ANTARES PHARMA INC
Form S-2
September 25, 2003
Table of Contents

As filed with the Securities and Exchange Commission on September 25, 2003

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-2

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

ph. (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

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

If the registrant elects to deliver its latest annual report to security holders, or a complete and legible facsimile thereof, pursuant to Item 11(a)(1) of this form, 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, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Shares To Be Registered	Amount To Be Registered (1)	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee

Common Stock, par value $.01 per share	17,397,658	$1.99	$34,621,340	$2,801

(1) Includes shares of common stock which may be offered pursuant to this registration statement, certain of which are issuable upon the exercise of warrants and certain of which are issuable upon conversion of our Series D Convertible Preferred Stock. The number of shares of common stock registered hereunder represents a good faith estimate by the Company of the number of shares of common stock issued and issuable upon exercise and conversion of such warrants and convertible stock. 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 as reported on the OTC Bulletin Board on Wednesday, September 24, 2003.

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.

Table of Contents

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

SUBJECT TO COMPLETION, DATED SEPTEMBER 25, 2003

PRELIMINARY PROSPECTUS

17,397,658 SHARES OF

ANTARES PHARMA, INC.

COMMON STOCK

This prospectus relates to the offering of 17,397,658 shares of our common stock which may be sold from time to time by the selling shareholders named in this prospectus.

The shares of our common stock are being registered to permit the selling shareholders to sell the shares from time to time in the public market. The shareholders may sell the shares in negotiated transactions or otherwise, at market prices prevailing at the time of sale or at negotiated prices. The timing and amount of any sale are within the sole discretion of the selling shareholders. In addition, the shares may be offered from time to time through ordinary brokerage transactions, directly to market makers of our shares or through any other means described in the section entitled Plan of Distribution beginning on page 20.

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 OTC Bulletin Board under the symbol ANTR. The last reported sales price of our common stock as reported on the OTC Bulletin Board on September 24, 2003 was $1.89 per share.

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

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

The date of this prospectus is , 2003.

Table of Contents

TABLE OF CONTENTS

Table of Contents

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 ide 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.

This prospectus is part of a registration statement on Form S-2 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.

RECENT DEVELOPMENTS

On each of July 7, 2003 and July 17, 2003, we sold to several investors an aggregate of 4,000,000 shares of our common stock and warrants to purchase an aggregate of 3,000,000 shares of our common stock. We received an aggregate of $4,000,000 in proceeds from these transactions.

On August 13, 2003, we amended certain agreements related to the issuance of warrants in our January 31, 2003 debt restructuring. Prior to the amendment, the warrants were classified as liabilities, and we were required to mark to market the value of the warrants each reporting period. As a result of the amendments, the value of the warrants, which was $4,437,269 on August 13, 2003, is now classified as equity rather than as a liability, and we are no longer required to adjust the market value of the warrants each reporting period. We recorded a non-cash charge of $1,714,061 during the third quarter of 2003 to increase the carrying value of the warrants from $2,723,208 at June 30, 2003 to $4,437,269 at August 13, 2003.

On September 12, 2003, holders of our 8% debentures exchanged the principal and accrued interest on such debentures for an aggregate of 243,749 shares of our Series D Convertible Preferred Stock. Each share of our Series D stock is, at September 25, 2003, convertible into ten shares of our common stock, or an aggregate of 2,437,490 shares of common stock, the same number of shares into which the debentures were convertible prior to their exchange. The debenture holders also executed lien release letters terminating the security interest they held in our assets. As consideration for this lien release, we agreed to reduce the exercise price on warrants issued to the debenture holders on January 31, 2003 from $0.55 to $0.40, which warrants are currently exercisable for an aggregate of 2,932,500 shares of our common stock.

