

ANTARES PHARMA INC  
Form 10-K  
March 27, 2007  
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (D) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
For transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-32302

**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 Number)

250 Phillips Boulevard, Suite 290, Ewing, NJ 08618  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (609) 359-3020

SECURITIES REGISTERED PURSUANT TO SECTION 12 (b) OF THE ACT: Common Stock, \$.01 Par Value

SECURITIES REGISTERED PURSUANT TO SECTION 12 (g) OF THE ACT: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES  NO

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one): Large Accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark if the registrant is a shell company (as defined in Rule 12b-2 of the Act.) YES  NO

Aggregate market value of the voting and non-voting common stock held by nonaffiliates of the registrant as of June 30, 2006, was approximately \$49,800,000 (based upon the last reported sale price of \$1.15 per share on June 30, 2006, on The American Stock Exchange).

There were 53,427,955 shares of common stock outstanding as of March 12, 2007.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for the registrant's 2007 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

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**PART I**

*Item 1. BUSINESS*

**SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS**

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act, Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties. You should not place undue reliance on those statements because they are subject to numerous uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. These statements often include words such as may, believe, expect, anticipate, intend, plan, estimate or similar expressions. These statements are based on assumptions that we have made in light of our industry experience as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this report, you should understand that these statements are not guarantees of performance results. They involve risks, uncertainties and assumptions. Although we believe that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect our actual financial results or results of operations and could cause actual results to differ materially from those in the forward-looking statements. You should keep in mind that forward-looking statements made by us in this report speaks only as of the date of this report. Actual results could differ materially from those currently anticipated as a result of a number of risk factors, including, but not limited to, the risks and uncertainties discussed under the caption Risk Factors. New risks and uncertainties come up from time to time, and it is impossible for us to predict these events or how they may affect us. We have no duty to, and do not intend to update or revise the forward-looking statements in this report after the date of this report. In light of these risks and uncertainties, you should keep in mind that any forward-looking statement in this report or elsewhere might not occur.

**Overview**

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 lead 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 Tablets Platform	Easy Tec	
	Needle-Free Reusable Injectors (MJ Platform)	

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Medi-Jector VISION® and Valeo

Mini-Needle Disposable Injectors

(AJ Platform) Vibex

Vaccine Intradermal Injectors

Injection Device

Platforms

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Product Candidates

Transdermal Delivery Gels

Fast-Melt Oral Dissolve Disintegrating Tablets (EasyTec )

Injection Devices

### 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. We believe that the ability of Easy Tec tablets to be manufactured without specialized equipment and their non-effervescent (highly moisture sensitive) qualities 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<sup>®</sup> 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 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.

## History

On January 31, 2001, the Company (formerly known as Medi-Ject Corporation or Medi-Ject) completed a business combination to acquire the three operating subsidiaries of Permaterc Holding AG (Permaterc), headquartered in Basel, Switzerland. Medi-Ject was at that time, focused on delivering drugs across the skin using needle-free technology, and Permaterc specialized in delivering drugs across the skin using transdermal patch and gel technologies as well as developing fast-melt tablet technology. With both companies focused on drug delivery but with a focus on different sectors, it was believed that a business combination would be attractive to both pharmaceutical partners and to the Company's stockholders. Upon completion of the transaction the Company's name was changed from Medi-Ject Corporation to Antares Pharma, Inc.

The U.S. device operation, located in Minneapolis, Minnesota, develops, manufactures with partners and markets novel medical devices, called jet injectors or needle-free injectors, which allow people to self-inject drugs at home. The Company makes a reusable, needle-free, spring-action injector device known as the Medi-Jector VISION®. Using an adapter, the liquid drug is drawn from a conventional vial into the plastic needle-free syringe, through a small hole at the end of the syringe. When the syringe is held against an appropriate part of the body and the spring is released, a piston drives the fluid stream into the tissues beneath the skin, from where the drug is dispersed into systemic circulation. A person may re-arm the device and repeat the process or attach a new sterile syringe between injections.

The Company was a pioneer in the invention of home use needle-free injection systems in the late 1970s. Prior to that, needle-free injection systems were powered by large air compressors or were relatively complex and expensive, so their use was limited to mass vaccination programs by the military, school health programs or for patients classified as needle phobic. Early injectors were painful in comparison to today's injectors, and their large size made home use difficult. The first home insulin injector was five times as heavy as the current injector, which today weighs five ounces. Today our insulin injector sells at a retail price of under \$300 compared to \$799 nine years ago. The first growth hormone injector was introduced in Europe in 1994. This was the Company's first success in achieving distribution of its device through a license to a pharmaceutical partner, and it has resulted in continuing market growth and, the Company believes, a high degree of customer satisfaction. Distribution of growth hormone injectors has expanded through the Company's pharmaceutical company relationships to now include Japan and other Asian countries.

