

ANTARES PHARMA INC
Form POS AM
August 11, 2005

As filed with the Securities and Exchange Commission on August 11, 2005

Registration No. 333-109114

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

POST-EFFECTIVE
AMENDMENT NO. 2 ON FORM S-3
TO FORM S-2
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ANTARES PHARMA, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

41-1350192
(I.R.S. Employer Identification No.)

707 Eagleview Boulevard

Suite 414

Exton, Pennsylvania 19341

(610) 458-6200

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(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Lawrence M. Christian

Chief Financial Officer

Antares Pharma, Inc.

707 Eagleview Boulevard, Suite 414

Exton, Pennsylvania 19341

(610) 458-6200

with a copy to:

Morris M. Sherman, Esq.

Leonard, Street and Deinard Professional Association

150 South Fifth Street, Suite 2300

Minneapolis, Minnesota 55402

(612) 335-1500

(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: As soon as practicable 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. _____

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. "

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

Pursuant to Rule 429(a) of the Securities Act of 1933, as amended (the Securities Act), a combined prospectus is being used in this registration statement, and pursuant to Rule 429(b) of the Securities Act, the earlier registration statement to which the combined prospectus relates and constitutes a post-effective amendment is the Registrant s Registration Statement on Form S-2 (Registration No. 333-114098).

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with 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 jurisdiction where the offer or sale is not permitted.

Subject to completion, dated August 11, 2005

Prospectus

20,329,105 Shares of Common Stock

Antares Pharma, Inc.

This prospectus relates to the resale of 20,329,105 shares of our common stock issued to the selling stockholders, including the resale of shares of our common stock issuable upon exercise of warrants issued to such selling stockholders.

We will not receive any of the proceeds from the resale shares of common stock, including the shares of common stock issuable upon exercise of the warrants. We have, however, paid the expenses of preparing this prospectus and related registration expenses.

Our common stock is listed on the American Stock Exchange under the ticker symbol AIS. The last reported sale price of our common stock on August 10, 2005 was \$0.95 per share.

*This investment involves significant risks. See **Risk Factors** beginning on page 3 to read about factors you should consider before buying our securities.*

Neither the Securities and Exchange Commission nor any state securities commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is [], 2005

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PROSPECTUS SUMMARY

This summary contains basic information about us and this offering. Because it is a summary, it does not contain all the information that you should consider before investing. You should read the entire prospectus carefully, including the section entitled Risk Factors and our consolidated financial statements and the accompanying notes which are incorporated by reference in this prospectus. Except as otherwise indicated or required by context, references to we, us, our, our company, Antares and similar references refer to Antares Pharma, Inc. and our subsidiaries.

Explanatory Note

We previously filed two registration statements on Form S-2 covering these securities. Each of these registration statements was declared effective by the Securities and Exchange Commission. When we originally filed these registration statements, we were not eligible to use Form S-3. In this prospectus, we have consolidated the prospectuses which formed a part of the two prior registration statements, and updated certain information originally set forth in such prospectuses.

The Offering

This prospectus relates to the offering of shares of our common stock which may be sold from time to time by the selling stockholders named in this prospectus. Certain of these selling stockholders 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 stockholders 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 stockholder also converted debt due and owing to him into shares of our common stock. The remaining selling stockholders received shares of our common stock or warrants to purchase shares of our common stock pursuant to investor relations agreements.

This prospectus also relates to the offering of additional shares of our common stock which may be sold from time to time by the selling stockholders named in this prospectus. Certain of these selling stockholders purchased our common stock and warrants to purchase shares of our common stock in three separate private placements that closed in February and March 2004. The remaining selling stockholders 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 stockholders to sell the shares from time to time in the public market. The selling stockholders will determine the timing and amount of any sale, and we will not receive any of the proceeds from the sale of the shares.