Additionally, on the same date, Dr. Jacques Gonella, our largest shareholder, converted all debt due and owing to him, together with accrued interest, at a conversion price of $1.00 per share, into 2,398,635 shares of our common stock. As further consideration for Dr. Gonella s agreement to convert the debt, we issued to him a five-year warrant to purchase 1,798,976 shares of our common stock at a per share conversion price of $1.25. The $1.00 conversion price and the $1.25 warrant exercise price were the same prices offered to our investors in our July 2003 private placements.

Table of Contents

We are currently evaluating the accounting consequences of the above-described debenture exchange and conversion of debt. We anticipate that we will record a non-cash charge during the quarter ended September 30, 2003 related to these transactions.

Also on September 12, 2003, we executed a Development and License Agreement with Eli Lilly and Company, under which we licensed certain of our technology to Lilly for use in the therapeutic fields of diabetes and obesity. We also granted to Lilly an option to apply the same technology in one other undisclosed therapeutic field. Finally, we issued to Lilly a ten-year warrant to purchase 1,000,000 shares of our common stock at a per share exercise price of $3.776.

We believe that the combination of equity financing received in the July 2003 financing transactions, the exchange of the debentures for preferred stock, the conversion of Dr. Gonella s debt to common stock and our projected product sales and product development and license revenues will provide us with sufficient working capital through the second quarter of 2004.

Table of Contents

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 Offering

This prospectus relates to the offering of 17,397,658 shares of our common stock which may be sold from time to time by the selling shareholders named in this prospectus. Certain of these selling shareholders purchased our common stock and warrants to purchase shares of our common stock in two separate private placements that closed in July 2003. Other selling shareholders exchanged debentures they held for shares of our Series D Convertible Preferred Stock, which stock is convertible into shares of our common stock. Our largest shareholder also converted debt due and owing to him into shares of our common stock. The remaining selling shareholders received shares of our common stock or warrants to purchase shares of our common stock pursuant to investor relations agreements. 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 selling shareholders will determine the timing and amount of any sale, and we will not receive any of the proceeds from the sale of the shares.

The Company and our Business

We develop, manufacture and market pressure assisted injection devices, called jet injectors, that allow people to self-inject drugs without using a conventional needle. Our needle-free injectors utilize a small spring-action device and attached disposable plastic syringes to hold a liquid drug. The 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. Our mini-needle injector utilizes a very small needle that is covered so that the user never sees it during the process of injection. The needle is used to break the skin, and the device then uses low pressure to accelerate the liquid stream into the tissue underneath the needle. Although our needle-free injector is our major product, we have also developed topical gel formulations that allow delivery of drugs across the skin.

We currently outsource the assembly of our devices and related products. However, we remain responsible for the release of our devices to the market. We specify procedures and processes to be utilized by the assembler, and any changes to such procedures and processes require our prior approval. We will not release any products to the market without first reviewing the assembler s testing of the product or conducting our own tests on the product.

We operate in the specialized drug delivery sector of the pharmaceutical industry. Companies in this sector generally bring technology and know-how in the area of drug formulation (in our case, injection devices and topical gels) to pharmaceutical manufacturers through licensing

and development agreements. Pharmaceutical manufacturers then use the technology licensed to them to offer alternative methods of administering their drug formulations. We have negotiated and executed licensing relationships for use of our reusable needle-free devices with human growth hormone in Europe and Asia, for hormone replacement therapy in the United States, Europe and other parts of the world and for diabetes and obesity therapy in the world. In addition, on a limited basis, we continue to sell our reusable needle-free devices directly for patient self-administration of insulin in the U.S. and certain other markets.

On January 31, 2001, we completed a business combination to acquire the three operating subsidiaries of Permatec Holding AG, headquartered in Basel, Switzerland. Our company (formerly called Medi-Ject) was

Table of Contents

focused on delivery of drugs across the skin using jet injectors, and Permatec 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 Permatec subsidiaries was accounted for as a reverse merger because upon the closing of the transaction, Permatec and its principal, Dr. Jacques Gonella, owned in excess of 67% of the outstanding shares of our common stock. The historical financial statements of Permatec thus became those of the company. Upon consummation of the transaction, the acquired Permatec subsidiaries were renamed Antares Pharma AG, Antares Pharma IPL AG and Antares Pharma NV, and we changed our name to Antares Pharma, Inc.