The Company has also developed variations of the jet injector by adding a very small hidden needle to a pre-filled, single-use disposable injector, called the Vibex mini-needle injection system. The mini-needle platform is an alternative to the Visio® system for use with unit dose injectable drugs and is suitable for branded and branded generic injectables.

Antares is also committed to drug delivery by way of its transdermal gel formulations and its fast-melt tablet products. The Company believes that its transdermal gels have advantages in cost, cosmetic elegance, ease of application and lack of irritancy as compared to better-known transdermal patches and have applications in such therapeutic markets as hormone replacement, over active bladder, osteoporosis, cardiovascular, pain management and central nervous system therapies. The Company also believes that its proprietary fast-melt tablets can enable delivery of certain drugs orally, such as nonsteroidal anti-inflammatory drugs.

The Company's first transdermal and fast-melt tablet products were developed in Argentina under Permaterc's name in the mid-1990s. Subsequently, the Argentine operations were moved to Basel, Switzerland, in late 1999. The transdermal product effort initially resulted in the commercialization of a seven-day estradiol patch in certain countries of South America in 2000. Over time, Permaterc's research efforts moved away from the more crowded transdermal patch field and focused on transdermal gel formulations, which allow the delivery of estrogens, progestins, testosterone and other drugs in a gel base without the need for occlusive or potentially irritating adhesive bandages. We believe the commercial potential for transdermal gels is attractive, and several licensing agreements with pharmaceutical companies of various sizes have led to successful clinical evaluation of Antares' formulations. The Company is now also developing its own transdermal gel-based products for the market and has reported Phase II clinical results for Anturool, its oxybutynin gel for overactive bladder.





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The Company operates in the specialized drug delivery sector of the pharmaceutical industry. Companies in this sector generally leverage technology and know-how in the area of drug formulation and/or delivery devices to pharmaceutical manufacturers through licensing and development agreements while continuing to develop their own products for the marketplace. The Company also views many pharmaceutical and biotechnology companies as collaborators and primary customers. The Company has negotiated and executed licensing relationships in the growth hormone segment (needle-free devices in Europe and Asia) and the transdermal hormone gels segment (several development programs in place worldwide, including the United States and Europe). In addition, the Company continues to market needle-free devices for the home administration of insulin in the U.S. market through distributors and has licensed its technology in the diabetes and obesity fields to Eli Lilly and Company.

The Company is a Delaware corporation. Principal executive offices are located at Princeton Crossroads Corporate Center, 250 Phillips Boulevard, Suite 290, Ewing, New Jersey 08618; telephone (609) 359-3020. The Company has wholly-owned subsidiaries in Switzerland (Antares Pharma AG and Antares Pharma IPL AG) and the Netherlands Antilles (Permatec NV).

### Industry Trends

Based upon experience in the industry, the Company believes the following significant trends in healthcare have important implications for the growth of its business.

When a drug loses patent protection, the branded version of the drug typically faces competition from generic alternatives. It may be possible to preserve market share by altering the delivery method, e.g., a single daily controlled release dosage form rather than two to four pills a day. The Company expects branded pharmaceutical companies will continue to seek differentiating drug delivery characteristics to defend against generic competition and to optimize convenience to patients. The altered delivery method may be an injection device or a novel oral or transdermal formulation that may offer therapeutic advantages, convenience or improved dosage schedules. Major pharmaceutical companies now focus on life cycle management of their products to maximize return on investment and often consider phased product improvement opportunities to maintain competitiveness.

The increasing trend of major pharmaceutical companies marketing directly to consumers, as well as focus on patient rights may encourage the use of innovative, user-friendly drug delivery systems. Part of this trend involves offering patients a wider choice of dosage forms. The Company believes the patient-friendly attributes of its transdermal gels, fast-melt tablets and injection technologies meet these market needs.

The Company envisions its transdermal gel formulations as a next-generation technology, replacing many transdermal patch products with more patient-friendly products. Topical gels offer patients more choices and added convenience with no compromise of efficacy. Our gel technology is based upon so-called GRAS ( Generally Recognized as Safe ) substances, meaning the toxicology profiles of the ingredients are known and widely used. We believe this approach has a major regulatory benefit and may reduce the cost and time of product development and approval.

