

ANTARES PHARMA INC

Form S-3

April 24, 2007

As filed with the Securities and Exchange Commission on April 24, 2007

Registration Statement No. 333-\_\_\_\_\_

## **UNITED STATES**

## **SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

## **FORM S-3**

## **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.)

250 Phillips Blvd., Suite 290

Ewing, NJ 08618

609-359-3020

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

Jack E. Stover

**President and Chief Executive Officer**

**Antares Pharma, Inc.**

**250 Phillips Blvd., Suite 290**

**Ewing, NJ 08618**

**609-359-3020**

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

*Copies to:*

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*Approximate date of commencement of proposed sale to 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.

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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.

### CALCULATION OF REGISTRATION FEE

| Title of Shares to be Registered         | Amount<br>to be<br>Registered(1) | Proposed<br>Maximum<br>Offering Price<br>Per Share | Proposed<br>Maximum<br>Aggregate<br>Offering Price | Amount of<br>Registration Fee |
|--|----------------------------------|--|--|-------------------------------|
| Common Stock, \$0.01 par value per share | 640,000                          | \$1.49 (2)   | \$953,600 (2)                                      | \$30                          |

- (1) This registration statement also relates to an indeterminate number of shares of common stock issued to prevent dilution resulting from stock splits, stock dividends or similar transactions in accordance with Rule 416.
- (2) Estimated solely for the purpose of computing the amount of the registration fee in accordance with Rule 457(g) under the Securities Act of 1933, as amended, based upon the average of the high and low prices on the American Stock Exchange on April 20, 2007.

**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 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus 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 the selling stockholders named in this prospectus are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.**

Subject to completion, dated April 24, 2007

PROSPECTUS

## **ANTARES PHARMA, INC.**

### **640,000 SHARES OF COMMON STOCK**

This prospectus relates to resales of shares of common stock underlying warrants previously issued by Antares Pharma, Inc. to the selling stockholders pursuant to our credit agreement with them dated February 26, 2007.

The selling stockholders identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. We will not receive any proceeds from the sale of the shares.

The selling stockholders may resell the common stock to or through underwriters, broker-dealers, or agents, who may receive compensation in the form of discounts, concessions, or commissions. The selling stockholders will bear all commissions and discounts, if any, attributable to the sales of shares. We will bear all costs, expenses, and fees in connection with the registration of the shares.

Shares of our common stock are quoted on the American Stock Exchange under the symbol AIS. On April 23, 2007, the last reported sale price of our common stock was \$1.49 per share. You are urged to obtain current market quotations for the common stock.

**Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 4.**

**Neither the Securities and Exchange Commission nor any state securities commission 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 \_\_\_\_\_, 2007.

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Our principal executive offices are located at 250 Phillips Blvd., Suite 290, Ewing, NJ 08618, our telephone number is 609-359-3020 and our Internet address is [www.antareshpharma.com](http://www.antareshpharma.com). The information on our Internet website is not incorporated by reference in this prospectus. We have included our Internet website address as an inactive textual reference only. Unless stated or the context otherwise requires, references in this prospectus to Antares, the Company, the Registrant, we, us, and our refer to Antares Pharma, Inc. and its subsidiaries.

You should rely only on the information contained in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. This prospectus is not an offer to sell, nor is it seeking an offer to buy, shares of our common stock in any jurisdiction in which the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

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**PROSPECTUS SUMMARY**

*This summary highlights selected features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under Risk Factors, before making an investment decision.*

**Antares Pharma, Inc.**

Antares Pharma, Inc. ( Antares or the Company ) is a specialized pharma product development and pipeline company with patented drug delivery platforms including Advanced Transdermal Delivery (ATD ) gels, fast-melt oral (Easy Tec ) tablets, disposable mini-needle injection systems (Vibex ), and reusable needle-free injection systems (VISION® AND Valeo ). Antares first proprietary ATD gel product is Anturoloxybutynin for the treatment of overactive bladder (OAB). These platforms and products are summarized and briefly described below:

**Delivery Platforms**

|                    |                      |               |
|--------------------|----------------------|---------------|
| Transdermal Drug   | Advanced Transdermal | Systematic or |
| Delivery Platforms | (ATD ) Gel           | Topical       |

|   |  |
|---|--|
| Fast-Melt Oral Disintegrating<br>Tablets Platform | Easy Tec                                     |
|   | Needle-Free Reusable Injectors (MJ Platform) |
|   | Medi-Jector VISION® and Valeo                |
| Injection Device                                  | Mini-Needle Disposable Injectors             |
| Platforms   | (AJ Platform) Vibex                          |
|   | Vaccine Intradermal Injectors                |