Our principal executive offices are located at 707 Eagleview Boulevard, Suite 414, Exton, Pennsylvania 19341, and our telephone number 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 facilities are located in Minneapolis, Minnesota.

Table of Contents

RISK FACTORS

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

Risks Related to Our Business

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

The report of our independent accountants in our Annual Report on Form 10-K for the fiscal year ended December 31, 2002 contains an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern as a result of negative working capital, recurring losses and negative cash flows from operations. We had negative working capital of ($11,712), ($4,188,234) and ($10,388,878) at December 31, 2001 and 2002 and June 30, 2003, respectively. We incurred net losses of ($9,499,101), ($11,608,765) and ($6,687,012) in the fiscal years ended 2001 and 2002 and the six months ended June 30, 2003, respectively. In addition, we have accumulated aggregate net losses from the inception of business through June 30, 2003 of ($47,852,806). 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.

During the six months ended June 30, 2003, we recognized a loss in the amount of $1,580,766 on the warrants, exercisable for 2,932,500 shares of our common stock, that we issued in our debt restructuring in January 2003. The losses are the result of the warrants being classified as debt under generally accepted accounting principles that require us to mark-to-market the warrants at each reporting period with changes in the warrant values being recorded in our consolidated statement of operations. Effective August 13, 2003, we amended the warrants and the related registration rights agreement to eliminate certain provisions that caused the warrants to be classified as a liability. On the date of the amendment, the fair value of the warrants was $4,437,269, and this amount was converted to equity. We recorded a non-cash charge of $1,714,061 during the third quarter of 2003 to increase the carrying value of the warrants from $2,723,208 at June 30, 2003 to $4,437,269 at August 13, 2003. We are also in the process of amending the warrants we issued in July 2003 to eliminate similar provisions and allow the warrants to be classified as equity. We intend to complete the amendments by September 30, 2003.

We recently completed transactions under which our debenture holders and our largest shareholder converted their debt into equity. We believe that the combination of the equity financing of $4,000,000 received in July 2003, the conversion of all debt to equity and projected product sales and product development and license revenues will provide us with sufficient working capital through the second quarter of 2004.

Long-term capital requirements will depend on numerous factors, including, but not limited to, the status of collaborative arrangements, the progress of research and development programs and the receipt of revenues from sales of products. Our ability to achieve and/or sustain profitable operations depends on a number of factors, many of which are beyond our control. These factors include, but are not limited to, the following:

the demand for our technologies from current and future biotechnology and pharmaceutical partners;

our ability to manufacture products efficiently and with the required quality;

our ability to increase manufacturing capacity to allow for new product introductions;

the level of product competition and of price competition;

our ability to develop additional commercial applications for our products;

Table of Contents

our ability to obtain regulatory approvals;

our ability to control costs; and

general economic conditions.

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

During fiscal 2002 and the six months ended June 30, 2003, we derived approximately 79% and 72% of our revenue, respectively, from the following two customers:

Ferring Pharmaceutical NV (approximately 49% in 2002 and approximately 62% in the six months ended June 30, 2003)

BioSante Pharmaceuticals, Inc. (approximately 30% in 2002 and approximately 10% in the six months ended June 30, 2003)

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

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

Pursuant to our license agreement with Ferring BV, we licensed certain of our intellectual property related to our needle-free injection devices, including a license that allows Ferring to manufacture our devices on its own for use with its human growth hormone product. This license becomes effective if we are unable to continue to supply product to Ferring under our current supply agreement. In accordance with the license agreement, we entered into a manufacturing agreement with a third party to manufacture our devices for Ferring. If we or this third party are unable to meet our obligations to supply Ferring with our devices, Ferring would own a fully paid up license to manufacture our devices and to use and exploit our intellectual property in connection with Ferring s human growth hormone product. In such event, we would no longer receive royalty revenues from Ferring, and we would no longer be able to license such technology to other parties for use in the field of human growth hormone therapy.