Many drugs, including selected hormones and protein biopharmaceuticals, are degraded in the gastrointestinal tract and may only be administered through the skin, the lung or by injection. Pulmonary delivery is complex and has recently been commercialized for limited therapeutic proteins intended for systemic delivery. Injection therefore remains the mainstay of protein delivery. The growing number of protein biopharmaceuticals requiring injection may have limited commercial potential if patient compliance with conventional injection treatment is not optimal. The failure to take all prescribed injections can lead to increased health complications for the patient, decreased drug sales for pharmaceutical companies and increased healthcare costs for society. In addition, it is becoming increasingly recognized that conventional needles and syringes are inherently unreliable and require special and often costly disposal methods.

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In addition to the increase in the number of drugs requiring self-injection, recommended changes in the frequency of insulin injections for the treatment of diabetes also may contribute to an increase in the number of self-injections. For many years, the standard treatment protocol was for insulin to be administered once or twice daily for the treatment of diabetes. However, according to major studies (the Diabetes Control and Complications Trial), tightly controlling the disease by, among other things, administration of insulin as many as four to six times a day,

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can decrease its debilitating effects. The Company believes that with the increasing incidence of diabetes coupled with an increasing awareness of this disease, the benefits of tightly controlling diabetes will become more widely known, and the number of insulin injections self-administered by people with diabetes will increase. The need to increase the number of insulin injections given per day may also motivate patients with diabetes to seek alternatives to traditional needles and syringes.

Due to the substantial costs involved, marketing efforts are not currently focused on drug applications administered by healthcare professionals. Jet injection systems, however, may be attractive to hospitals, doctors' offices and clinics, and such applications may be explored in the future. The issues raised by accidental needle sticks and disposal of used syringes have led to the development of syringes with sheathed needles as well as the practice of administering injections through intravenous tubing to reduce the number of contaminated needles. In 1998, the State of California banned the use of exposed needles in hospitals and doctors' offices, if alternatives exist, and several additional states have adopted similar legislation. In November 2000 the Federal Government issued guidelines encouraging institutions to replace needles wherever practical. The Company believes that needle-free injection systems or its shielded mini-needle products may be attractive to healthcare professionals as a further means to reduce accidental needle sticks and the burdens of disposing of contaminated needles.

The importance of vaccines in industrialized and emerging nations is expanding as the prevalence of infectious diseases increases. New vaccines and improved routes of administration are the subject of intense research in the pharmaceutical industry and the Company has been researching the feasibility of using its devices for vaccines and new vaccine ingredients including evaluating opportunities in recent bio-terrorism initiatives.

The Company's fast-melt technology also addresses industry trends by focusing on the needs of specific market segments such as geriatric and pediatric patients who often have difficulty swallowing conventional oral medications. We believe that better health outcomes can be expected when patients are compliant with recommended medication regimens. The Company's fast-melt technology offers consumers a potentially important alternative oral delivery system.

### Market Opportunity

According to a March 2006 Cowen & Co. publication, the worldwide market for urinary incontinence is estimated to be \$1.6 billion in 2005 and growing to \$2.6 billion by 2010. Older incontinence drugs, such as immediate release oxybutynin, are plagued by anticholinergic effects including moderate to severe dry mouth (seen in 70% of the patients), constipation and confusion. It is also estimated that half of the 20 million U.S. adults suffering from overactive bladder either are too embarrassed to discuss the symptoms or are not aware that pharmacological treatment is available. It is further estimated that only 47% of U.S. incontinence patients sought treatment in 2005 and that 16% of incontinence patients were compliant with their treatment in 2005 estimated to increase to only 18% by 2010.

According to a March 2006 Cowen & Co. publication, the worldwide hormone replacement market is expected to grow from \$1.3 billion in 2005 to \$1.9 billion by 2010. Further growth in this sector may be achieved by the use of testosterone products in both male and female applications. According to the same comprehensive study by Cowen & Co., the female sexual dysfunction ( FSD ) market is estimated to be 78 million sufferers worldwide rising to 95 million by 2010. Additionally, the worldwide sexual dysfunction market is projected to be \$3.9 billion in 2005 growing to \$5.6 billion by 2010. The importance of gel products containing testosterone for men has been exemplified with the success of Androgel® (Unimed-Solvay) for treatment of male hypogonadism, where sales in the U.S. were recently estimated at approximately \$500 million per year. A new market opportunity also exists with the use of low dose testosterone for treatment of FSD, a disorder according to published reports that affects an estimated 40-55% of all women and for which no drug is currently approved in the U.S. Antares Pharma, along with its U.S. partner BioSante, has a low dose testosterone product named Libi-Gel , which has completed Phase II testing for FSD and is currently in Phase III clinical trials. We have the exclusive market rights in Europe and elsewhere outside the United States for Libi-Gel . As evidenced in Europe and, more specifically, in France, the leading country in the use of transdermal hormone replacement therapy, the Company believes that patient demand for transdermal hormone therapy products will continue to increase. Evidence of this belief is the recent commercial launch, in France, by Proctor and Gamble of the Intrinsa® Patch, a testosterone transdermal patch for FSD. According to an industry report, 64.8% of treated menopausal women in France used either patch (44.7%) or gel