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Product Candidates

Transdermal Delivery Gels

Fast-Melt Oral Dissolve Disintegrating Tablets (EasyTec )

Injection Devices

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### Transdermal Drug Delivery Platform

Antares' transdermal drug delivery platform is dedicated to developing gels that offer a cosmetically superior option to patches, while delivering medication efficiently with less potential for skin irritation and minimizing the gastrointestinal impact, as well as, the initial liver metabolism effect of some orally ingested drugs. The Company's gels are hydro-alcoholic and contain a combination of permeation enhancers to promote rapid drug absorption through the skin following application typically to the arms, shoulders, or abdomen. The Company's transdermal gel systems provide the options for delivering both systemically (penetrating into and through the subcutaneous tissues and then into the circulatory system) as well as locally (e.g. topically for skin and soft tissue injury, infection and local inflammation). Typically, the gel is administered daily, and is effective on a sustained release basis over approximately a 24-hour period of time. The Company's gel systems are known as our Advanced Transdermal Delivery (ATD) gels.

### Fast-Melt Oral Disintegrating Tablets

Our Easy Tec fast-melt oral disintegrating tablets are designed to help patients who experience difficulty swallowing pills, tablets or capsules, while providing the same effectiveness as conventional oral dosage forms. Our tablet features a disintegrant addition that facilitates the disintegration of the oral drug to promote quick and easy administration in saliva without water. This could play an important role in our ability to target the pediatric market segment as well as the rapidly expanding geriatric market. Easy Tec tablets can be manufactured without specialized equipment and because the tablets are not effervescent (highly moisture sensitive), we believe it represents several significant processing and packaging advantages over conventional competitors. Our Easy Tec tablets may also be of interest to pharmaceutical firms seeking line extensions in the marketplace and could represent a step in our evolution as a specialty pharmaceutical company with its own products.

### Injection Device Platforms

Antares' injection device platform features three distinct products: reusable needle-free injectors, disposable mini-needle injectors, and its vaccine intradermal injectors. Each product is briefly described below:

*Reusable needle-free injectors* deliver precise medication doses through high-speed, pressurized liquid penetration of the skin without a needle. These reusable, variable-dose devices are engineered to last for a minimum of two years and are designed for easy use, facilitating self-injection with a disposable syringe to assure safety and efficacy. The associated disposable, plastic, needle-free syringe is designed to last for approximately one week. The Company has sold the Medi-Jector VISION<sup>®</sup> for use in more than 30 countries to deliver either insulin or human growth hormone (hGH). The Medi-Jector VISION employs a disposable plastic needle-free syringe, which offers high precision liquid medication delivery through an opening that is approximately half the diameter of a standard, 30-gauge needle. The product is available over-the-counter (OTC) or by prescription in the United States for use by patients with diabetes, and available through our partners in Europe, Japan and Asia for hGH. To date, we believe that more than 100 million such injections have been performed worldwide.

*Disposable mini-needle injectors (Vibex)* employ the same basic technology developed for the Medi-Jector VISION<sup>®</sup>, combining spring-powered source with a tiny hidden needle in a disposable, single-use injection system compatible with conventional glass drug containers. The Vibex system is designed to economically provide highly reliable subcutaneous injections with reduced discomfort and improved convenience in conjunction with the enhanced safety of a shielded needle. After use, the device can be disposed of without the typical sharps disposal concerns. Antares and its potential partners have successfully tested the device in multiple patient preference and bioavailability tests, and the Company continues to explore product extensions within this category, including multiple dose, variable dose and user-fillable applications.

*Vaccine intradermal injectors* are a variation of the Vibex disposable mini-needle injection technology and are being developed to deliver vaccines into the dermal and subdermal layers of the skin (a preferred

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site of administration in the vaccine industry). The Company believes that this proprietary device will offer easier and more rapid dosing compared with conventional needle-based devices.

### THE OFFERING

|  |   |
|--|---|
| Common Stock offered by selling stockholders | 640,000 shares issuable upon the exercise of warrants to purchase common stock held by the selling stockholders |
| Use of proceeds                              | We will not receive any proceeds from the sale of shares in this offering                                       |
| American Stock Exchange symbol               | AIS   |

### RISK FACTORS

*An investment in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties and all other information contained or incorporated by reference in this prospectus before you purchase our common stock. The risks and uncertainties described below are not the only ones facing our company. There may be additional risks that we presently do not know or that we currently believe are immaterial which could also impair our business or financial condition. Any of the following risks, either alone or taken together, could materially and adversely, affect our business, financial condition or operating results. As a result, the trading price of our common stock could decline, and you could lose part or all of your investment.*

#### Risks Related to Our Operations

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

We incurred net losses of (\$8,099,846) and (\$8,497,956) in the fiscal years ended 2006 and 2005, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2006 of (\$99,322,453). 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 may not ever become profitable and if we do not become profitable your investment would be harmed.