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

Our past assembly, testing and manufacturing experience for certain of our technologies has involved the assembly of products from machined stainless steel and composite components in limited quantities. Our planned future drug delivery technologies necessitate significant changes and

additions to our manufacturing and assembly process to accommodate new components. These systems must be manufactured in compliance with regulatory requirements, in a timely manner and in sufficient quantities while maintaining quality and acceptable manufacturing costs. In the course of these changes and additions to our manufacturing and production methods, we may encounter difficulties, including problems involving yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment, component supplies and shortages of personnel, any of which could result in significant delays in production. Additionally, in February 2003, we entered into a manufacturing agreement under which a third party will assemble certain component parts of our MJ6B and MJ7 devices. There can be no assurance that this third-party manufacturer will be able to meet these regulatory requirements or our own quality control standards. Therefore, there can be no assurance that we will be able to successfully produce and manufacture our drug delivery technology. Any failure to do so would negatively impact our business, financial condition and results of operations.

Table of Contents

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

Our business ultimately depends on patient and physician acceptance of our needle-free injectors, gels and our other drug delivery technologies as an alternative to more traditional forms of drug delivery, including injections using a needle and transdermal patch products. To date, our device technologies have achieved only limited acceptance from such parties. The degree of acceptance of our drug delivery systems depends on a number of factors. These factors include, but are not limited to, the following:

- advantages over alternative drug delivery systems or similar products from other companies;
- demonstrated clinical efficacy, safety and enhanced patient compliance;
- cost-effectiveness;
- convenience and ease of use of injectors and transdermal gels; and
- marketing and distribution support.

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

A 2002 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 (FDA) halted the Women s Health Institute s (WHI) long-term study being conducted on oral female hormone replacement therapy (HRT) using a combination of estradiol and progestin because the study showed an increased risk of breast cancer, heart disease and blood clots in women taking this dosage regimen. In January 2003, the FDA announced that it would require new warnings on combination HRT products, and it advised patients to consult with their physicians about whether to continue treatment with continuous combined HRT and to consider all alternatives before initiating treatment. Subsequently, additional analysis from the WHI study has suggested a slight increase in the risk of cognitive dysfunction developing in patients on long-term combined HRT. These results and recommendations impacted the use of HRT, and product sales have diminished significantly. We cannot yet assess the impact the study s results may have on our contracts for our transdermal gel products designed for HRT. We also cannot predict whether our alternative route of transdermal administration of these products will result in similar effects.

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

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

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

Table of Contents

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 negatively impact our business as a whole

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

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

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

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

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

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 a technology s 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

Our business plans require us to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use and marketing of drug delivery technologies with

Table of Contents

specific drug therapies. Under these arrangements, the partner company typically assists us in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. Our licensees will also be responsible for distribution and marketing of the technologies for these drug therapies either worldwide or in specific territories. We are currently a party to a number of such agreements, all of which are currently in varying stages of development. We may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product) and thus, would not receive the fees expected from such arrangements. Moreover, there can be no assurance that we will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of our drug delivery technologies. In such event, our business, results of operations and financial condition could be adversely affected, and our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability. As a result of our collaborative agreements, we are dependent upon the development, data collection and marketing efforts of our licensees. The amount and timing of resources such licensees devote to these efforts are not within our control, and such licensees could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales of our drug delivery technology.