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(20.1%) therapy. Gel products are also being formulated to address equally large opportunities in other sectors of the pharmaceutical industry, including cardiovascular, pain, infectious diseases, addiction and central nervous system therapies.

The field of melt-in-the-mouth, or fast-dissolve, tablets clearly has a significant role to play in effective product administration to the elderly and to those who have difficulty swallowing. While many products have been developed to meet this need, many have disadvantages, including lack of applicability to all drug candidates, dose limitations, high cost of manufacturing, and product robustness issues that can challenge packaging and distribution systems. Using its Easy Tec<sup>®</sup> technology, Antares has undertaken to develop products that could be applicable over a wide dose range, could be manufactured under conventional conditions and would meet the standards of performance necessary to provide the desired patient benefits of rapid dissolution, good mouth feel and ease of handling.

To date, needles and syringes are the mainstay for drugs that require injection. The Company believes that a significant portion of these needles and syringes are used for the administration of drugs that could be delivered using its injectors, but only a small percentage of people who self-administer drugs currently use jet injection systems. The Company believes that this lack of market penetration is due to older examples of needle-free technology not meeting customer needs owing to cost and performance limitations as well as the small size of the companies directly marketing the technology to consumers not being able to gain a significant share of voice in the marketplace. The Company believes that its technology overcomes most of these limitations of the past and that its business model of working with pharmaceutical company partners has the potential for improved market penetration. However, to date neither the Company nor its competitors have achieved substantial market penetration.

Antares' device focus is specifically on the market for delivery of self-administered injectable drugs. The largest and most mature segments of this market consist of insulin for patients with diabetes and human growth hormone for children with growth retardation. According to a March 2006 publication by Cowen & Co., the worldwide insulin market is estimated to grow from \$7.7 billion in 2005 to \$14.6 billion in 2010, of which \$2 billion in 2010 is inhaled insulin. The Company believes that the number of insulin injections will increase with time as the result of new diabetes management techniques, which recommend more frequent injections as evidenced by the U.S. insulin market projected to grow from \$2.7 billion in 2005 to \$5.8 billion in 2010. A second attractive market has developed with growth hormone; children and young adults suffering from growth retardation take daily hormone injections for an average of five years. The number of children with growth retardation is small relative to diabetes, but most children are needle averse. The Company's pharmaceutical partner in Europe, Ferring Pharmaceuticals BV (Ferring), has made significant inroads using its injectors in the hGH market, and the Company expects similar progress in other geographic regions where partnerships have already been established. Other injectable drugs that are presently self-administered and may be suitable for injection with the Company's systems include therapies for the prevention of blood clots and the treatment of multiple sclerosis, migraine headaches, inflammatory diseases, impotence, infertility, AIDS and hepatitis. Antares also believes that many injectable drugs currently under development will be administered by self-injection once they reach the market. This is supported by the continuing development of important chronic care products that can only be given by injection, the ongoing effort to reduce hospital and institutional costs by early patient release, and the gathering momentum of new classes of drugs that require injection. A partial list of such drugs introduced in recent years that all require home injection include Enbrel<sup>®</sup> (Amgen, Wyeth) for treatment of rheumatoid arthritis, Aranesp<sup>®</sup> (Amgen) for treatment of anemia, Kineret<sup>®</sup> (Amgen) and Humira<sup>®</sup> (Abbott) for rheumatoid arthritis, Forteo (Lilly) for treatment of osteoporosis, Intron<sup>®</sup> A (Schering Plough) and Roferon<sup>®</sup> (Roche) for hepatitis C, Lantus<sup>®</sup> (Aventis Pharma) for diabetes, Rebif<sup>®</sup> (Serono) for multiple sclerosis, Copaxone<sup>®</sup> (Teva) for multiple sclerosis and Gonal-F<sup>®</sup> for fertility treatment. We believe the dramatic increase in numbers of products for self-administration by injection and the breadth of therapeutic areas covered by this partial listing represents an opportunity for Antares' device portfolio.

