights; and
- o political and economic instability.

A significant portion of our international revenues is denominated in foreign currencies. An increase in the value of the U.S. dollar relative to these currencies may make our products more expensive and, thus, less competitive in foreign markets.

#### Future Terrorist Attacks Could Substantially Harm Our Business

On September 11, 2001, the United States was the target of terrorist attacks of unprecedented scope. The U.S. government and media agencies were also subject to subsequent acts of terrorism through the distribution of anthrax through the mail. Such attacks and the U.S. government's ongoing response may lead to further acts of terrorism, bio-terrorism and financial and economic instability. The precise effects of these attacks, future attacks or the U.S. government's response to the same are difficult to determine, but they could have an adverse effect on our business, profitability and financial condition.

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#### Risks Related to our Common Stock

We have received multiple notices from Nasdaq regarding our failure to comply with Nasdaq's listing standards, and it is likely that our stock will soon be delisted

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Our stock is currently traded on the Nasdaq SmallCap Market. In the past several months, we have received multiple notices from Nasdaq regarding our failure to meet Nasdaq's minimum bid price listing standard and Nasdaq's minimum shareholders' equity standard. We have corresponded with Nasdaq regarding potential steps we may take to meet these standards. However, following review of these proposals, Nasdaq notified us of its intent to delist our common stock as of May 7, 2003. We then requested an oral hearing with Nasdaq's Listing Qualifications Panel to appeal Nasdaq's determination. This hearing request will stay the delisting of our common stock pending the panel's decision. The hearing has been scheduled for May 29, 2003. However, there is no assurance that this hearing will result in the continued listing of our stock on the Nasdaq SmallCap Market.

If our stock is delisted and thus no longer eligible for quotation on the Nasdaq SmallCap Market, it may trade in the over-the-counter market, which is viewed by most investors as a less desirable and less liquid marketplace. The loss of our listing on the Nasdaq SmallCap Market would also complicate compliance with state blue-sky laws. Furthermore, our ability to raise additional capital would be severely impaired. As a result of these factors, the value of the common stock would decline significantly. Finally, the failure of our stock to be listed on the Nasdaq SmallCap Market would constitute a breach of the covenants we made pursuant to the sale of our 8% debentures, and, therefore, would constitute an event of default under the debentures and allow the debenture holders to declare the debentures immediately due and payable. In such event, we would be required to pay to the debenture holders 130% of the outstanding principal. If our stock is delisted, we will be in default of our 8% debentures, and the debenture holders will be able to take title to a substantial portion of our assets, up to the amount of indebtedness we owe them.

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All decisions affecting our company are under the control of a single shareholder who currently owns a majority of the voting power of our common stock, and this could lower the price of our common stock

As a result of our reverse business combination with Permaterc in January 2001, Permaterc Holding AG and its controlling shareholder, Dr. Jacques Gonella own a majority of (currently approximately 52%) the outstanding shares of our common stock. Because of Permaterc's and Dr. Gonella's control of the Company, investors will be unable to affect or change the management or the direction of the Company. As a result, some investors may be unwilling to purchase our common stock. If the demand for our common stock is reduced because of Permaterc's and Dr. Gonella's control of the Company, the price of our common stock could be materially depressed.

Additionally, as a result of our recent debt restructuring, we issued convertible debentures and warrants to Xmark Fund, Ltd., Xmark Fund, L.P. and SDS Merchant Fund, LP. These debentures and warrants could ultimately be converted into or exercised for an aggregate of 6,200,734 shares of our common stock. In such event, these funds would own in excess of 34% of our common stock.

Because the parties described above either currently own or could potentially own a large portion of our stock, they will be able to generally determine the outcome of all corporate actions requiring shareholder approval. As a result, these parties will be in a position to control all matters affecting our company, including decisions as to our corporate direction and

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policies; future issuances of our common stock or other securities; our incurrence of debt; amendments to our articles of incorporation and bylaws; payment of dividends on our common stock; and acquisitions, sales of our assets, mergers or similar transactions, including transactions involving a change of control.

Sales of our common stock by our officers and directors may lower the market price of our common stock

As of May 21, 2003, our officers and directors beneficially owned an aggregate of 6,804,942 shares (or approximately 57%) of our common stock, including stock options exercisable within 60 days. If our officers and directors, or other shareholders, sell a substantial amount of our common stock, it could cause the market price of our common stock to decrease and could hamper our ability to raise capital through the sale of our equity securities.