*We may need additional capital in the future in order to continue our operations*

In February of 2007 we received gross proceeds of \$5,000,000 upon closing of the first tranche of a \$10,000,000 credit facility, to help fund working capital needs. A second tranche of \$5,000,000 is available after September 30, 2007 but before December 31, 2007 under certain conditions. In March of 2006 we completed a private placement of our common stock in which we received aggregate gross proceeds of \$10,962,500. We believe that the combination of the debt and equity financings and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations beyond 2007. However, if we need additional financing and are unable to obtain such financing when needed, or obtain it on favorable terms, 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, at the appropriate commercial scale, and with the required quality;

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our ability to increase and continue to outsource 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;

patient acceptance of our current and future products;

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.

*As we 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 and reusable needle free 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*

During 2006, we derived approximately 39% and 24% of our revenue, from Ferring and BioSante, respectively.

The loss of either of these customers/partners could 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.

The Company has entered into three License, Development and/or Supply agreements since November of 2005 with Teva Pharmaceutical Industries Ltd. and/or an affiliate of Teva. Although certain upfront payments have been received, there have been no commercial sales and there can be no assurance that there ever will be commercial sales under these agreements or any other agreements we have with third parties.

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*If we or our third-party manufacturer are unable to supply Ferring 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, 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 under certain circumstances for use with its human growth hormone product. 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 manufacturing margins from Ferring.

*If we do not develop and maintain relationships with manufacturers of our drug candidates, then we may not successfully manufacture and sell our pharmaceutical products.*

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We do not possess the capabilities, resources or facilities to manufacture Anturol<sup>®</sup>, which is currently in development for over active bladder, or any other of our future drug candidates. We must contract with manufacturers to produce Anturol<sup>®</sup> according to government regulations. Our future development and delivery of our product candidates depends on the timely, profitable and competitive performance of these manufacturers. A limited number of manufacturers exist which are capable of manufacturing our product candidates. We may fail to contract with the necessary manufacturers or we may contract with manufactures on terms that may not be favorable to us. Our manufacturers must obtain FDA approval for their manufacturing processes, and we have no control over this approval process.

We have not contracted with a commercial supplier of active pharmaceutical ingredients of oxybutynin for Anturol<sup>®</sup> at this time. We are currently working towards selecting a manufacturer to provide us with oxybutynin in a manner which meets FDA requirements.

We have contracted with Patheon, a manufacturing development company, to supply clinical quantities of Anturol<sup>®</sup> in a manner that meets FDA requirements. The FDA has not approved the manufacturing processes of Patheon. Any failure by Patheon to achieve compliance with FDA standards could significantly harm our business since we do not currently have an approved secondary manufacturer for Anturol<sup>®</sup>.

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

Our past assembly, testing and device manufacturing experience for certain of our device technologies has involved the assembly of products from machined stainless steel and composite components in limited quantities. Our planned future drug delivery device 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 scale-up, yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment, component supplies and shortages of personnel, any of which could result in significant delays in production. Additionally, we entered into a manufacturing agreement under which a third party assembles our MJ7 devices and certain related disposable component parts. 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 products. Any failure to do so would negatively impact our business, financial condition and results of operations. We continue to outsource manufacturing of our disposable injection 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. Additionally, we have not entered into any manufacturing agreement for these products.

*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 and mini-needle injectors, transdermal 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;  
marketing and distribution support; and

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successful launch of our pharmaceutical partners products which utilize our devices.

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. In 2006 the FDA approved Elestrin<sup>®</sup>, an estrogen gel developed by our partner BioSante for the treatment of vasomotor symptoms associated with menopause. The determination by the FDA of Elestrin's efficacy and safety may not impact the acceptance by physicians and patients of this newly approved product.

*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 partners and consumers have little experience with such products. Our assumption of higher value may not be shared by the potential partner and 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 are developing Anturol, our oxybutynin gel for overactive bladder. We may seek a pharmaceutical partner to assist in the payment for the development and marketing of this potential product. We may be unsuccessful in partnering Anturol which may delay or affect the timing of the clinical program due to availability of resources.