### Products and Technology

Antares is leveraging its experience in drug delivery systems to enhance the product performance of established drugs as well as new drugs in development. The Company's current technology platforms include transdermal Advanced Transdermal Delivery (ATD) gels; fast-melt oral disintegrating tablets (Easy Tec<sup>®</sup>); disposable mini-needle injection systems (Vibex<sup>®</sup>); and reusable needle-free injection systems (Medi-Jector VISION<sup>®</sup> and Valeo<sup>®</sup>).



### Transdermal Drug Delivery

Transdermal drug delivery has emerged as a generally safe and patient-friendly method of drug delivery. The commercialization of transdermal patches for controlled drug delivery began over two decades ago and has resulted in the appearance of diverse products on the market. Among them are nitroglycerin for angina, scopolamine for motion sickness, fentanyl for pain control, nicotine for smoking cessation, estrogen for HT, clonidine for hypertension, lidocaine for topical anesthesia, testosterone for hypogonadism, and a combination of ethinyl estradiol and norelgestromin for contraception. Skin penetration enhancers are often used to enhance drug permeation through the dermal layers.

The primary goal of transdermal drug delivery is to effectively penetrate the surface of the skin via topical administration, such as a patch or gel. When successful, transdermal drug delivery provides an easy and painless method of administration. The protective capabilities of the skin, however, often act as a barrier to effective delivery. Since the primary role of the skin is to provide protection against infection and physical damage, the organ often prevents many pharmaceuticals from entering the body as well. Large molecules may not be as effectively absorbed by the skin and enter the body in prohibitively small amounts, significantly reducing their therapeutic potential. As a result, a limited number of active substances are able to cross the skin's surface.

Despite these limitations, transdermal drug delivery is still viewed as a highly attractive route of administration for certain therapeutics. As a high concentration of capillaries is located immediately below the skin, transdermal administration provides an easy means of access to systemic circulation. Transdermal systems can be designed to minimize absorption of the active drug in the blood circulation as is needed in topical applications. This allows a build-up of drug in the layers underlying the skin, leading to an increased residence time in the targeted tissue. Transdermal systems can also be designed to release an active ingredient over extended periods of time, providing benefits similar to depot injections and implants, without the need for an invasive procedure. If required, patients are also able to interrupt dosing by removing a patch or discontinuing the application of a gel. Finally, this delivery technology minimizes first-pass metabolism by the liver as well as many of the gastrointestinal concerns of many orally ingested drugs.

### Transdermal Gels

While transdermal patches remain an important aspect of the transdermal drug delivery market, transdermal gels have emerged as a viable means of administering a wide array of active pharmaceutical treatments. The concept of transdermal gels parallels that of the transdermal patch in the creation of a drug reservoir to provide sustained delivery of therapeutic quantities of a drug. While a patch provides this from an external reservoir, gel formulations create a subdermal reservoir of the medication.

To address the penetration capabilities of transdermal products, Antares has developed its ATD gel technology that utilizes a combination of permeation enhancers to further bolster a pharmaceutical agent's ability to penetrate the skin. This new generation of products leads to a sustained plasma profile of the active agent, without the irritation and cosmetic concerns often associated with patches.

Gels also provide drug developers with an opportunity to explore a wide variety of potential applications. Due to the physicochemical properties of the excipients employed in gels, combined with the enhanced solubilization properties, a broad range of active agents can be formulated. These solubilization properties allow for higher concentrations of the active ingredient to be incorporated for delivery. The enhanced viscosity in gels further enhances the patient's ability to apply the product with little-to-no adverse cosmetic effect. There is also relatively little limitation in the surface area to which a gel can be applied, as opposed to patches, allowing greater quantities of drug to be transported if required.