Sales of our common stock by the holders of the 8% debentures and warrant holders may lower the market price of our common stock

As of May 21, 2003, \$1,634,117 principal amount of 8% debentures were issued and outstanding. Based on the current conversion price of \$.50 per share, the debentures are convertible into an aggregate of 3,268,234 shares of common stock. The holders of the 8% debentures also hold warrants exercisable for up to 2,932,500 shares of our common stock. Purchasers of common stock could therefore experience substantial dilution of their investment upon conversion of the debentures or exercise of the warrants. The debentures and warrants are not registered and may be sold only if registered under the Securities Act of 1933, as amended,

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or sold in accordance with an applicable exemption from registration, such as Rule 144. Certain of the shares of common stock into which the debentures may be converted are currently registered and may be sold without restriction. The remaining shares of common stock into which the debentures and warrants may be converted or exercised are being registered pursuant to this registration statement.

As of May 21, 2003, 6,200,735 shares of common stock were reserved for issuance upon conversion of the debentures and exercise of the warrants. As of May 21, 2003, there were 11,982,706 shares of common stock outstanding. Of these outstanding shares, 4,886,664 shares were freely tradable without restriction under the Securities Act of 1933, as amended, unless held by affiliates.

We do not expect to pay dividends in the foreseeable future

We intend to retain all earnings in the foreseeable future for our continued growth and, thus, do not expect to declare or pay any cash dividends in the foreseeable future.

Anti-takeover effects of certain by-law provisions and Minnesota law could discourage, delay or prevent a change in control

Our articles of incorporation and bylaws along with Minnesota law could discourage, delay or prevent persons from acquiring or attempting to acquire us. Our articles of incorporation authorize our board of directors, without action by our shareholders, to designate and issue preferred stock in one or more series, with such rights, preferences and privileges as the board of directors

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shall determine. In addition, our bylaws grant our board of directors the authority to adopt, amend or repeal all or any of our bylaws, subject to the power of the shareholders to change or repeal the bylaws. In addition, our bylaws limit who may call meetings of our shareholders.

As a public corporation, we are prohibited by the Minnesota Business Corporation Act, except under certain specified circumstances, from engaging in any merger, significant sale of stock or assets or business combination with any shareholder or group of shareholders who own at least 10% of our common stock.

### USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares of our common stock by the selling shareholders.

### SELLING SHAREHOLDERS

#### Debenture Holders

In connection with a Securities Purchase Agreement dated July 12, 2002, we sold our 10% Secured Convertible Debentures to four primary investors. On January 24, 2003 and January 31, 2003, we borrowed an aggregate of \$621,025 from Xmark Fund, LP and Xmark Fund, Ltd. to repurchase the 10% debentures held by AJW Partners, LLC, AJW Offshore, Ltd., AJW Qualified Partners, LLC and OTATO Limited Partnership. The repurchase price included

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accrued interest and a premium paid to these investors. In connection with the repurchase, we also issued to the AJW funds warrants to purchase 79,200 shares of our common stock. On February 7, 2003, pursuant to a Debenture and Warrant Purchase Agreement, in exchange for the surrender and cancellation of the promissory notes we issued the Xmark funds when we borrowed these funds, we issued to the Xmark funds 8% Senior Secured Convertible Debentures in the same principal amount as the promissory notes.

Pursuant to a separate Debenture and Warrant Purchase Agreement dated the same date, we also issued Amended and Restated 8% Senior Secured Debentures in the aggregate principal amount of \$992,230 to the Xmark funds and SDS Merchant Fund, LP, another of the original four primary holders of the 10% debentures, in exchange for the surrender by them of the remaining 10% debentures. On March 31, 2003, we issued an additional \$20,862 principal amount to holders of all of our 8% debentures to satisfy the quarterly interest due on the principal. All of the 8% debentures are convertible into shares of our common stock at a per share price of \$.50. We also issued to the Xmark funds and to SDS warrants to purchase an aggregate of 2,932,500 shares of our common stock at an exercise price of \$.55 per share.

At the time of the July 12, 2002 transaction, we registered the shares of our common stock issuable upon conversion of the 10% debentures. On February 18, 2003, we filed a supplemental prospectus to that registration statement to reflect the repurchase of a portion of the debentures and the issuance of the Amended and Restated 8% debentures. In connection with the issuance of the 8% debentures in exchange for the surrender of the promissory notes by the Xmark funds, and the issuance of the warrants to the Xmark funds and SDS, we entered into a Registration Rights Agreement under which we agreed to register the stock issuable upon conversion of the 8% debentures and the stock issuable upon exercise of the warrants. We have filed a registration statement on Form S-3, of which this prospectus is a part, to register the shares of common stock issuable

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upon conversion of the debentures and exercise of the warrants for resale by the selling shareholders to meet this obligation.