Our Company

We are a specialized pharma product development company with patented drug delivery systems and injectable device engineering capabilities. Our current technology platforms include our ATD (Advanced Transdermal Delivery) gel system, Easy Tec oral fast-melt technology, and subcutaneous injection technology platforms (Vibex disposable mini-needle injection device and Valeo and Vision[®] reusable needle-free injection devices). We are committed to leveraging our multiple drug delivery platforms to add value to existing drugs and to create new products and devices. We believe our product pipeline addresses unmet medical needs by reducing side effect profiles, improving safety, increasing effectiveness, and improving patient compliance and convenience.

We have active partnering programs with several pharmaceutical and distribution companies for a number of indications and applications, including diabetes, growth disorders, obesity, anxiety, overactive bladder, female sexual dysfunction and other hormone therapies. Our needle-free injector system is distributed in more than 30 countries for the administration of insulin and is marketed for use with human growth hormone through licensees in most major regions of the world. Licensees also market an ibuprofen gel using Antares Pharma's ATD gel technology in several major European countries. In addition, we are undertaking development or conducting research on several product opportunities that we expect will form the basis of our specialized pharma program.

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 (Permatec NV). Our United States research and manufacturing facilities are located in Minneapolis, Minnesota. In April 2005, we reincorporated under the laws of the State of Delaware.

Risk Factors

Investing in our securities involves significant risks. You should carefully read the section entitled "Risk Factors" beginning on page 3 for an explanation of these risks before investing in our securities.

The Offering

This prospectus relates to the resale of 20,329,105 shares of our common stock issued to the selling stockholders, including the resale of shares of our common stock issuable upon exercise of warrants issued to the selling stockholders.

American Stock Exchange Symbol

Our common stock is listed on the American Stock Exchange under the ticker symbol AIS.

RISK FACTORS

You should carefully consider the following risk factors and all of the other information contained in, or incorporated by reference in, this prospectus before purchasing our securities. Investing in our securities involves a high degree of risk. Any of the following risks could materially harm our business and could result in a complete loss of your investment. Additional risks and uncertainties not presently known or that we currently believe to be less significant may also adversely affect us.

Risks Related to Our Business

We have incurred significant losses to date, and there is no guarantee that we will ever become profitable

We have incurred losses since inception and expect to continue to do so for the foreseeable future. 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 that we may soon require additional financing, which may not be available to us when needed, or obtain it on favorable terms. To the extent such additional required financing is not available when needed, we may be required to curtail development of new drug technologies, limit expansion of operations, accept financing terms that are not as attractive as we may desire or be forced to liquidate and close operations.

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, maintain or acquire patent positions;

our ability to develop additional commercial applications for our products;

our limited regulatory and commercialization experience;

our reliance on outside consultants;

our ability to obtain regulatory approvals;

our ability to attract the right personnel to execute our plans;

our ability to control costs; and

general economic conditions.

Since we have changed our business model to be more commercially oriented by further developing our own products, we may not have sufficient resources to fully execute our plan

We must make choices as to the drugs that we will combine with our transdermal gel, fast-melt tablet and disposable mini-needle technologies to move into the marketplace. We may not make the correct choice of drug or technologies when combined with a drug, which may not be accepted by the marketplace as we expected or at all. FDA approval processes for the drugs and drugs with devices may be longer in time and/or more costly and/or require more extended clinical evaluation than anticipated. Funds required to bring our own products to market may be more than anticipated or may not be available at all. We have limited experience in development of compounds and in regulatory matters and bringing such products to market; therefore, we may experience difficulties in making this change or not be able to achieve the change at all.

We currently 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 and impact our liquidity

We have historically derived significant portions of our revenue from a limited number of customers, and expect to continue to do so for the foreseeable future. The loss of any 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 royalties or manufacturing margins from Ferring.

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 our MJ7 devices and certain related disposable component parts. There can be no assurance that any of our third-party manufacturers 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 products. Any failure to do so would negatively impact our business, financial condition and results of operations. We will also need to outsource manufacturing of our AJ products to third parties. Such products will be price sensitive and may be required to be manufactured in large quantities, and we have no assurance that this can be done.