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

Pharmaceutical company partners help us develop, obtain regulatory approvals for, manufacture and sell our products. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of the products as planned, our revenues and profits may not reach expectations or may decline. We may not be able to control the timing and other aspects of the development of products because pharmaceutical company partners may have priorities that differ from ours. Therefore, commercialization of products under development may be delayed unexpectedly. We do not intend to have a direct marketing channel to consumers for our drug delivery technologies except through current distributor agreements in the United States for our insulin delivery device. Therefore, the success of the marketing organizations of the pharmaceutical company partners, as well as the level of priority assigned to the marketing of the products by these entities, which may differ from our priorities, will determine the success of the products incorporating our technologies. Competition in this market could also force us to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability.

We face increasing competition, and our business could suffer if we are unable to effectively compete with our competitors technologies

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

Table of Contents

In general, injection is used only with drugs for which other drug delivery methods are not possible, in particular with biopharmaceutical proteins (drugs derived from living organisms, such as insulin and human growth hormone) that cannot currently be delivered orally, transdermally (through the skin) or pulmonarily (through the lungs). Transdermal patches and gels are also used for drugs that cannot be delivered orally or where oral delivery has other limitations (such as high first pass drug metabolism, meaning that the drug dissipates quickly in the digestive system and, therefore, requires frequent administration). Many companies, both large and small, are engaged in research and development efforts on less invasive methods of delivering drugs that cannot be taken orally. The successful development and commercial introduction of such a non-injection technique would likely have a material adverse effect on our business, financial condition, results of operations and general prospects.

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

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

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

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

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

Currently, we have been granted 28 patents in the United States and 37 patents in other countries. We have also made application for a total of 114 patents, both in the United States and other countries. Any patent applications we may have made or may make relating to inventions for our actual or potential products, processes and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for our inventions. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain their own patents that may have an adverse effect on our ability to conduct business, or are able to otherwise circumvent our patents. Further, we may not have the necessary financial resources to enforce or defend our patents or patent applications.

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 and independently develop the same or similar 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

Table of Contents

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

If the pharmaceutical companies to which we license our technologies lose their patent protection or face patent infringement claims for their drugs, our revenues may decrease

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 expected revenues, in that event, may not materialize or may decline.

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

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

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

In other jurisdictions, we, and the pharmaceutical companies with whom we are developing technologies, must obtain required regulatory approvals from regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market the products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues may not materialize or may decline. 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 and, as a result, are subject to sanctions

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

warning letters;

fines;

Table of Contents

product seizures or recalls;

injunctions;

refusals to permit products to be imported into or exported out of the applicable regulatory jurisdiction;

total or partial suspension of production;

withdrawals of previously approved marketing applications; or

criminal prosecutions.

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

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

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

The testing, manufacturing and marketing of products utilizing our drug delivery technologies may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical companies with whom we are developing drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses that may have been suffered. A successful product liability claim against us, if not covered by, or if in excess of our product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations. Adverse claim experience for our products or licensed technologies or medical device, pharmaceutical or insurance industry trends may make it difficult for us to obtain product liability insurance or we may 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.

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

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

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

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

increased complexity and costs of managing international operations;

Table of Contents

protectionist laws and business practices that favor local companies;

dependence on local vendors;

multiple, conflicting and changing governmental laws and regulations;

difficulties in enforcing our legal rights;

reduced or limited protections of intellectual property rights; and

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.

Geopolitical, economic and military conditions, including terrorist attacks and other acts of war, may materially and adversely affect the markets on which our common stock trades, the markets in which we operate, our operations and our profitability

Terrorist attacks, such as those that occurred on September 11, 2001, and other acts of war, and any response to them, may lead to armed hostilities and such developments would likely cause instability in financial markets. Armed hostilities and terrorism may directly impact our facilities, personnel and operations which are located in the United States and Switzerland, as well as those of our clients. Furthermore, severe terrorist attacks or acts of war may result in temporary halts of commercial activity in the affected regions, and may result in reduced demand for our products. These developments could have a material adverse effect on our business and the trading price of our common stock.