### Other Selling Shareholders

In the past year, we have entered into several investor relations agreements with certain firms. We have issued shares of our common stock to these firms to pay for their services, and we have agreed to register the shares of common stock issued to these firms to date. Below is a description of the agreements we have with each of these firms.

1. Consulting Agreement with Piedmont Consulting, Inc., dated May 31, 2002, under which Piedmont provided certain public and investor relations services to us. In return for Piedmont's services, we issued 30,000 shares to Piedmont Consulting, Inc. The agreement terminated four months following its inception.

2. Consulting Agreement with Piedmont Consulting, Inc., dated May 21, 2003, under which Piedmont is to continue to provide certain public and investor relations services to us. As compensation to Piedmont for these services, we issued 120,000 shares of our common stock to Piedmont, along with a three-year warrant to purchase 50,000 shares of our common stock at an exercise price of \$1.00 per share. Piedmont may earn additional shares of our common stock in the future upon the achievement of certain milestones, and such shares will carry with them piggyback registration rights. The agreement terminates on November 21, 2003, unless we mutually agree with Piedmont to renew it.

3. Letter Agreement with Mark Wachs and Associates, Inc., dated October 11, 2002, under which March Wachs and Associates provides public relations services to us. The agreement is for an initial term of six months and renews upon mutual agreement of the parties. Pursuant to the agreement, we issued to Mark Wachs and Associates 5,000 shares of common stock per month from October 2002 to December 2002. As of January 2003, we began issuing Mark Wachs and Associates 10,000 shares of common stock per month. As of May 21, 2003, we have issued a total of 65,000 shares to Mark Wachs and Associates.

4. Advisory Agreement with Duncan Capital LLC, dated December 17, 2002, under which Duncan Capital provides advisory services to us, including introductions to institutional and individual investors, private equity firms and analysts. This agreement automatically renews each month unless either party provides written notice of termination at least ten days prior to the expiration of the month. Pursuant to the agreement, on the first of each month, we issue to Duncan Capital LLC a number of shares of our common stock equal in value to \$10,000, based on the market price of our common stock on the issue date. As of May 21, 2003, we have issued a total of 121,519 shares to Duncan Capital.

5. Market Access Program Marketing Agreement with Madison & Wall Worldwide, Inc., dated April 21, 2003, under which Madison & Wall will, among other things, provide us with exposure to a network of brokers interested in our company. The agreement lasts for a term of thirty days. Pursuant to the agreement, we issued 27,000 shares of common stock to Madison & Wall.

We have agreed with each of the above investor relation firms to register the shares of common stock we have issued to them as of May 21, 2003.

Additionally, in connection with a Convertible Note Purchase Agreement dated January 25, 2000, Dr. Jacques Gonella, our principal shareholder, agreed to purchase two convertible promissory notes from us, both of which were ultimately converted into our common stock. At the same time, we entered into a registration rights agreement with respect to the stock issued upon conversion of the convertible promissory notes. In the registration rights agreement, we granted to Dr. Gonella the right to demand that we register the stock issued to

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him upon conversion of the notes. Dr. Gonella has exercised these demand rights.

We have filed a registration statement on Form S-3, of which this prospectus is a part, to register the shares of common stock for resale by Dr. Gonella and by the investor relation firms listed above.

Based on information provided by the selling shareholders, the following table lists the selling shareholders and other information regarding their beneficial ownership of the shares of our common stock. The following table sets forth (i) the number of shares of common stock beneficially owned by each selling shareholder at May 21, 2003, assuming full conversion of the 8% debentures, full exercise of the warrants and full conversion of the Amended and Restated 8% Secured Convertible Debentures (which shares are registered pursuant to the effective registration statement (Registration No. 33-96739)); (ii) the number of shares of common stock to be offered for resale by each selling shareholder pursuant to this prospectus; and (iii) the number and percentage of outstanding shares of common stock to be held by each selling shareholder after completion of the offering (assumes the sale of all shares offered pursuant to this prospectus and pursuant to the effective registration statement (Registration No. 33-96739) covering the resale of certain shares of common stock issuable upon conversion of the debentures).

