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ANTARES PHARMA INC
Form S-3/A
September 10, 2002

As Filed with the Securities and Exchange Commission on September 10, 2002.
Registration No. 333-96739

Securities and Exchange Commission
Washington, D.C. 20549

Pre-Effective Amendment No. 2
to
Form S-3

Registration Statement
Under
The Securities Act of 1933

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

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

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)

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. []

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. []_____

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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 | 3,555,556 | \$1.52 | \$5,404,446 | \$ 273 |

(1) Includes shares of common stock which may be offered pursuant to this registration statement, which shares are issuable upon conversion of secured convertible debentures. As required by the terms of such debentures, the Company has registered approximately 200% of the shares which may be issued upon conversion of such debentures. 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 Friday, September 6, 2002.

(3) The registrant previously registered 1,600,000 shares with its initial registration statement filed on July 19, 2002, and paid the corresponding registration fee in accordance with Rule 457(c). The current fee of \$273 is based on the 1,955,556 additional shares being registered, resulting in an additional aggregate offering price of \$2,972,445 (1,955,556 shares X \$1.52 = \$2,972,445 potential aggregate offering price).

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 prospective 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.

SUBJECT TO COMPLETION, DATED SEPTEMBER 10, 2002

PRELIMINARY PROSPECTUS

3,555,556 SHARES OF

ANTARES PHARMA, INC.

COMMON STOCK

This prospectus relates to the offering of 3,555,556 shares of our common stock which may be sold from time to time by the selling shareholders named in this prospectus. These shares of common stock are issuable to the selling shareholders upon conversion of secured convertible debentures. The debentures are convertible at a per share price which is the lower of \$2.50 or 75% of the average of the three lowest intraday trading prices of our common stock, as reported on the Nasdaq SmallCap Market, during the 20 trading days prior to the conversion date.

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 18.

We will not receive any of the proceeds from the sale of the shares although we have paid 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 September 6, 2002 was \$1.73 per share. The three lowest intraday trading prices of our common stock during the 20 trading days ending on September 6, 2002 were \$1.65, \$1.61 and \$1.24.

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.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES REGULATORS HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS

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PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is _____, 2002.

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FORWARD LOOKING STATEMENTS

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.

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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 Annual Report on Form 10-K for the fiscal year ended December 31, 2001, filed with the SEC on April 15, 2002;
- o our Quarterly Report on Form 10-Q for the quarter ended March 31, 2002, filed with the SEC on May 13, 2002;
- o our Current Report on Form 8-K filed with the SEC on June 28, 2002, announcing the conversion of \$2 million principal amount of debt plus accrued interest payable to Jacques Gonella into 509,137 shares of common stock;
- o our Current Report on Form 8-K filed with the SEC on July 17, 2002, announcing the completion of the sale of our 10% convertible debentures;
- o our Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, filed with the SEC on August 14, 2002;
- 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

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Because our common stock is listed on the Nasdaq SmallCap Market, we are subject to the NASD Nasdaq Marketplace Rules. 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 the shares of common stock issuable upon conversion of convertible debentures we recently sold in a private placement. We held a special meeting of our shareholders on August 23, 2002. At the special meeting, we received shareholder approval to issue common stock in excess of 19.99% of our currently outstanding shares of common stock upon conversion of the debentures.

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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.

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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 pre-filled, single-use injector.

With the Permateg combination, we are also committed to other methods of drug delivery, including transdermal patches and topical gel formulations. We intend for these other drug delivery methods to become a material part of our business moving forward.

We plan to 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 customer is the pharmaceutical manufacturer. 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

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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 unimportant 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

We will require additional capital to continue operations beyond approximately October 2002

Following our receipt of a \$2 million loan from our majority shareholder, Jacques Gonella (which was converted into shares of our common stock on June 20, 2002), and our receipt of the proceeds of the sale of an aggregate of \$2 million of our 10% convertible debentures, of which we have received \$1,400,000 to date,

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our cash position will be insufficient to fund working capital requirements beyond approximately October 2002 and will not be sufficient for us to reach profitability. We expect our working capital needs over the next twelve months to approximate \$10.0 million. This amount consists of approximately \$7.0 million for research and development, \$500,000 for business development, \$1.2 million for marketing and sales, \$600,000 for regulatory and quality assurance and \$5.7 million for general and administrative expenses, all of which is offset by approximately \$5.1 million of projected license fees and net product margins. We are currently seeking funds through additional equity or debt offerings, equity investments by our strategic partners/customers and divestment of 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 or expansion of manufacturing capacity or cease operations altogether.