Risks Related to our Common Stock

On July 1, 2003, our stock was delisted from Nasdaq for failure to comply with Nasdaq s listing standards, and investors may perceive our listing on the OTC Bulletin Board as less desirable

On July 1, 2003, our stock was delisted from the Nasdaq SmallCap Market, and it now trades in the over-the-counter market, which is viewed by most investors as a less desirable and less liquid marketplace. Trading of our common stock in the over-the-counter market may be more difficult because of lower trading volumes, transaction delays and reduced security analyst and news media coverage. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. Additionally, trading of our common stock in an over-the-counter market may make us less desirable to institutional investors and may, therefore, limit our future equity funding options.

Three of our shareholders own a majority of our stock, and this could lower the price of our common stock

As a result of our reverse business combination with Permatec in January 2001 and subsequent additional debt and equity financing, Permatec Holding AG and its controlling shareholder, Dr. Jacques Gonella own a substantial portion of (currently approximately 44%) the outstanding shares of our common stock. Dr. Gonella also owns warrants to purchase an aggregate of 4,198,976 shares of common stock and options to purchase 25,000 shares of common stock. Additionally, three investors (Xmark Fund, Ltd., Xmark Fund, L.P. and SDS Merchant Fund, LP) own Series D Convertible Preferred Stock and warrants that are, as of September 25, 2003, convertible into or exercisable for an aggregate of 6,869,990 shares of our common stock. These investors also directly own an aggregate of 2,950,000 shares of our common stock. If Dr. Gonella and these investors converted all of the Series D stock and exercised all of the warrants owned by them, Dr. Gonella would own approximately 42%, and the investors as a group would own approximately 32%, of our fully-diluted common stock.

Table of Contents

Because the parties described above either currently own or could potentially own a large portion of our stock, they will be able to generally determine the outcome of all corporate actions requiring shareholder approval. As a result, these parties will be in a position to control all matters affecting our company, including decisions as to our corporate direction and 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. As a result, some investors may be unwilling to purchase our common stock. If the demand for our common stock is reduced because of these shareholders control of the Company, the price of our common stock could be materially depressed.

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

As of September 25, 2003, our officers and directors beneficially owned an aggregate of 13,615,995 shares (or approximately 67%) of our common stock, including stock options exercisable within 60 days. If our officers and directors, or other shareholders, sell a substantial amount of our common stock, it could cause the market price of our common stock to decrease and could hamper our ability to raise capital through the sale of our equity securities.

Sales of our common stock by the holders of our Series D stock and warrant holders may lower the market price of our common stock

As of September 25, 2003, 243,749 shares of our Series D Convertible Preferred Stock were issued and outstanding. Each share of Series D stock is, as of September 25, 2003, convertible into ten shares, or an aggregate of 2,437,490 shares of common stock. The holders of the Series D stock also hold warrants (issued in connection with the sale of our 8% debentures and issued in the July 7, 2003 transaction) exercisable at prices of $.40 per share and $1.25 per share for an aggregate of 4,432,500 shares of our common stock. Purchasers of common stock could therefore experience substantial dilution of their investment upon conversion of the Series D stock or exercise of the warrants. The Series D stock and warrants 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 warrants issued with the debentures may be exercised are currently registered and may be sold without restriction. The remaining shares of common stock into which the Series D stock may be converted and into which the warrants issued on July 7, 2003 may be exercised are being registered pursuant to this registration statement.

As of September 25, 2003, 5,369,986 shares of common stock were reserved for issuance upon conversion of the Series D stock and exercise of the warrants. As of September 25, 2003, there were 19,784,398 shares of common stock outstanding. Of these outstanding shares, 5,782,683 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 any 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.