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| Name                                    | Number of shares<br>of Common Stock<br>beneficially owned<br>at May 21,<br>2003 (1) | Number of shares<br>of Common Stock<br>to be Offered (1) | Shares Owned af<br>Completion of<br>Offering (1) | Per   |
|---|---|--|--|-------|
| -----                                   | -----   | -----  | -----  | ----- |
| <b>Debenture Holders</b>                |   |  |  |       |
| AJW Partners, LLC (2)                   | 17,325  | 17,325   | 0  |       |
| AJW Offshore, Ltd. (3)                  | 44,550  | 44,550   | 0  |       |
| AJW Qualified Partners, LLC             | 17,325  | 17,325   | 0  |       |
| Xmark Fund, L.P. (5)                    | 1,147,135   | 910,736  | 0  |       |
| Xmark Fund, Ltd. (6)                    | 3,419,929   | 2,643,043  | 0  |       |
| SDS Merchant Fund, LP (7)               | 1,641,480   | 737,515  | 0  |       |
| OTATO Limited Partnership<br>(8)        | 182,745   | 182,746  | 0  |       |
| <b>Other Selling Shareholders</b>       |   |  |  |       |
| Piedmont Consulting, Inc.<br>(9)        | 200,000   | 200,000  | 0  |       |
| Mark Wachs and Associates,<br>Inc. (10) | 65,000  | 65,000   | 0  |       |
| Duncan Capital LLC (11)                 | 121,519   | 121,519  | 0  |       |
| Madison & Wall Worldwide, Inc.<br>(12)  | 27,000  | 27,000   | 0  |       |
| Jacques Gonella (13)                    | 6,264,886   | 250,000  | 6,014,886  |       |
|   | 13,148,895  | 5,216,759  |  |       |

(1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Each entity named in the

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table has sole voting and investment power, exercised by the individuals indicated in the following footnotes, with respect to all shares of stock listed as owned by such entity.

- (2) AJW Partners, LLC is a private investment fund that is owned by its investors and managed by SMS Group, LLC. SMS Group, LLC, of which Corey S. Ribotsky is the fund manager, has voting and investment control over the shares owned by AJW Partners, LLC. The number of shares listed for AJW Partners, LLC represents shares issuable upon conversion of the warrant issued to AJW Partners, LLC in connection with the Company's repurchase of its 10% debentures.
- (3) AJW Offshore, Ltd. (formerly AJW/New Millennium Offshore, Ltd.) is a private investment fund that is managed by First Street Manager II, LLC. First Street Manager II, LLC, of which Corey S. Ribotsky is the fund manager, has voting and investment control over the shares owned by AJW Offshore, Ltd. The number of shares listed for AJW Offshore, Ltd. represents shares issuable upon conversion of the warrant issued to AJW Offshore, Ltd. in connection with the Company's repurchase of its 10% debentures.
- (4) AJW Qualified Partners, LLC (formerly Pegasus Capital Partners, LLC) is a private investment fund that is owned by its investors and managed by AJW Manager, LLC, of which Corey S. Ribotsky and Lloyd A. Groveman are the fund managers. AJW Manager, LLC has voting and investment control over the shares owned by AJW Qualified Partners, LLC. The number of shares listed for AJW Qualified Partners, LLC represents shares issuable upon conversion of the warrant issued to AJW Qualified Partners, LLC in connection with the Company's repurchase of its 10% debentures.

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- (5) Xmark Fund, L.P., a Delaware limited partnership, is a private investment fund that is owned by its investors and managed by its general partner, Brown Simpson Capital, L.L.C., a Delaware limited liability company. Brown Simpson Capital, L.L.C., of which Mitchell D. Kaye is the managing member, has voting and investment control over the shares owned by Xmark Fund, L.P. The number of shares beneficially owned by Xmark Fund, L.P. represents 569,325 shares issuable upon exercise of its warrant, 334,035 shares issuable upon conversion of its 8% debentures (7,500 of which are issuable upon conversion of its Amended and Restated 8% debentures, which shares were not included on the previous registration statement and prospectus, as supplemented), 7,376 shares issuable upon conversion of additional principal amount received as an interest payment on the debentures on March 31, 2003, and 236,399 shares issuable upon conversion of the Amended and Restated 8% Secured Convertible Debentures (which shares are registered for resale pursuant to the effective registration statement (Registration No. 33-96739)).
- (6) Xmark Fund, Ltd., a Cayman Islands corporation, is a private investment fund that is owned by its investors and managed by Brown Simpson Asset Management, LLC, a Delaware limited liability company. Brown Simpson Asset Management, LLC, of which Mitchell D. Kaye is the managing member, has voting and investment control over the shares owned by Xmark Fund, Ltd. The number of shares beneficially owned by Xmark Fund,



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Ltd. represents 1,680,675 shares issuable upon exercise of its warrant, 940,164 shares issuable upon conversion of its 8% debentures (24,649 of which are issuable upon conversion of its Amended and Restated 8% debentures, which shares were not included on the previous registration statement and prospectus, as supplemented), 22,204 shares issuable upon conversion of additional principal amount received as an interest payment on the debentures on March 31, 2003, and 776,886 shares issuable upon conversion of the Amended and Restated 8% Secured Convertible Debentures (which shares are registered for resale pursuant to the effective registration statement (Registration No. 33-96739)).