Our products have achieved only limited acceptance by patients and physicians, which continues to restrict marketing penetration and the resulting sales of more units

Our business ultimately depends on patient and physician acceptance of our needle-free injectors, gels, fast-melt tablets and our other drug delivery technologies as an alternative to more traditional forms of drug delivery, including injections using a needle, orally ingested drugs and more traditional 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 National Institute of Health (NIH) study and the 2003 findings from the Million Women Study first launched in 1997 in the U.K. 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 NIH halted a long-term study, known as the Women's Health Initiative, 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 the combination therapy. The arm of the study using estrogen alone was stopped in March 2004 after the NIH concluded that the benefits of estrogen did not outweigh the stroke risk for women in this trial. The halted study looked at only one brand of oral combined HRT and of estrogen, and there is no information on whether brands with different levels of hormones would carry the same risk. In January 2003, the FDA announced that it would require new warnings on the labels of HRT products, and it advised patients to consult with their physicians about whether to continue treatment with continuous combined HRT and to limit the period of use to that required to manage post-menopausal vasomotor symptoms only. Subsequently, additional analysis from the NIH study has suggested a slight increase in the risk of cognitive dysfunction developing in patients on long-term combined HRT. The Million Women Study, conducted in the U.K., confirmed that current and recent use of HRT increases a woman's chance of developing breast cancer and that the risk increased with duration of use. Other HRT studies have found potential links between HRT and an increased risk of dementia and asthma. These results and recommendations impacted the use of HRT, and product sales have diminished significantly. We cannot yet assess the impact any of the studies' results may have on our contracts or on our partners' perspective of the market for transdermal gel products designed for HRT. We also cannot predict whether our alternative route of transdermal administration of HRT products will carry the same risk as the oral products used in the study.

Our gel products, under development, may draw increased scrutiny from regulatory bodies

Due to heightened public health issues, regulatory agencies or other public health organizations, may issue advisories or additional testing requirements regarding newly discovered or emerging public health concerns associated with gel products we have in development or contemplate placing in development. Such agencies and organizations could also require market withdrawal of certain gel products. If such events occur, we may be delayed in getting our gel products to market or may be prohibited from doing so at all.

If transdermal gels do not achieve greater market acceptance, we may be unable to achieve profitability

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 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 perform certain development work on our gel technologies and to supply components for our device products, and any failure to retain relationships with these third parties could negatively impact our ability to development and/or manufacture our products

Certain of our gel technologies require clinical testing and regulatory development by various third parties and our device products contain a number of customized components manufactured by various third parties. Regulatory requirements applicable to medical products and device manufacturing can make substitution of service providers and parts component suppliers costly and time-consuming. In the event that we could not obtain these testing and regulatory services or 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 services or components within a reasonable period of time, on acceptable terms or at all. The unavailability of adequate development services or component quantities, the inability to develop alternative sources, a reduction or interruption in services or component supply or a significant increase in the price of such services or components could have a material adverse effect on our ability to develop, 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 not be able to receive adequate reimbursement or may be unable to afford to use our products, which could substantially reduce our revenues and negatively impact our business as a whole

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 legally marketed and 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 products and technologies.

We are subject to pricing pressures and uncertainties regarding healthcare reimbursement and reform.

Many pharmaceutical products are subject to increasing pricing pressures, including pressures arising from recent Medicare reform. Our ability to commercialize products successfully depends, in part, upon the extent to which health care providers are reimbursed by third party payors, such as governmental agencies, including the Centers for Medicare and Medicaid Services, private health insurers and other organizations, such as HMOs, for the cost of such products. In addition, if health care providers do not view Medicare reimbursements for our products favorably, then they may not prescribe our products when we bring them to market. Third-party payors are increasingly challenging the pricing of pharmaceutical products by, among other things, limiting the pharmaceutical products that are on their formulary lists. As a result, competition among pharmaceutical companies to place their products on these formulary lists has reduced product prices. If reasonable reimbursement for our products is unavailable

when we bring them to market or if significant downward pricing pressures in the industry occur, then we could be materially adversely affected.