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

The report of our independent accountants in our 10-K for the fiscal year ended December 31, 2001, 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 (\$2,439,577), (\$11,712) and (\$2,016,280) at December 31, 2000 and 2001, and June 30, 2002, respectively. We incurred net losses of (\$3,967,366), (\$5,260,387), (\$9,499,101) and (\$4,113,524) in 1999, 2000 and 2001, and in the six months ended June 30, 2002, respectively. In addition, we have accumulated aggregate net losses from the inception of business through June 30, 2002, of approximately \$33,570,557.

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 expect to report a net loss for the year ending December 31, 2002, 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 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 the following:

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- o the demand for our technologies;
- o our ability to manufacture products efficiently and with the required quality;
- o our ability to increase manufacturing capacity;
- o the level of product and 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

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During the first seven months of 2002, we derived 86% of our revenue from the following three customers:

- o Ferring Pharmaceutical NV (57%)
- o BioSante Pharmaceuticals, Inc. (25%)
- o Solvay Pharmaceuticals B.V. (4%)

The loss of any one of these customers could cause revenues to decrease significantly, resulting in, or increasing, our losses from operations. 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.

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 addition, our plans call for significantly increased levels of production and a shift to performing more manufacturing functions internally rather than relying on third-party suppliers, which will require us to eventually expand beyond our current facilities. 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. There can be no assurance that we will be able to 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 technologies have achieved only limited acceptance by patients and physicians, which could have a negative effect on our revenue

Our revenues depend on ultimate patient and physician acceptance of our needle-free injectors, gels, patches and our other potential drug delivery technologies as an alternative to more traditional forms

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of drug delivery including injections using a needle, tablets and liquid formulas. To date, these delivery technologies have achieved only limited acceptance from such parties. If our drug delivery technologies are not accepted in the marketplace, the pharmaceutical company partners may be unable to successfully 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 the following:

- o demonstrated clinical efficacy and safety;
- o cost-effectiveness;

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- o convenience and ease of administration of injectors, transdermal gels and patches;
- o advantages over alternative drug delivery systems; and
- o marketing and distribution support.

Physicians may refuse to prescribe products incorporating our drug delivery technologies if the physicians believe that the active ingredient is better administered to a patient using alternative drug delivery technologies or the physicians believe that the delivery method will result in patient noncompliance. Factors such as allergic reactions, patient perceptions that a gel is inconvenient and cosmetic considerations about patches may cause patients to reject our drug delivery technologies.

In addition, we expect that the pharmaceutical company partners will price products incorporating their drug delivery technologies slightly higher than conventional methods, which may impair their acceptance. Because only a limited number of products incorporating our drug delivery technologies are commercially available, we cannot yet assess the level of market acceptance of our drug delivery technologies.

Our success depends on the market acceptance of alternative drug delivery technologies, and the failure to obtain such acceptance could substantially reduce our revenue

Our success will, in large part, depend upon increasing market acceptance of our drug delivery technologies as an alternative to traditional delivery systems. During the time period since initial commercial introduction, our products have had only limited success competing with traditional drug delivery systems for a variety of reasons, including the size, cost and complexity of use and maintenance of our drug delivery technologies and the relatively small number of drugs that have been self-administered. In order to increase market acceptance, we believe that we must successfully develop improvements in the design and functionality of future drug delivery technology that will reduce cost and increase appeal to users, thereby making these technologies desirable despite their premium cost over traditional drug delivery systems. Projected improvements in functionality and design may not adequately address the actual or perceived complexity of using our drug delivery technologies or adequately reduce cost. In addition, we believe that our future success depends upon our ability to enter into additional collaborative agreements with drug and medical device manufacturers, as discussed below. There can be no assurance that we will be successful in these efforts or that our drug delivery technologies will ever gain sufficient market acceptance to achieve and/or sustain profitable operations.

Although transdermal patches are a well-accepted method of drug delivery, many other companies compete in this sector. Because the cost of manufacturing equipment for transdermal patches is high, most manufacturing is done by a limited number of contract manufacturers. Therefore, our costs will remain high and our pricing options will be limited. We may develop a superior patch, but we may not be able to price it competitively, or our margins may not justify maintaining the business if our market share is low. Patches are not central to our business strategy and may suffer from lack of attention. There can be no assurance that we will be successful in the transdermal patch market.

Because transdermal gels are a newer, less understood method of drug delivery, our potential consumers, the pharmaceutical manufacturers, have little experience with manufacturing costs or pricing parameters. Our assumption of

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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.