*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 manufacturing can make substitution of suppliers costly and time-consuming. In the event that we could not obtain adequate quantities of these customized components from our suppliers, there can be no assurance that we would be able to access alternative sources of such components within a reasonable

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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 (Elestrin®). 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 elsewhere for use with human growth hormone and in the United States for use with insulin. In the case of human growth hormone, our products are generally provided to users at no cost by the drug supplier. In the United States the injector products are 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.

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Elestrin<sup>®</sup>, for which we will receive royalties from our partner based on any commercial sales, has not been commercially launched to date. Therefore, we have no way of knowing at this time if health insurance companies will reimburse patients for the use of Elestrin<sup>®</sup>.

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

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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 companies typically assist us in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. Our licensees 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, related future royalties or product sales. 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 or drug device 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.

*If we cannot develop and market our products as rapidly or cost-effectively as our competitors, then we may never be able to achieve profitable operations.*

Competitors in the over active bladder, transdermal gel drug delivery and needle-free injector and other markets, some with greater resources and experience than us, may enter these markets, as there is an increasing recognition of a need for less invasive methods of delivering drugs. Additionally, there is an ever increasing list of competitors in the oral disintegrating fast-melt tablet business. 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., Auxillium, BioChemics, Inc., Aradigm, Cellegy Pharmaceuticals, Inc., Watson Pharmaceuticals, Cardinal Health, CIMA Laboratories, Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc., The Medical House 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.

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Additionally, new drug delivery technologies are mostly 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 or transdermally. 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 non-injection techniques could 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.

*Although we have applied for, and have received, several patents, 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.

We currently hold approximately 70 patents and have an additional 98 applications pending in the U.S. and other countries. Late in 2006 we received two notices of allowances from the U.S. patent office on patents expected to be issued shortly in our ATD gel platform including a patent related to our formulation of Elestrin<sup>®</sup>, an estradiol gel product approved by the FDA for hormone replacement therapy and a patent related to our core gel technology. The patents have expiration dates ranging from 2015 to 2022. In addition to issued patents and patent applications, we are also protected by trade secrets in all of our technology platforms.

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, or obtain licenses on acceptable terms, we may not be able to continue to develop and commercialize our product candidates.

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Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property. If we 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 patents of others. Even if we were able to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. 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. Furthermore, in the event a patent infringement suit is brought against

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us, the development, manufacture or potential sale of product candidates claimed to infringe on a third party's intellectual property may have to stop or be delayed. Ultimately, we may be unable to commercialize some of our product candidates as a result of patent infringement claims, which could harm our business.

We are aware of a recently issued US Patent relating to a gel formulation of oxybutynin. We believe that we do not infringe this patent and that it should not have been issued. We may seek to invalidate this patent but there can be no assurance that we will prevail. If the patent is determined to be valid and if Anturol is approved, we may be delayed in our marketing and the potential market value of Anturol may be affected.

*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.

*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 European Community, Asia 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.

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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.

*If we make any acquisitions, we will incur a variety of costs and might never successfully integrate the acquired product or business into ours.*

We might attempt to acquire products or businesses that we believe are a strategic complement to our business model. We might encounter operating difficulties and expenditures relating to integrating an acquired product or business. These acquisitions might require significant management attention that would otherwise be available for ongoing development of our business. In addition, we might never realize the anticipated benefits of any acquisition. We might also make dilutive issuances of equity securities, incur debt or experience a decrease in cash available for

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our operations, or incur contingent liabilities and/or amortization expenses relating to goodwill and other intangible assets, in connection with future acquisitions.

*If we do not have adequate insurance for product liability claims, then we may be subject to significant expenses relating to these claims.*

Our business entails the risk of product liability claims. Although we have not experienced any material product liability claims to date, any such claims could have a material adverse impact on our business. We maintain product liability insurance with coverage of \$5 million per occurrence and an annual aggregate maximum of \$5 million. We evaluate our insurance requirements on an ongoing basis.

### **Risks Related to Regulatory Matters**

*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. 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 internally and pursuant to our license agreements. 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.

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.

We are currently evaluating Anturol for the treatment of overactive bladder (OAB). Anturol is the anticholinergic oxybutynin delivered by our proprietary ATD gel that is used to achieve therapeutic blood levels of the active compound that can be sustained over 24 hours after a single, daily application.

In February 2006, we announced the results of our Phase II dose ranging study for our ATD oxybutynin gel product Anturol. The study was an open label, single period, randomized study using 48 healthy subjects and three different doses of Anturol over a 20 day period. Our overall conclusions of the study were positive.

The FDA however, may not concur with our analysis of the data and we may never receive FDA approval for Anturol and without FDA approval, we cannot market or sell Anturol.