Recent reforms in Medicare added a prescription drug reimbursement benefit beginning in 2006 for all Medicare beneficiaries. In the meantime, a temporary drug discount card program was established for Medicare beneficiaries. Although we cannot predict the full effects on our business of the implementation of this legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers, and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to generate revenues. In addition, managed care organizations, HMOs, preferred provider organizations, institutions and other government agencies continue to seek price discounts. In addition, certain states have proposed and certain other states have adopted various programs to control prices for their seniors and low-income drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries, such as Canada and bulk purchasing of drugs.

We encounter similar regulatory and legislative issues in most other countries. In the EC and some international markets, the government provides health care at low direct cost to consumers and regulates pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored health care system. This price regulation may lead to inconsistent prices and some third-party trade in our products from markets with lower prices.

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

One of our business pathways requires us to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use and marketing of drug delivery technologies with specific drug therapies. Under these arrangements, the partner company 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 may 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 or related future royalties. 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 as planned may result in us not meeting revenue and profit targets

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. Generally speaking, in the near term, we do not intend to have a direct marketing channel to consumers for our drug delivery products or technologies except through current distributor agreements in the United States for our insulin delivery device. Therefore, the success of the marketing organizations of our 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.

Our business could suffer if we are unable to effectively compete with our competitors

Additional competitors in the needle-free injector market, many 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. Additionally, there is an ever increasing list of competitors in the oral disintegrating fast-melt tablet business. 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 rapidly evolving fields. 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., Bentley Pharmaceuticals, Inc., Aradigm, Cellegy Pharmaceuticals, Inc., Cardinal Health, CIMA Laboratories, Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc. and Novavax, Inc., along with other companies. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do, and, therefore, represent significant competition.

In general, injection is used only with drugs for which other drug delivery methods are not possible, in particular with biopharmaceutical proteins (drugs derived from living organisms, such as insulin and human growth hormone) that cannot currently be delivered orally, transdermally (through the skin) or pulmonarily (through the lungs). Transdermal patches and gels are also used for drugs that cannot be delivered orally or where oral delivery has other limitations (such as high first pass drug metabolism, 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.

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 29 patents and an additional 104 applications pending in the U.S. 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 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, we may not realize our revenue or profit plan

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 or our licensees 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. In the future we, or our partners, may need to seek approval for newly developed products. 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;

finest;

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.

We and our facilities are subject to extensive government regulation, which may adversely affect our ability to manufacture and market our products.

Early in 2005, Antares Pharma AG, our wholly owned subsidiary in Switzerland, received a GMP approval for the production and wholesaling of medicaments. Any finding by regulatory authorities that we are not in substantial compliance with GMP regulations or that we or our employees have engaged in activities in violation of these regulation could interfere with the manufacture and distribution of our products, including a potential recall of previously distributed products. Any loss of our GMP approval could also affect our ability to obtain new approvals until such issues are resolved. The regulatory authorities conduct scheduled periodic regulatory inspections of our facilities to ensure compliance with GMP regulations. Any determination that we are not in substantial compliance with these regulations or are otherwise engaged in improper or illegal activities could have a material adverse effect on us.

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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 or if we are not able to add additional key officers or employees necessary to reach our goals

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 consider our employee relations to be good; however, competition for personnel is intense and we cannot assume that we will continue to be able to attract and retain personnel of high caliber.

We are involved in 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 EC 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:

increased complexity and costs of managing international operations;

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

Together, certain of our stockholders own or have the right to acquire a significant portion of our stock and could ultimately control decisions regarding our company

As a result of our reverse business combination with Permiatec in January 2001 and subsequent additional debt and equity financings, Permiatec Holding AG and its controlling stockholder, Dr. Jacques Gonella, own a substantial portion of our outstanding shares of common stock. Dr. Gonella, who is the Chairman of our Board of Directors, also owns warrants and options to purchase a significant number of our shares of common stock. Additionally, certain of our investors own preferred and/or warrants that are also convertible into or exercisable for a significant number of shares of our common stock.

Because the parties described above either currently own or could potentially own a large portion of our stock, they may be able to generally determine or they will be able to significantly influence the outcome of corporate actions requiring stockholder approval. As a result, these parties may be in a position to control matters affecting our company, including decisions as to our corporate direction and policies; future issuances of certain securities; our incurrence of debt; amendments to our certificate 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. In addition, if the demand for our common stock is reduced because of these stockholders' control of our company, the price of our common stock could be materially depressed.