Table of Contents

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

USE OF PROCEEDS

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

SELLING SHAREHOLDERS

July 2003 Private Placement Selling Shareholders

In connection with two separate Purchase Agreements dated July 7, 2003 and July 17, 2003, we sold to several investors 4,000,000 shares of our common stock and warrants to purchase 3,000,000 shares of our common stock at a price of $1.00 per share. In connection with the issuance of the common stock and warrants, we entered into a Registration Rights Agreement under which we agreed to register the common stock issued and the common stock issuable upon exercise of the warrants. To meet this obligation, we have filed a registration statement on Form S-2, of which this prospectus is a part, to register for resale by the selling shareholders the shares of common stock issued in the above transactions.

Selling Shareholders Holding Series D Convertible Preferred Stock

On September 12, 2003, the holders of our 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures (who were also participants in our July 7, 2003 private placement) exchanged their 8% debentures for 243,749 shares of our Series D Convertible Preferred Stock. As of September 25, 2003, each share of Series D stock is convertible into ten shares of our common stock, or 2,437,490 shares. As a result, the Series D stock is convertible into the same number of shares as were the debentures prior to their exchange. In connection with the issuance of the Series D stock, we amended the July 7, 2003 Registration Rights Agreement to require registration of the shares of common stock issuable upon conversion of the Series D stock. To meet this obligation, we have filed a registration statement on Form S-2, of which this prospectus is a part, to register such shares of common stock for resale by the selling shareholders.

Dr. Jacques Gonella

On September 12, 2003, Dr. Jacques Gonella, our largest shareholder, converted $2,300,000 aggregate principal amount of debt owed to him, together with $98,636 in accrued interest, into 2,398,635 shares of our common stock, at a price of $1.00 per share (the same price at which we issued 4,000,000 shares of our common stock in the private placements in July 2003). As further consideration for Dr. Gonella s agreement to convert his debt, we issued to Dr. Gonella a five-year warrant to purchase 1,798,976 shares of our common stock at an exercise price of $1.25 per share. In connection with Dr. Gonella s initial loans to us, we had previously issued him warrants to purchase an aggregate of 2,400,000 shares of our common stock at an exercise price of ($0.55) per share. These warrants expire in 2008. We granted Dr. Gonella customary piggyback registration rights with respect to the shares of common stock issued and issuable upon exercise of the warrants, and he has elected to

register such shares.

Other Selling Shareholders

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

Table of Contents

shares of common stock issued to these firms to date. Below is a description of the agreements we have with each of these firms.

1. Equity Advisor Agreement, dated March 28, 2002, with Spencer Trask Ventures, Inc., pursuant to which we issued to Spencer Trask warrants to purchase 160,000 shares of common stock at an exercise price of $2.50 per share. Portions of the warrants exercisable for an aggregate of 128,000 shares of our common stock were subsequently assigned by Spencer Trask to Douglass Bermingham, John Clarke and Don Spongberg, and the assignees of the warrants have elected to exercise the piggyback registration rights contained in such warrants with this registration statement. Our agreement with Spencer Trask was terminated on November 13, 2002.

2. Advisory Agreement with Duncan Capital LLC, dated December 17, 2002, under which Duncan Capital provides advisory services to us, including introductions to institutional and individual investors, private equity firms and analysts. We have notified Duncan Capital of our decision to terminate this agreement as of September 30, 2003. Pursuant to the agreement, on the first of each month, we issued to Duncan Capital LLC a number of shares of our common stock equal in value to $10,000, based on the market price of our common stock on the issue date. From June 1 to September 1, 2003, we issued an aggregate of 34,557 shares which have not yet been registered.

3. Letter Agreement with Mark Wachs and Associates, Inc., dated October 11, 2002, under which Mark Wachs and Associates provides public relations services to us. The agreement was for an initial term of six months and renews upon mutual agreement of the parties. Pursuant to the agreement, in each of May and June 2003, we issued 10,000 shares of common stock to Mark Wachs and Associates. In July 2003, the agreement was amended, and we began issuing 5,000 shares of common stock per month. As of August 22, 2003, we had issued a total of 35,000 shares to Mark Wachs and Associates that have not yet been registered.

4. Marketing Agreement with Madison & Wall Worldwide, Inc., dated