Although the injectable gel research field is active, there is essentially no data regarding consumer acceptance. Regulatory compliance and approvals can take a substantial amount of time due to clinical evaluations that are required for this type of method but not for other drug delivery methods. 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 study being conducted on oral female hormone replacement therapy (HRT) because the study showed an increased risk of breast cancer, heart disease and blood clots in women taking HRT. The study looked at only one brand of oral HRT, and there is no information on whether other brands with different levels of hormones would carry the same risks. Because the FDA's findings are very recent, we cannot assess what impact, if any, they will have on the HRT market as a whole, or on our own HRT product line. Additionally, there is no 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.

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 and pursue additional proprietary drug delivery technologies. Even if enhanced or additional 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 be uneconomical to market; or
- o we may not receive necessary regulatory approvals for the potential technologies.

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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 United States the injector products are only available for use with insulin. A transdermal patch containing estradiol for hormone replacement therapy is sold in Chile. 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 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

We believe that the introduction and broad acceptance of our drug delivery technologies is in part dependent upon the success of our current and any future development and licensing arrangements with pharmaceutical and medical device companies covering the development, manufacture, use and marketing of drug delivery technologies with specific parenteral drug therapies. We anticipate that under these arrangements the pharmaceutical or medical device company will assist 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. The pharmaceutical or medical device company also will 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. There can be no assurance that we will be successful in executing additional agreements with pharmaceutical or medical device companies or that existing or future agreements will result in increased sales of our drug delivery technologies. If we do not enter into additional agreements in the future, or if our current or future agreements do not result in

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successful marketing of our products, 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 these arrangements, we are dependent upon the development, data collection and marketing efforts of such pharmaceutical and medical device companies. The amount and timing of

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resources such pharmaceutical and medical device companies devote to these efforts are not within our control, and such pharmaceutical and medical device companies 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 of our drug delivery technology.

Additional risks that we face related to our collaborative agreements include the following:

- o other pharmaceutical and biotechnology companies may not consider our technology the most appropriate to provide the additional benefit such companies require in order for them to justify investment in our technology, and as a result we may be unable to enter into collaborative agreements to develop additional products using drug delivery technologies;
- o any existing or future collaborative agreements may not result in additional commercial products;
- o additional commercial products that we may develop may not be successful;
- o 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; and
- o we may not be able to develop successful new drug delivery technologies that will be attractive to potential pharmaceutical company partners.

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. Further, we may incorporate certain of our drug delivery technologies into the oral dosage forms of products marketed and sold by pharmaceutical company partners. We do not have a direct marketing channel to consumers for drug delivery technologies. Therefore, the success of the marketing organizations of the pharmaceutical

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company partners, as well as the level of priority assigned to the marketing of the products by these entities, which may differ from our priorities, will determine the success of the products incorporating our technologies.

Because the barriers to entry in our product market are low, we face increasing competition which could force us to reduce our prices and, consequently, decrease our planned profits

Our current competition comes primarily from traditional hypodermic needles and syringes that are used for the vast majority of injections administered today and from transdermal patch and gel products marketed by others. Currently, competition in the needle-free injection market is limited to small companies with limited financial and other resources, but the barriers to entry are currently low, and additional competitors may enter the needle-free injection systems market, including companies with substantially greater resources and experience than us. There can be no assurance that we will be able to

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compete effectively against our current or potential competitors in the drug delivery market, or that such competitors will not succeed in developing or marketing products that will be more accepted in such market. 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 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 23 patents in the United States and 23 patents in other countries. We have also made application for a total of 44 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, we may have to seek licenses, defend infringement actions or challenge the

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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.

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

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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 the 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 us or our partners. 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, we, and the pharmaceutical companies, may be subject to sanctions, including the following:

- 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.

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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 could suffer if our competitors develop a superior drug delivery technology, and we are unable to effectively compete with that technology

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., Weston Medical Group plc, 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. Many companies, both large and small, are engaged in research and development efforts on novel techniques aimed at delivering such drugs through the skin, either without needle injection or by patch and gel. The successful 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. Developments by competitors may render our products, or potential products, noncompetitive or obsolete.

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We expect our quarterly revenues and operating results to fluctuate for a number of reasons, which could cause our stock price to fluctuate

Our operating results may vary significantly from quarter to quarter, in part because of changes in consumer buying patterns, aggressive competition, the timing of the recognition of licensing or development fee payments and the timing of, and costs related to, any future technology or new drug use introductions. Our operating results for any particular quarter are not necessarily indicative of any future results. The uncertainties associated with the introduction of any new technology or drug use and with general market trends may limit management's ability to forecast short-term results of operations accurately. Fluctuations caused by variations in quarterly operating results or our failure to meet analysts' projections or public expectations as to results may adversely affect the market price of our Common Stock.