Certain of our stockholders own large blocks of our common stock and own securities exercisable into shares of our common stock, and any exercises or sales by these stockholders could substantially lower the market price of our common stock

Several of our stockholders, including Dr. Gonella, whose sales are subject to volume limitations, own large blocks of our common stock or could own sizeable blocks of our common stock upon exercise of warrants or options. With the exception of a portion of the stock controlled by Dr. Gonella, the shares of our common stock owned by these stockholders (or issuable to them upon exercise of warrants or options) are registered. Future sales of large blocks of our common stock by any of these investors could substantially depress our stock price.

Future conversions or exercises by holders of warrants or options could substantially dilute our common stock

Purchasers of common stock could experience substantial dilution of their investment upon exercise of significant outstanding warrants or options to purchase shares of our common stock.

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

Our officers and directors beneficially own a considerable percentage of the outstanding shares of our common stock, including stock options. If our officers and directors, or other stockholders, 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.

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains certain forward-looking statements within the meaning of the federal securities laws. Statements that are not historical facts, including statements about our beliefs and expectations, are forward-looking statements. Forward-looking statements include statements preceded by, followed by or that include the words plans, projects, intends, expects or similar expressions. These statements include, among others, statements regarding our expected financial condition, business, financing plans, strategies, prospects, revenues, working capital, sources of liquidity, capital needs, interests costs and income.

Forward-looking statements are estimates and projections reflecting our best judgment and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These statements are based on beliefs and assumptions of our management, which in turn are based on currently available information. Important assumptions relating to the forward-looking statements include, among others, assumptions regarding the items summarized below. These assumptions could prove inaccurate. Although we believe that the estimates and projections reflected in the forward-looking statements are reasonable, our expectations may prove to be incorrect.

We believe these forward-looking statements are reasonable; however, undue reliance should not be placed on any forward-looking statements, which are based on current expectations. Further, forward-looking statements speak only as of the date they are made, and we undertake no obligation to update publicly any of them in light of new information or future events.

SELLING STOCKHOLDERS

Based on information provided by the selling stockholders and our internal corporate records, the following table lists the selling stockholders 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 stockholder at August 1, 2005, assuming exercise of warrants and options (exercisable within 60 days) held by certain of the selling stockholders; (ii) the number of shares of common stock to be offered for resale by each selling stockholder pursuant to this prospectus; and (iii) the number and percentage of outstanding shares of common stock to be held by each selling stockholder after completion of the offering.

Name	Number of shares of Common Stock beneficially owned at August 1, 2005 (1)	Number of shares of Common Stock to be Offered (1)	Shares Owned after Completion of Offering (1) (2)	
			Number	Percentage
Xmark Fund, L.P. (3) (5)	238,125	238,125	0	0%
Xmark Fund, Ltd. (4) (5)	511,875	511,875	0	0%
SDS Merchant Fund, LP (6)	1,385,880	1,385,880	0	0%
Jacques Gonella (7)	13,661,385	4,447,611	9,213,774	20%
SCO Capital Partners LLC (8)	1,264,400	1,264,400	0	0%
North Sound Legacy Fund LLC (9)	47,083	47,083	0	0%
North Sound Legacy Institutional Fund LLC (10)	461,250	461,250	0	0%
North Sound Legacy International Ltd. (11)	1,143,800	1,143,800	0	0%
Paul Scharfer (12)	291,667	291,667	0	0%
Vertical Ventures Investments, LLC (13)	150,000	150,000	0	0%
Douglass Bermingham (14)	25,000	25,000	0	0%
Sabbatical Ventures, LLC (15)	349,999	349,999	0	0%
David C. Cavalier (16)	349,999	349,999	0	0%
Alfred Mansour (17)	75,000	75,000	0	0%
Alan Tuchman (18)	105,000	105,000	0	0%
Richard Burgoon (19)				