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Additionally, we are developing, with partners, injection devices for use with our partner's drugs. The regulatory path for approval of such combination products maybe subject to review by several centers within the FDA and although precedent and guidance exists for the requirements for such combination products, there is no assurance that the FDA will not change what it requires or how it reviews such submissions. Additionally, there is no assurance that the FDA will not require human clinical testing in order to commercialize these devices. Such changes in review processes or the requirement for clinical studies could delay anticipated launch dates or be at a cost which makes launching the device cost prohibitive for our partners. Such delay or failure to launch these devices could adversely affect our revenues and future profitability.

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

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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.

*The 505(b)(2) regulatory pathway for many of our potential pharmaceutical products is uncertain and could result in unexpected costs and delays of approvals.*

Transdermal and topical products indicated for the treatment of systemic or local treatments respectively are regulated by the FDA in the U.S. and other similar regulatory agencies in other countries as drug products. Transdermal and topical products are considered to be controlled release dosage forms and may not be marketed in the U.S. until they have been demonstrated to be safe and effective. The regulatory approval routes for transdermal and topical products include the filing of an NDA for new drugs, new indications of approved drugs or new dosage forms of approved drugs. Alternatively, these dosage forms can obtain marketing approval as a generic product by the filing of an ANDA, providing the new generic product is bioequivalent to and has the same labeling as a comparable approved product or as a filing under Section 505(b)(2) where there is an acceptable reference product. Other topical products for local treatment do not require the filing of either an NDA or ANDA, providing that these products comply with existing OTC monographs. The combination of the drug, its dosage form and label claims and FDA requirement will ultimately determine which regulatory approval route will be required.

Many of our transdermal product candidates may be developed via the 505(b)(2) route. The 505(b)(2) regulatory pathway is continually evolving and advice provided in the present is based on current standards, which may or may not be applicable when we potentially submit an NDA. Additionally, we must reference the most similar predicate products when submitting a 505(b)(2) application. It is therefore probable that:

should a more appropriate reference product(s) be approved by the FDA at any time before or during the review of our NDA, we would be required to submit a new application referencing the more appropriate product; the FDA cannot disclose whether such predicate product(s) is under development or has been submitted at any time during another company's review cycle.

Accordingly, these regulations and the FDA's interpretation of them might impair our ability to obtain product approval or effectively market our products.

*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.

*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 we or a pharmaceutical company partner fails to obtain from the Division of Drug Marketing acceptable marketing claims for a product incorporating our drug

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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 in practice or in clinical development. 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.

### **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 and impact stock price*

As a result of our reverse business combination with Permaterc in January 2001 and subsequent additional debt and equity financings, Permaterc Holding AG and its controlling shareholder, Dr. Jacques Gonella, own a substantial portion (as of April 5, 2007, approximately 17%) of our outstanding shares of common stock. Dr. Gonella, who is the Chairman of our Board of Directors, also owns warrants to purchase an aggregate of 4,198,976 shares of common stock and options to purchase 114,500 shares of common stock. Additionally, four investors (Crestview Capital Master Fund, Perceptive Life Sciences Fund, SCO Capital Group and SDS Funds) own warrants that are, as of April 5, 2007, exercisable into an aggregate of 4,894,400 shares of our common stock. Some of these investors may also directly own shares of our common stock. If Dr. Gonella and all of the above investors exercised all of the warrants and options owned by them, Dr. Gonella would own approximately 22%, and the four investors as a group would own, at a minimum, over 7% 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 may 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 the Company, the price of our common stock could be adversely affected. Additionally, future sales of large blocks of our common stock by any of the above investors could substantially adversely affect our stock price.

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

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As of April 5, 2007, we have warrants outstanding that are exercisable, at prices ranging from \$0.55 per share to \$5.00 per share, for an aggregate of approximately 20,580,000 shares of our common stock. We also have options outstanding that are exercisable, at exercise prices ranging from \$0.70 to \$15.65 per share, for an aggregate of

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approximately 5,050,000 shares of our common stock. Purchasers of common stock could therefore experience substantial dilution of their investment upon exercise of the above warrants or options. The majority of the shares of common stock issuable upon exercise of the warrants or options held by these investors are currently registered.

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

As of April 5, 2007, our officers and directors beneficially owned an aggregate of approximately 15,800,000 shares (or approximately 26%) of our common stock, including stock options exercisable within 60 days. 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.

*Anti-takeover effects of certain certificate of incorporation and bylaw provisions could discourage, delay or prevent a change in control.*

Our certificate of incorporation and bylaws could discourage, delay or prevent persons from acquiring or attempting to acquire us. Our certificates of incorporation authorizes our board of directors, without action of our stockholders, 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 stockholders to change or repeal the bylaws. In addition, our bylaws limit who may call meetings of our stockholders.