### Antares Advanced Transdermal Delivery (ATD) System



Antares ATD system successfully penetrates the skin to deliver a variety of treatments. The gels consist of a hydro-alcoholic base including a combination of permeation enhancers. The gels are also designed to be absorbed quickly through the skin after application typically to the arms, shoulders, or abdomen. In comparison with commonly used patch delivery systems, the gels cause minimal skin irritation or occlusion following application and

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possess a distinct cosmetic advantage over other approaches. The following is a summary of the benefits of our ATD gel platform:

### Benefits of ATD Gel Platform

- Discrete
- Easy application
- Cosmetically appealing compared with patches
- Reduced irritancy compared with patches
- Application of once per day for most products
- Potential for delivery of larger medication doses
- Potential for delivery of multiple active drugs
- Ability to be either systemic or topical

Antares ATD gels can deliver both a single active ingredient as well as a combination of active ingredients with different release profiles, and have demonstrated potential in a variety of therapeutic areas. One of our licensed gels, an estrogen gel for women to treat vasomotor symptoms associated with menopause (Elestrin<sup>®</sup>), has recently been approved by the FDA. Other current ATD drug gels in development encompass an oxybutynin gel for treatment of over active bladder (Anturol ), a low dose testosterone gel to treat low libido in women (Libi-Gel ), a testosterone gel for men to treat hypogonadism, a contraception gel, a gel for an undisclosed central nervous system ( CNS ) disorder with a pharmaceutical partner and an alprazolam gel for anti-anxiety. Antares has also licensed an ibuprofen gel in 11 countries for several years. ATD gels may be extended to a variety of fields, including the treatment of cardiovascular disease and chronic pain, in which potent compounds may require alternatives to oral and injectable delivery for the following reasons:

- poor oral uptake;
- high first-pass liver effect;
- requirement for less frequent administration;
- desire to provide an alternative dosage form;
- reducing peak plasma levels to avoid side effects; and
- reduction in gastrointestinal side effects.

The Company has also formulated several combination gels demonstrating the ability to deliver multiple actives with different release profiles.

### Oral Delivery

The majority of all drugs are administered orally. Despite this, there remain limitations for those patients who have difficulty swallowing conventional oral dosage forms or where an underlying disease state (for example, migraine, Parkinsonism or cancer) impacts a person's ability to swallow. Additionally, where patients are resistant to oral drug delivery, the phenomenon of cheeking (hiding a pill between the cheek and gum) and subsequent drug disposal is quite well known. New generations of oral product forms are being developed to address these issues.

Fast-Dissolving Tablets

Fast-dissolving tablet technology is an oral delivery method that offers an alternative to patients who experience difficulty ingesting conventional oral dosage forms. As a result, formulators are focusing on the development of tablet dosage formulations for oral administration that dissolve rapidly in saliva without need for the patient to drink water. This formulation is easy to take and possesses similar therapeutic benefits to traditional oral technologies, thus appealing to a wide demographic population.

One of the primary realities influencing the development of fast-dissolving technologies is the increased life expectancy of a growing geriatric population. As many elderly individuals experience difficulty taking conventional oral dosage forms, such as solutions, suspensions, tablets and capsules, the need for more user-friendly formulations

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is expanding. While swallowing difficulties often affect the elderly population, many young individuals also experience difficulty as a result of underdeveloped muscular and nervous systems. Other groups, including the mentally ill, the developmentally disabled and uncooperative patients also require special attention. Other circumstances, such as motion sickness, allergic attacks and an unavailable source of water also necessitate fast-dissolving oral formulations.

The development of a fast-dissolving tablet also provides pharmaceutical companies with an opportunity for product line extensions. A wide range of drugs (e.g. neuroleptics, cardiovascular drugs, analgesics, antihistamines, and drugs for erectile dysfunction) may be considered candidates for this technology.

### *Antares Easy Tec Fast-Melt Oral Disintegrating Tablet*

Antares patented Easy Tec technology is based on the simultaneous use of two disintegrants in an oral formulation. Two primary advantages of Easy Tec over competing technologies are that Easy Tec tablets can be manufactured with conventional tableting equipment and no unique packaging requirements are necessary. The Company also believes that Easy Tec possesses several other key advantages over competing fast-melt technologies;

#### Easy Tec Competitive Advantages

- Higher drug dose loading is possible
- Friability within pharmaceutical specifications
- Moisture sensitivity lower compared with many competitor products
- Blister packaging sufficient to prevent moisture uptake
- Cost-effective, easy, time-saving process
- Easily transferable to final product site
- No specific facility required, compared to effervescent products

In addition to being easy to take, such products are perceived as being fast acting because of rapid dispersion in the mouth. Additionally, there may be further benefits if Easy Tec can be formulated with certain actives to provide buccal absorption. Antares believes that there may be attractive opportunities to develop its own fast-melt products using generic active ingredients as part of its specialty pharmaceutical strategy and to achieve product approval based on an Abbreviated New Drug Application ( ANDA ) or 505(b)(2) filing in the United States and equivalent regulatory submissions in other parts of the world. Antares has formulated its first Easy Tec based product, a non-steroidal anti inflammatory (NSAID) generic currently called AP-1022 for the treatment of pain. Additionally, the Company has signed a feasibility and development agreement with an unnamed partner in the area of opioid dependence.