- (7) SDS Merchant Fund, L.P. is a limited partnership of which SDS Capital Partners, LLC is the general partner. Steve Darby is the managing member of SDS Capital Partners, LLC, and exercises voting and investment control over the shares owned by SDS Merchant Fund, L.P. The number of shares beneficially owned by SDS Merchant Fund, LP represents 682,500 shares issuable upon exercise of its warrant, 42,873 shares issuable upon exercise of its Amended and Restated 8% debenture (which shares were not included on the previous registration statement and prospectus, as supplemented), 12,142 shares issuable upon conversion of additional principal amount received as an interest payment on the debentures on March 31, 2003, and 903,965 shares issuable upon conversion of the Amended and Restated 8% Secured Convertible Debentures (which shares are registered for resale pursuant to the effective registration statement (Registration Statement No. 33-96739)).

- (8) OTATO Limited Partnership is a limited partnership for which OTA Grand Cayman, Inc., a Delaware corporation, is the general partner. By reason of such relationship, OTA Grand Cayman, Inc. may be deemed to share voting the dispositive power over the shares of common stock beneficially owned by OTATO Limited Partnership. As of August 1, 2002, Messrs. Frederick Berdon and Paul Masters, registered representatives of a registered broker-dealer at which OTATO Limited Partnership maintains a brokerage account, have discretionary authority to trade the shares included in the table. By reason of such discretionary authority, these individuals may be deemed to share dispositive power over the shares of stock beneficially owned by OTATO Limited Partnership. The number of

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shares listed for OTATO Limited Partnership reflect shares issued to OTATO upon its conversion of the 10% debentures prior to the Company's repurchase of such debentures, which shares were not previously covered by the original registration statement and prospectus, as supplemented.

- (9) Piedmont Consulting, Inc. is a Georgia corporation. Keith Fetter is President of the corporation and has voting and investment control over the shares owned by the corporation. The number of shares beneficially owned by Piedmont includes the 30,000 shares issued to Piedmont in connection with the May 31, 2002 Consulting Agreement, the 120,000 shares issued to Piedmont in connection with the May 21, 2003 Consulting Agreement, and the 50,000 shares issuable to Piedmont upon exercise of the warrant issued in connection with the May 21, 2003 Consulting Agreement.
- (10) Mark Wachs and Associates, Inc. is a New York corporation. Mark Wachs is the president of the corporation and has voting and investment

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control over the shares owned by the corporation.

- (11) Duncan Capital LLC is a Delaware limited liability company. Michael Crow is the President of Duncan Capital LLC, and he has voting and investment control over the shares owned by the company.
- (12) Madison & Wall Worldwide, Inc. is a Florida corporation. Bruce Elliot is the President of Madison & Wall, and he has voting and investment control over the shares owned by the corporation.
- (13) Jacques Gonella owns controlling interest in Permateg Holding AG, and the shares beneficially owned by him as of May 1, 2003 include 3,364,886 shares held by Permateg Holding AG, as well as 2,650,000 shares individually held by him that are not being registered hereby.

### CERTAIN INFORMATION ABOUT THE SELLING SHAREHOLDERS

The number of shares set forth in the table for the selling shareholders represents a good faith estimate of the number of shares of common stock to be offered by the selling shareholders, which, for the debenture holders, is based on the conversion price of \$.50 per share and the warrant exercise price of \$.55 per share. In addition, the actual number of shares of common stock offered in this prospectus, and included in the registration statement of which this prospectus is a part, includes such additional number of shares of common stock as may be issued or issuable to the selling shareholders by reason of any stock split, stock dividend or similar transaction involving the common stock, in accordance with Rule 416 under the Securities Act of 1933, as amended.

Under the terms of the debentures, the debentures are convertible by any holder only to the extent that the number of shares of common stock issuable pursuant to such securities, together with the number of shares of common stock owned by such holder and its affiliates (but not including shares of common stock underlying unconverted shares of debentures) would not exceed 9.99% of the then outstanding common stock as determined in accordance with Section 13(d) of the Exchange Act. Each holder may, upon providing us with 61 days' written notice, waive this 9.99% cap on conversions.

### PLAN OF DISTRIBUTION

The selling shareholders may offer and resell the shares of our common stock being registered hereby from time to time, either in increments or in a single transaction. They may also decide not to sell all the shares they are allowed to resell under this prospectus. The selling shareholders will act independently of us in making decisions with respect to the timing, manner and size of each sale.