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

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results or financial condition. We plan on hiring personnel to work in the areas of regulatory/clinical, device production and administrative support. Competition for such personnel is intense, and there can be no assurance that we will be successful in attracting and retaining key personnel in the future.

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.

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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.

Risks Related to our Common Stock

Our stock price has been, and is likely to continue to be, volatile, which may result in a loss to our shareholders

The market price for our common stock has been volatile. As of September 6, 2002, the 52-week low and high sales prices of our common stock reported by the Nasdaq SmallCap market ranged from \$1.59 per share to \$5.00 per share. The trading prices of our common stock could be subject to wide fluctuations in response to events or factors, many of which are beyond our control. These could include, without limitation (i) quarter to quarter variations in our operating results, (ii) announcements by us or our competitors regarding the results of regulatory approval filings, clinical trials or testing, (iii) developments or disputes concerning proprietary rights, (iv) technological innovations or new commercial products, (v) material changes in our collaborative arrangements and (vi) general conditions in the medical technology industry. Moreover, the stock

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market has experienced extreme price and volume fluctuations, which have particularly affected the market prices of many medical technology and device companies and which have often been unrelated to the operating performance of such companies.

All decisions affecting our company are under the control of a single shareholder who 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 63.8%) 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.

Because Permaterc and Dr. Gonella own more than 50% of the combined voting power of our stock, they will be able to generally determine the outcome of all corporate actions requiring shareholder approval. As a result, Permaterc and Dr. Gonella will be in a position to control all matters affecting our Company, including decisions as to our corporate direction and 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 September 6, 2002, our officers and directors beneficially owned an aggregate of 6,772,234 shares (or 66.5%) 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

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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 convertible debentures may lower the market price of our common stock

As of September 6, 2002, \$1,400,000 principal amount of secured convertible debentures were issued and outstanding. Investors have agreed to fund an additional \$600,000 of principal amount of convertible debentures upon this registration statement becoming effective. The debentures are convertible into such number of shares of common stock as is determined by dividing the principal amount thereof by the then current conversion price. The per share conversion price for the debentures is the lower of \$2.50 or 75% of the average of the three lowest intraday trading prices, as reported on the Nasdaq SmallCap Market, during the twenty trading days prior to the conversion date. If converted on September 9, 2002, the conversion price would have been \$1.125, and the outstanding debentures would have been convertible into approximately 1,244,444 shares of common stock, but this number of shares could prove to be significantly greater in the event of a decrease in the trading price of our common stock. If the aggregate \$2 million principal amount of debentures were

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outstanding at September 9, 2002, they would be currently convertible into 1,777,778 shares of our common stock, which could also prove to be significantly greater in the event of a decrease in the trading price of our common stock. Purchasers of common stock could therefore experience substantial dilution of their investment upon conversion of the debentures. In addition, as the per share conversion price of the debentures into common stock is substantially lower than the current market price of our common stock, we will be recording an accounting charge for the beneficial in-the-money conversion feature of the debentures. This charge will be material to our financial statements and could equal the principal amount of the converted debentures. The debentures are not registered and may be sold only if registered under the Securities Act of 1933, as amended, or sold in accordance with an applicable exemption from registration, such as Rule 144. The shares of common stock into which the debentures may be converted are being registered pursuant to this registration statement.

As of September 6, 2002, 3,555,556 shares of common stock were reserved for issuance upon conversion of the debentures. As of September 6, 2002, there were 9,790,325 shares of common stock outstanding. Of these outstanding shares, 3,022,802 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 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.

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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.

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SELLING SHAREHOLDERS

In connection with a Securities Purchase Agreement dated July 12, 2002, the selling shareholders purchased, and agreed to purchase, 10% Convertible Debentures in the aggregate amount of \$2,000,000. At the same time, we entered into a Registration Rights Agreement under which we agreed to register the stock issuable upon conversion of the debentures. Under the terms of the Registration Rights Agreement, we agreed to file a registration statement for the conversion stock within 15 days of the closing of the transaction. 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 upon conversion of the debentures for resale by the selling shareholders to meet this obligation.

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 September 6, 2002; (ii) the number of shares of common stock to be offered for resale by each selling shareholder; 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).

| Name | Number of shares of Common Stock beneficially owned at September 6, 2002 (1) | Number of shares of Common Stock to be Offered (1) | Shares Owned after Comp Offering (1) Number | Perc |
|---------------------------------|--|--|---|------|
| AJW Partners, LLC (2) | 244,444 | 244,444 | 0 | |
| AJW Offshore, Ltd. (3) | 400,000 | 400,000 | 0 | |
| AJW Qualified Partners, LLC (4) | 244,444 | 244,444 | 0 | |
| Xmark Fund, LP (5) | 207,378 | 207,378 | 0 | |
| Xmark Fund, Ltd. (6) | 681,512 | 681,512 | 0 | |
| SDS Merchant Fund, LP (7) | 888,889 | 888,889 | 0 | |
| OTATO Limited Partnership (8) | 888,889 | 888,889 | 0 | |

- (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 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.
- (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.