#### Injection Delivery

According to industry sources, an estimated 9-12 billion needles and syringes are sold each year. While the need for these components will always exist, burgeoning development efforts are focused on easing the dependence on needles in favor of more user-friendly injection systems. Currently available data suggest that injection with needle-free systems matches the performance of needle-based systems with regard to drug bioavailability, and offers benefits in the speed and quality of injections as well as the lack of requirement for needle disposal.

Needle-Free Injection

The most significant challenge beyond discovery of new molecules is how to effectively deliver them by means other than conventional injection technology. The majority of these molecules have not, to date, been amenable to oral administration due to a combination of several factors, including breakdown in the gastrointestinal tract, fundamentally poor absorption, or high first pass liver metabolism. Pulmonary delivery of these molecules, as an alternative to injections, has also been pursued and only recently one such application has been approved by the FDA. It remains to be seen how clinical success will be accepted by patients, doctors and third party payers. Many

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companies have expended considerable effort in searching for less invasive ways to deliver such molecules that may allow them to achieve higher market acceptance, particularly for those requiring patient self-administration.

Needle-free injection is a form of parenteral drug delivery that continues to gain acceptance among the medical community. Encompassing a wide variety of sizes and designs, this technology operates by using pressure to force the drug, in solution or suspension, through a minute perforation, creating an ultra-thin stream of liquid that penetrates the skin and deposits the drug into the subcutaneous tissue. Needle-free injection systems are being developed as small, pre-filled single-use devices, refillable devices for repeat usage and specialized systems for high throughput applications in mass immunization campaigns.

Needle-free injection represents a combination of an accepted technology - injection, with the elimination of the part of the injection - the needle, that concerns patients that have to self administer and health care professionals concerned about risks to themselves. Improving patient comfort through needle-free injection may increase compliance and mitigate the problem of daily injections. Needle-free delivery eliminates the risk of needlestick injuries as well, which occurs frequently in institutions in the U.S., and can result in disease transmission to healthcare workers. In response to concerns about needlestick injuries, the Occupational Safety and Health Administration ( OSHA ) issued a Bloodborne Pathogens Standard in November 1999, updated in 2001, mandating the use of safer needles and requiring that healthcare facilities perform annual reviews of safety and compliance programs. The National Institute for Occupational Safety and Health has also urged healthcare providers to avoid unnecessary use of needles where safe and effective alternatives are available.

One of the primary factors influencing development in the category of needle-free injection is the inherent problematic dependence on needles. It is also recognized that greater willingness to accept injection therapy could have a beneficial impact on disease outcomes. For example, patients with diabetes appear to be reluctant to engage in intensive disease management, at least in part because of concerns over increased frequency of injections. Similarly, patients with diabetes who are ineffectively managed with oral hypoglycemic agents are reluctant to transition to insulin injections in a timely manner because of injection concerns.

The advent of these technologies has, to date, had a minor influence within the injectable sector, and they have failed to produce the deep market penetration that many within the industry believe they are capable of gaining. Several factors are believed to contribute to this lack of market penetration, beginning with older needle-free injection systems. Many of the early needle-free injection systems had an assortment of drawbacks associated with both performance and cost efficiency. With potential consumers aware of these historical shortcomings, current technologies promising greater efficiency and lower prices have failed to gain wide acceptance in the industry.

### *Antares Medi-Jector Series of Needle-Free Injectors*

The Medi-Jector VISION® represents the seventh in a series of Medi-Jector devices, with each generation offering improvements over the previous versions. Antares pioneered the development of needle-free injection systems for individual use in 1979 and remains among the industry leaders as the technology continues to advance and is marketed worldwide. The Company's current revenue stream is derived primarily from sales of needle-free injectors and related disposable syringes for human growth hormone delivery in Europe and elsewhere.

### Medi-Jector VISION® (MJ7)

The Medi-Jector VISION® has been sold for use in more than 30 countries to deliver either insulin or human growth hormone. The product features a reusable, spring-based power source and disposable needle-free syringes, which eliminate the need for routine maintenance of the nozzle and allow for easy viewing of the medication dose prior to injection. The device's primary advantage over earlier devices is its ease of use and cost efficiency. The product is also reusable, with each device designed to last for approximately 3,000 injections (or approximately two years) while the needle-free syringe is disposable after approximately one week of continuous use.