### **SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION**

This prospectus includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy, progress and timing of development programs and related trials and the efficacy of our product candidates, the commercial benefits available to us as a result of our agreements with third parties, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words may, will, should, would, expect, intend, plan, anticipate, believe, estimate, predict, potential, continue, or appear or the negative of these terms or similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included or incorporated in this prospectus, particularly under the heading **Risk Factors**, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements.

### **USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares by the selling stockholders.

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The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, American Stock Exchange listing fees and fees and expenses of our counsel and our accountants.

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**SELLING STOCKHOLDERS**

We issued warrants to purchase 640,000 shares of common stock pursuant to a credit agreement dated February 26, 2007 between us and the selling stockholders. The issuance of the warrants was exempt from the registration requirements of the Securities Act of 1933, as amended. We have agreed with each selling stockholder to file a registration statement to register for resale the shares of common stock underlying warrants we issued in connection with the credit agreement. Such shares may also be sold by donees, pledgees, and other transferees or successors in interest of the selling stockholders. Except as noted in the footnotes below, none of the selling stockholders has held any position or office with us or any of our predecessors or affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years other than as a result of the ownership of our shares or other securities.

The information in the table below is based on information provided by or on behalf of the selling stockholders. Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting or investment power with respect to the securities. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock that could be issued upon the exercise of outstanding options and warrants held by that person that are currently exercisable or exercisable within sixty days are considered outstanding. These shares, however, are not considered outstanding as of March 31, 2007 when computing the percentage ownership of each other person. Percentage of ownership is based on 53,427,955 shares outstanding on March 15, 2007. The information in the table below regarding the shares of common stock beneficially owned after the offering assumes that all of the shares offered by the selling stockholders, including the shares of common stock acquired upon exercise of warrants, are sold, and that the selling stockholders acquire no additional shares of common stock before completion of the offering. Unless otherwise indicated in the footnotes to this table, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

| Name of Selling Stockholder    | Shares of<br>Common<br>Stock<br>Beneficially<br>Owned<br>Prior to<br>Offering | Number of<br>Warrant<br>Shares<br>Being<br>Offered (1) | Shares of Common<br>Stock to be Beneficially<br>Owned After Offering |            |
|--------------------------------|---|--|--|------------|
|                                |   |  | Number   | Percentage |
| HSBC Capital (Canada) Inc. (2) |   | 319,936  | 0  | *          |
| MMV Financial Inc.             |   | 320,064  | 0  | *          |

\* Less than one percent.

(1) Represents the shares of common stock being registered pursuant to this prospectus that the selling stockholder may acquire upon the exercise of warrants issued in connection with the credit agreement dated February 26, 2007, of which 240,000 shares underlying the warrants are conditional on the occurrence of the drawdown of the second tranche of the credit facility. The warrants have an initial exercise price of \$1.25 per share and are subject to adjustment pursuant to anti-dilution adjustment provisions as further described in the warrants.

(2) HSBC is affiliated with HSBC Securities (Canada) Inc. and HSBC Securities (USA) Inc., both NASD registered broker-dealers.



**PLAN OF DISTRIBUTION**

We are registering the shares of common stock on behalf of the selling stockholders. Sales of shares may be made by selling stockholders, including their respective donees, transferees, pledgees or other successors-in-interest directly to purchasers or to or through underwriters, broker-dealers or through agents. Sales may be made from time to time on the American Stock Exchange, any other exchange or market upon which our shares may trade in the future, in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

- a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction (including crosses in which the same broker acts as agent for both sides of the transaction);
- purchases by a broker-dealer as principal and resale by such broker-dealer, including resales for its account, pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchases;
- through options, swaps or derivatives;
- in privately negotiated transactions;
- in making short sales or in transactions to cover short sales; and
- put or call option transactions relating to the shares.

The selling stockholders may effect these transactions by selling shares directly to purchasers or to or through broker-dealers, which may act as agents or principals. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principals, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities.

The selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, the broker-dealers or other financial institutions may engage in short sales of the shares or of securities convertible into or exchangeable for the shares in the course of hedging positions they assume with the selling stockholders. The selling stockholders may also enter into options or other transactions with broker-dealers or other financial institutions which require the delivery of shares offered by this prospectus to those broker-dealers or other financial institutions. The broker-dealer or other financial institution may then resell the shares pursuant to this prospectus (as amended or supplemented, if required by applicable law, to reflect those transactions).