### Donees; Pledges and Transferees

The term "selling shareholder" includes donees, i.e., persons who receive shares from the selling shareholders after the date of this prospectus by gift. The term also includes pledgees, i.e., persons who upon contractual default by the selling shareholders may seize shares which the selling shareholders pledged to such person, and other transferees or successors-in-interest.

### Types of Sale Transactions

The selling shareholders may sell the shares in one or more types of transactions (which may include block transactions):

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- o on the Nasdaq SmallCap Market or any national securities exchange or other U.S. inter-dealer system of a registered national securities association on which the common stock may be listed or quoted at the time of sale;
- o in the over-the-counter market;
- o in negotiated transactions;
- o through option transactions, whether the options are listed on an options exchange or otherwise;
- o through settlement of short sales; or
- o any combination of such methods of sale.

The debenture holders may enter into hedging transactions with third parties, which may in turn engage in short sales of the common stock into which the debentures and warrants are convertible or exercisable in the course of hedging the position they assume. The debenture holders may also enter into short positions or other derivative transactions relating to the common stock into which the debentures and warrants are convertible or exercisable, or interests in the common stock, and deliver the common stock, or interests in the common stock, to close out their short or other positions or otherwise settle short sales or other transactions, or loan or pledge the common stock into which the debentures and warrants are convertible or exercisable, or interests in the common stock, to third parties that in turn may dispose of these securities.

The shares may be sold at market prices prevailing at the time of sale, or at negotiated prices. Such transactions may or may not involve underwriters, brokers or dealers. The selling shareholders have informed us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of the shares. They have also informed us that no one is acting as underwriter or coordinating broker in connection with the proposed sale of shares. The selling shareholders shall have the sole and absolute discretion not to accept any purchase offer or make any sale of shares if they deem the purchase price to be unsatisfactory at any particular time.

#### Costs and Commissions

We will not receive any proceeds from the sale of the stock by the selling shareholders and will bear all costs, fees and expenses incident to our obligation to register the shares of common stock registered hereby. The selling shareholders will pay all brokerage commissions and similar selling expenses, if any, attributable to the sale of the shares.

#### Sales to or through Underwriters and Broker-Dealers

The selling shareholders may conduct such transactions either by selling shares directly to purchasers, or by selling shares to, or through underwriters or broker-dealers. Such underwriters or broker-dealers may act either as an agent of the selling shareholders, or as a principal for their own account. Such underwriters or broker-dealers may receive compensation in the form of discounts, concessions, or commissions from the selling shareholders and/or the purchasers of the shares. This compensation might also exceed customary commissions.

#### Deemed Underwriting Compensation

The selling shareholders and any third parties that act in connection with the sale of shares may be deemed to be "underwriters" within the meaning of Section 2(a)(11) of the Securities Act. Any discounts, commissions, concessions or profits they earn on the disposition of the shares of common stock may be deemed to be underwriting discounts or commissions under the Securities Act. The selling shareholders have purchased the shares of our common stock in the ordinary course of his business, and at the time the selling shareholders purchased the shares of common stock, they were not a party to any agreement or other understanding to distribute the shares, directly or indirectly.

#### Indemnification

We have agreed to indemnify the selling shareholders against certain liabilities, including liabilities arising under the Securities Act or to contribute to payments the selling shareholders may be required to make in respect of such liabilities. The selling shareholders may agree to indemnify any underwriter, agent or broker-dealer that participates in transactions involving sales of shares against certain liabilities, including liabilities under the Securities Act.

#### Prospectus Delivery Requirements

Because they may be deemed to be underwriters, the selling shareholders must deliver this prospectus and any supplements to this prospectus in the manner required by the Securities Act. This might include delivery through the facilities of the Nasdaq SmallCap Market in accordance with Rule 153 of the Securities Act. In addition, the selling shareholders' sales in the market may be subject to the antimanipulative provisions of Regulation M under the Securities Exchange Act of 1934, as amended, or the Exchange Act. These provisions may restrict certain activities of, and limit the timing of purchases and sales of any of the shares by, the selling shareholders or any other such person. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to specified exceptions or exemptions. Such limitations may affect the marketability of the shares.

#### State Requirements

Some states require that any shares sold in that state may only be sold through registered or licensed brokers or dealers. In addition, some states require that the shares have been registered or qualified for sale in that state, or that an exemption exists from the registration or qualification requirement and that the exemption or qualification requirements have been complied with.

#### Sales under Rule 144

The selling shareholders may also resell all or a portion of their

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shares in open market transactions in reliance upon Rule 144 under the Securities Act. To do so, they must meet the criteria and conform to the requirements of Rule 144.