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- (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.
- (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.
- (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.
- (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.
- (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.

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. The debentures are convertible at a price which is the lesser of \$2.50 or 75% of the average of the three lowest intraday trading prices of our common stock, as reported on the Nasdaq SmallCap Market, for the twenty trading days prior to the conversion date. The actual number of shares of common stock issuable upon conversion of the debentures is indeterminate, is subject to adjustment and could be materially less or more than such estimated number depending on factors which cannot be predicted by us at this time including, among other factors, the future market price of the common stock. Under the terms of our Registration Rights Agreement with the selling shareholders listed herein, we are obligated to register 200% of the number of shares which may be issued upon conversion of the convertible debentures held by the selling shareholders. 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 upon conversion of the debentures 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, if the debentures had actually been converted on September 9, 2002, the conversion price would have been \$1.125.

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

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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 4.9% of the then outstanding common stock as determined in accordance with Section 13(d) of the Exchange Act.

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PLAN OF DISTRIBUTION

We are registering the resale of certain shares of common stock into which the debentures are convertible on behalf of the selling shareholders. The selling shareholders may offer and resell such shares 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):

- 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 selling shareholders may enter into hedging transactions with third parties, which may in turn engage in short sales of the common stock into which the debentures are convertible in the course of hedging the position they assume. The selling shareholders may also enter into short positions or other derivative transactions relating to the common stock into which the debentures are convertible, 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 are convertible, 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

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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.

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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 issuable upon conversion of the debentures under the terms of the registration rights agreement. 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

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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.

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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 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
- o 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.

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EXPERTS

The consolidated financial statements and schedule of Antares Pharma, Inc. as of December 31, 2000 and 2001 and for each of the years in the three-year period ended December 31, 2001 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, 2001, 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 covering the December 31, 2001, consolidated financial statements refers to a change to the cumulative deferral method of revenue recognition for licensing arrangements in 2000.

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

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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.

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

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 | \$611.00 |
| Legal Fees and Expenses | 30,000.00 |
| Accounting Fees and Expenses | 25,000.00 |
| Miscellaneous | 889.00 |
| | ----- |
| Total | \$61,500.00 |
| | ===== |

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

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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 ----- |
|----------------------------|---|
| 4.1* | Form of our Common Stock Certificate. |
| 5.1+ | Opinion of Leonard, Street and Deinard Professional Association. |
| 10.29# | Securities Purchase Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund, L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership. |
| 10.30# | Registration Rights Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund, L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership. |
| 10.31# | Security Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund, L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership. |
| 10.32# | Form of Secured Convertible Debenture, dated July 12, 2002. |
| 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). |
| * | 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 July 17, 2002, and incorporated herein by reference. |
| + | Previously filed as an exhibit to our Form S-3, filed with the SEC on July 19, 2002, 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
 - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) to reflect in the prospectus any facts or events arising after

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the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering

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range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(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 September 10, 2002.

ANTARES PHARMA, INC.

By: /s/ Roger G. Harrison, Ph.D.

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

| Signature ----- | Title ----- | |
|---|---|----|
| /s/ Roger G. Harrison, Ph.D. ----- Roger G. Harrison, Ph.D. | Chief Executive Officer and Director (principal executive officer) | Se |
| /s/ Lawrence M. Christian ----- Lawrence M. Christian | Vice President of Finance, Chief Financial Officer and Secretary (principal financial and accounting officer) | Se |
| * | Director, Chairman of the Board | Se |
| ----- Dr. Jacques Gonella | | |
| * | Director, Vice Chairman of the Board | Se |
| ----- Franklin Pass, M.D. | | |
| * | Director | Se |
| ----- James Clark | | |
| * | Director | Se |
| ----- Prof. Ubaldo Conte | | |
| * | Director | Se |
| ----- Dr. Philippe Dro | | |
| * | Director | Se |
| ----- Kenneth Evenstad | | |
| * | Director | Se |
| ----- Dr. Thomas Rinderknecht | | |
| * | Director | Se |

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John Gogol

*

Director

Jacques Rejeange

*By: /s/ Roger G. Harrison, Ph.D.

Attorney-in-Fact

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