The selling stockholders and any broker-dealers that act in connection with the sale of shares may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act of 1933, and any commissions received by broker-dealers or any profit on the resale of the shares sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against liabilities, including liabilities arising under the Securities Act. We have agreed to indemnify each of the selling stockholders and each selling stockholder has agreed, severally and not jointly, to indemnify us against some liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act.

The selling stockholders will be subject to the prospectus delivery requirements of the Securities Act. We

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have informed the selling stockholders that the anti-manipulative provisions of Regulation M promulgated under the Securities Exchange Act of 1934 may apply to their sales in the market.

Selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided they meet the criteria and conform to the requirements of Rule 144.

Upon being notified by a selling stockholder that a material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required pursuant to Rule 424(b) under the Securities Act, disclosing:

- the name of each such selling stockholder and of the participating broker-dealer(s);
- the number of shares involved;
- the initial price at which the shares were sold;
- the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;
- that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and
- other facts material to the transactions.

In addition, if required under applicable law or the rules or regulations of the Commission, we will file a supplement to this prospectus when a selling stockholder notifies us that a donee or pledgee intends to sell more than 500 shares of common stock.

We are paying all expenses and fees customarily paid by the issuer in connection with the registration of the shares. The selling stockholders will bear all brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

### LEGAL MATTERS

The validity of the shares offered by this prospectus has been passed upon by Morgan, Lewis & Bockius LLP, Philadelphia, Pennsylvania.

### EXPERTS

The consolidated financial statements and schedule of Antares Pharma, Inc. as of December 31, 2006 and 2005, and for each of the years in the three-year period ended December 31, 2006, have been incorporated by reference herein in reliance upon the reports of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, D.C. 20549. You may also obtain copies of this information by mail from the SEC's Public Reference Room at prescribed rates. You should call 1-800-SEC-0330 for more information on the SEC's Public Reference Room. Our SEC filings are also available to you free of charge at the SEC's Internet website at <http://www.sec.gov>. Most of our SEC filings are also available to you free of charge at our Internet website at <http://www.antareshpharma.com>.

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This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's Internet website.

### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC permits us to incorporate into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. The information incorporated by reference is considered to be part of this prospectus. Information contained in this prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 (other than information furnished to, and not filed with, the SEC), prior to the sale of all the shares covered by this prospectus.

- (1) Our Annual Report on Form 10-K for the year ended December 31, 2006;
- (2) Our Current Reports on Form 8-K filed with the SEC on January 22, 2007 and March 2, 2007.
- (3) All of our filings pursuant to the Exchange Act after the date of filing the initial registration statement and prior to effectiveness of the registration statement; and
- (4) The description of our common stock contained in a registration statement filed on Form 8-A under the Securities Exchange Act of 1934 filed on September 22, 2004, including any amendments or reports filed for the purpose of updating that description.

You may request a copy of these documents, which will be provided to you at no cost, by writing or telephoning us using the following contact information:

Antares Pharma, Inc.

250 Phillips Blvd., Suite 290

Ewing, NJ 08618

Attention: Investor Relations

Telephone: (609) 359-3020

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of the securities being registered hereby, all of which will be borne by Antares Pharma, Inc. (except any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares). All amounts shown are estimates except the Securities and Exchange Commission registration fee.

|   |               |
|---|---------------|
| Filing Fee Securities and Exchange Commission . | \$ 30         |
| Legal fees and expenses                         | \$ 5,000      |
| Accounting fees and expenses                    | \$ 10,000     |
| Miscellaneous expenses                          | \$ 2,070      |
| <br>Total Expenses                              | <br>\$ 17,100 |

**Item 15. Indemnification of Directors and Officers.**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. The Registrant's Certificate of Incorporation provides that a director of the Registrant shall not be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, except to the extent that such exemption from liability or limitation thereof is not permitted under the General Corporation Law of the State of Delaware as currently in effect or as the same may hereafter be amended.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnify for such expenses which the Court of Chancery or such other court shall deem proper.

The Registrant's by-laws provide that the Registrant will, to the maximum extent permitted under the laws of the State of Delaware, indemnify and advance expenses upon request to each director and officer of the Registrant against any and all judgments, penalties, fines and amounts reasonably paid in settlement that are incurred by such director or officer or on such director's or officer's behalf in connection with any threatened, pending or completed proceeding or any claim, issue or matter of which he or she is, or is threatened to be made, a party to or participant in by reason of his or her corporate status. Unless ordered by a court, the Registrant will not provide indemnification to such a director or officer unless a determination has been made that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Registrant and, with respect to any criminal proceeding, such person had no reasonable cause to believe his or her conduct was unlawful. Such a determination will be made by (a) a majority vote of disinterested directors or an appointed committee of disinterested directors, (b) if there are no disinterested directors or if the disinterested directors direct, by independent legal counsel or (c) by the stockholders of the Registrant.