### Distribution Arrangements

If a selling shareholder notifies us that any material arrangement has been entered into with an underwriter, broker-dealer or agent for the sale of shares through a

- o block trade,
- o special offering,
- o exchange distribution or secondary distribution, or
- o purchase by an underwriter or broker-dealer,

we will then file, if required, a supplement to this prospectus under Rule 424(b) under the Securities Act.

The supplement will disclose the following:

- o the name of the selling shareholder and of the participating underwriter(s) or broker-dealer(s);
- o the number of shares involved;
- o the price at which such shares are sold;
- o the commissions paid or discounts or concessions allowed to such underwriter(s) or broker-dealer(s), where applicable;
- o that such underwriter(s) or broker-dealer(s) did not conduct any investigation to verify the information in this prospectus; and
- o any other facts material to the transaction.

### LEGAL MATTERS

For the purpose of this offering, Leonard, Street and Deinard Professional Association, Minneapolis, Minnesota is giving an opinion of the validity of the issuance of the securities offered in this prospectus.

### EXPERTS

The consolidated financial statements and schedule of Antares Pharma, Inc. as of December 31, 2001 and 2002 and for each of the years in the three-year period ended December 31, 2002 have been incorporated by reference herein and in the registration statement in reliance upon the reports of KPMG LLP, independent certified public accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

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The audit report covering the December 31, 2002, consolidated financial statements contains an explanatory paragraph that states that the Company's negative working capital, recurring losses and negative cash flows from operations raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty. The audit report on the 2002 financial statements refers to the Company's adoption of the cumulative deferral method of revenue recognition for licensing arrangements in 2000 and the provisions of Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets," on January 1, 2002.

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### INDEMNIFICATION

Minnesota Statutes Section 302A.521 provides that a corporation shall indemnify any person made or threatened to be made a party to a proceeding by reason of the former or present official capacity of such person against judgments, penalties, fines (including, without limitation, excise taxes assessed against such person with respect to any employee benefit plan), settlements and reasonable expenses, including attorneys' fees and disbursements, incurred by such person in connection with the proceeding, if, with respect to the acts or omissions of such person complained of in the proceeding, such person

- o has not been indemnified therefor by another organization or employee benefit plan; o acted in good faith;
- o received no improper personal benefit and Section 302A.255 (with respect to director conflicts of interest), if applicable, has been satisfied;
- o in the case of a criminal proceeding, had no reasonable cause to believe the conduct was unlawful; and
- o reasonably believed that the conduct was in the best interests of the corporation in the case of acts or omissions in such person's official capacity for the corporation or reasonably believed that the conduct was not opposed to the best interests of the corporation in the case of acts or omissions in such person's official capacity for other affiliated organizations.

Article 7 of our Third Amended and Restated Articles of Incorporation provides that we will indemnify directors to the fullest extent permitted by the Minnesota Business Corporation Act as now enacted or hereafter amended.

We also maintain an insurance policy to assist in funding indemnification of directors and officers for certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

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### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our filings are available to the public over the internet at the SEC's web site at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Rooms in Washington, D.C., New York, New York, and Chicago, Illinois. A Public Reference Room is located at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for additional information on the Public Reference Rooms.

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PART II

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### INFORMATION NOT REQUIRED IN PROSPECTUS

#### ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of common stock being registered. All amounts, except the SEC registration fee, are estimates.

|                                    |                          |
|------------------------------------|--------------------------|
| SEC Registration Fee .....         | \$ 351.00                |
| Legal Fees and Expenses .....      | 8,000.00                 |
| Accounting Fees and Expenses ..... | 5,000.00                 |
| Miscellaneous .....                | 1,649.00                 |
| <br>Total .....                    | <br>\$15,000.00<br>===== |

#### ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Minnesota Statutes Section 302A.521 provides that a corporation shall indemnify any person made or threatened to be made a party to a proceeding by reason of the former or present official capacity of such person against judgments, penalties, fines (including, without limitation, excise taxes assessed against such person with respect to any employee benefit plan), settlements and reasonable expenses, including attorneys' fees and disbursements, incurred by such person in connection with the proceeding, if, with respect to the acts or omissions of such person complained of in the proceeding, such person:

- o has not been indemnified therefor by another organization or employee benefit plan;
- o acted in good faith;
- o received no improper personal benefit and Section 302A.255 (with respect to director conflicts of interest), if applicable, has been satisfied;
- o in the case of a criminal proceeding, had no reasonable cause to believe the conduct was unlawful; and
- o reasonably believed that the conduct was in the best interests of the corporation in the case of acts or omissions in such person's official capacity for the corporation or reasonably believed that the conduct was not opposed to the best interests of the corporation in the case of acts or omissions in such person's official capacity for other affiliated organizations.

Article 7 of our Third Amended and Restated Articles of Incorporation provides that we will indemnify directors to the fullest extent permitted by the Minnesota Business Corporation Act as now enacted or hereafter amended.

We also maintain an insurance policy to assist in funding indemnification of directors and officers for certain liabilities.

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#### ITEM 16. EXHIBITS

EXHIBIT  
NUMBER

DOCUMENT

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|        |  |
|--------|--|
| -----  | -----  |
| 4.1*   | Form of our Common Stock Certificate.  |
| 5.1    | Opinion of Leonard, Street and Deinard Professional Association.   |
| 10.39# | Debenture and Warrant Purchase Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP. |
| 10.40# | Debenture and Warrant Purchase Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P. and Xmark Fund, Ltd.                         |
| 10.41# | Registration Rights Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP.            |
| 10.42# | Amended and Restated Security Agreement, dated January 21, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP.  |
| 10.43# | Form of Warrant, dated January 31, 2003.   |
| 10.44# | Form of 8% Senior Secured Convertible Debenture, dated January 31, 2003.   |
| 10.45# | Form of Amended and Restated 8% Senior Secured Convertible Debenture, dated January 31, 2003.  |
| 10.46# | Form of Promissory Note  |
| 23.1   | Consent of KPMG LLP, Independent Certified Public Accountants.   |
| 23.2   | Consent of Leonard, Street and Deinard Professional Association (included in Exhibit 5.1).   |
| 24.1+  | Power of Attorney (See page II-4).   |

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\* Previously filed as an exhibit to our Form S-3, filed with the SEC on May 31, 2001, and incorporated herein by reference.

# Previously filed as an exhibit to our Form 8-K, filed with the SEC on February 12, 2003, and incorporated herein by reference.

+ Previously filed as an exhibit to our Form S-3, filed with the SEC on March 21, 2003, and incorporated herein by reference.

### ITEM 17. UNDERTAKINGS

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

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



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

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Exton, Pennsylvania, on May 22, 2003.

ANTARES PHARMA, INC.

By: /s/ Roger G. Harrison

-----

Roger G. Harrison, Ph.D.  
Chief Executive Officer

Signature

-----

Title

-----

/s/ Roger G. Harrison

-----

Chief Executive Officer and Director  
(principal executive officer)

May

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Roger G. Harrison, Ph.D.

|   |   |     |
|---|---|-----|
| /s/ Lawrence M. Christian<br>-----<br>Lawrence M. Christian | Vice President of Finance,<br>Chief Financial Officer and Secretary<br>(principal financial and accounting officer) | May |
|---|---|-----|

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|                                   |                                      |     |
|-----------------------------------|--------------------------------------|-----|
| *<br>-----<br>Dr. Jacques Gonella | Director, Chairman of the Board      | May |
| *<br>-----<br>Franklin Pass, M.D. | Director, Vice Chairman of the Board | May |
| *<br>-----<br>James Clark         | Director                             | May |
| *<br>-----<br>Dr. Philippe Dro    | Director                             | May |
| *<br>-----<br>John Gogol          | Director                             | May |

\*By /s/ Roger G. Harrison  
 -----  
 Attorney-in-fact

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| EXHIBIT<br>NUMBER<br>----- | DOCUMENT<br>-----  |
|----------------------------|--|
| 4.1*                       | Form of our Common Stock Certificate.  |
| 5.1                        | Opinion of Leonard, Street and Deinard Professional Association.   |
| 10.39#                     | Debenture and Warrant Purchase Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP. |
| 10.40#                     | Debenture and Warrant Purchase Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P. and Xmark Fund, Ltd.                         |
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| 10.42#                     | Amended and Restated Security Agreement, dated January 21,   |

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2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP.

10.43# Form of Warrant, dated January 31, 2003.

10.44# Form of 8% Senior Secured Convertible Debenture, dated January 31, 2003.

10.45# Form of Amended and Restated 8% Senior Secured Convertible Debenture, dated January 31, 2003.

10.46# Form of Promissory Note

23.1 Consent of KPMG LLP, Independent Certified Public Accountants.

23.2 Consent of Leonard, Street and Deinard Professional Association (included in Exhibit 5.1).

24.1+ Power of Attorney (See page II-4).

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\* Previously filed as an exhibit to our Form S-3, filed with the SEC on May 31, 2001, and incorporated herein by reference.

# Previously filed as an exhibit to our Form 8-K, filed with the SEC on February 12, 2003, and incorporated herein by reference.

+ Previously filed as an exhibit to our Form S-3, filed with the SEC on March 21, 2003, and incorporated herein by reference.