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The Registrant has purchased directors and officers liability insurance which would indemnify its directors and officers against damages arising out of certain kinds of claims which might be made against them based on their negligent acts or omissions while acting in their capacity as such.

### Item 16. Exhibits

#### EXHIBIT

#### NUMBER DESCRIPTION

3.1

Certificate of Incorporation of the Registrant (Filed as exhibit 4.1 to Form S-3 on April 12, 2006 and incorporated herein by reference.)

3.2

Bylaws of the Registrant (Filed as exhibit 4.2 to Form S-3 on April 12, 2006 and incorporated herein by reference.)

4.1

Registration Rights Agreement by and among Antares Pharma, Inc., MMV Financial Inc. and HSBC Capital (Canada) Inc., dated February 26, 2007 (Filed as exhibit 4.1 to Form 8-K on March 2, 2007 and incorporated herein by reference.)

4.2

Warrant for the Purchase of Shares of Common Stock issued by Antares Pharma, Inc. to MMV Financial Inc., dated February 26, 2007 (Filed as exhibit 4.2 to Form 8-K on March 2, 2007 and incorporated herein by reference.)

4.3

Warrant for the Purchase of Shares of Common Stock issued by Antares Pharma, Inc. to HSBC Capital (Canada) Inc., dated February 26, 2007 (Filed as exhibit 4.3 to Form 8-K on March 2, 2007 and incorporated herein by reference.)

4.4

Credit Agreement by and among Antares Pharma, Inc., MMV Financial Inc. and HSBC Capital (Canada) Inc., dated February 26, 2007 (Filed as exhibit 10.1 to Form 8-K on March 2, 2007 and incorporated herein by reference.)

5.1

Opinion of Morgan, Lewis & Bockius LLP.

23.1

Consent of KPMG LLP.

23.2

Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1 filed herewith).

24.1

Power of Attorney (included on signature page of the Registration Statement).

### Item 17. Undertakings.

The undersigned Registrant hereby undertakes:

- (a) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the Securities Act );

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(ii) To reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereto) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective Registration Statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement;

*provided, however,* that paragraphs (a)(i), (a)(ii) and (a)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ), that are incorporated by reference in this Registration Statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) of the Securities Act that is part of the Registration Statement.

- (b) That, for the purposes of determining any liability under the Securities Act, each post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial *bona fide* offering thereof.
- (c) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (d) That, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (e) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the indemnification provisions described herein, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ewing, State of New Jersey, on April 24, 2007.

### ANTARES PHARMA, INC.

/s/Jack E. Stover

Jack E. Stover

President and Chief Executive Officer

### POWER OF ATTORNEY

We, the undersigned officers and directors of Antares Pharma, Inc. hereby severally constitute and appoint Jack E. Stover and Robert F. Apple and each of them singly, our true and lawful attorneys with full power to any of them, and to each of them singly, to sign for us and in our names in the capacities indicated below the Registration Statement on Form S-3 filed herewith and any and all pre-effective and post-effective amendments to said Registration Statement and generally to do all such things in our name and behalf in our capacities as officers and directors to enable Antares Pharma, Inc. to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorneys, or any of them, to said Registration Statement and any and all amendments thereto.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| <u>Signature</u>                           | <u>Title</u>  | <u>Date</u>    |
|--|---|----------------|
| /s/Jack E. Stover<br>Jack E. Stover        | President, Chief Executive Officer and Director<br><br>(principal executive officer)<br><br>Senior Vice President and Chief Financial Officer | April 24, 2007 |
| /s/Robert F. Apple<br>Robert F. Apple      | (principal financial and accounting officer)  | April 24, 2007 |
| /s/ Jacques Gonella<br>Dr. Jacques Gonella | Director, Chairman of the Board   | April 24, 2007 |
| /s/Thomas J. Garrity<br>Thomas J. Garrity  | Director  | April 24, 2007 |
| /s/Anton Gueth<br>Anton Gueth              | Director  | April 24, 2007 |

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/s/Rajesh Shrotriya  
Dr. Rajesh Shrotriya

Director

April 24, 2007

/s/Paul Wotton  
Dr. Paul Wotton

Director

April 24, 2007

/s/Leonard S. Jacob  
Dr. Leonard S. Jacob

Director

April 24, 2007

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**EXHIBIT INDEX**

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