Antares believes this method of administration is a particularly attractive alternative to the needle and syringe for the groups of patients described below.

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#### Patient Candidates for Needle-Free Injection

- Young adults and children
- Patients looking for an alternative to needles
- Patients mixing insulins
- Patients unable to comply with a prescribed needle program
- Patients transitioning from oral medication to insulin
- New patients beginning an injection treatment program

The Medi-Jector VISION<sup>®</sup> is primarily used in the U.S. to provide a needle-free means of administering insulin to patients with diabetes. Patients with insulin-dependent diabetes are often required to make a life-long commitment to daily self-administration of insulin. In an effort to improve both the comfort and performance of this injected hormone, needle-free injection could become an important alternative method of choice for administration.

The Medi-Jector VISION<sup>®</sup> administers insulin by using a spring to push insulin in solution or suspension through a micro-fine opening in the needle-free syringe. The opening is approximately half the diameter of a standard 30-gauge needle. A fine liquid stream of insulin then penetrates the skin, and the insulin dose is dispersed into the layer of fatty, subcutaneous tissue. The insulin is subsequently distributed throughout the body, successfully producing the desired effect.

The Medi-Jector VISION<sup>®</sup> is primarily used in Europe, Asia, Japan and elsewhere to provide a needle-free means of administering human growth hormone to patients with growth retardation. The Company typically sells its injection devices to partners in these markets who manufacture and/or market human growth hormone directly. The partners then market the Company's device with their growth hormone. The Company receives benefits from these agreements in the form of product sales and royalties on sales of products.

#### *Development Efforts: MJ8 (Valeo ) Needle-Free Injection Systems*

In addition to the Medi-Jector VISION<sup>®</sup>, Antares is also developing a reusable Medi-Jector device, the Medi-Jector MJ8 (Valeo ) with unique needle-free injection capabilities. The Medi-Jector Valeo accepts a conventional drug cartridge to create a completely self-contained, multi-dose, needle-free injection system. With these improvements, the Medi-Jector Valeo aspires to provide more user-friendly capabilities than its predecessors and, if marketed, the Company believes it would be the smallest reusable needle-free injector on the market.

#### Vibex Pre-filled, Disposable Mini-Needle Injector

Beyond reusable needle-free injector technologies, the Company has designed disposable, mini-needle devices to address acute medical needs, such as allergic reactions, migraine headaches, acute pain and other daily therapies, as well as for the delivery of vaccines. The Company's proprietary Vibex disposable, mini-needle product combines a low-energy, spring-based power source with a small, hidden needle, which delivers the needed drug solution subcutaneously or, in the case of vaccines, subdermally.



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In order to minimize the anxiety and perceived pain associated with injection-based technologies, the Vibex disposable mini-needle injector features a triggering collar that shields the needle from view. The patented retracting collar springs back and locks in place as a protective needle guard after the injection, making the device safe for general disposal. In clinical studies, this device has outperformed other delivery methods in terms of completeness of injection, while limiting pain and bleeding. A summary of the key benefits of the Vibex disposable mini-needle product is provided below.

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Benefits of Vibex Disposable Mini-Needle Injectors

- Rapid injection
- Eliminates sharps disposal
- Ease of use in emergencies
- Reduces psychological barriers since the patient never sees the needle
- Highly dependable subcutaneous injection
- Designed around conventional cartridges or pre-filled syringes

The primary goal of the Vibex disposable mini-needle injector is to provide a fast, safe, and time-efficient method of self-injection that addresses the patient's need for immediate relief. This device is designed around conventional cartridges or pre-filled syringes, which are primary drug containers, offering ease of transition for potential pharmaceutical partners.

Disposable Mini-Needle Vaccine Delivery Device

Antares disposable vaccine delivery device is at an earlier stage and is derived from its mini-needle injector technology (see above section). The disposable device is designed to deliver vaccines intradermally and to subdermal layers of the skin. Effective intradermal injection methods, using variants of conventional needles, depend extensively on the skill of the person administering the injection. Antares vaccine delivery technology simplifies the process for intradermal delivery, minimizing the dependence on skilled individuals administering the injection, and providing for a more comfortable means of vaccine delivery.

**Research and Development**

We currently have one pharmaceutical product candidate in our own clinical studies listed below. Additionally, pharmaceutical partners are developing compounds using our technology (see Collaborative Arrangements and License Agreements ).

**ANTUROL** . We are currently evaluating Anturool for the treatment of over active bladder (OAB). Anturool 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. It is believed that Anturool may offer equal or increased oxybutynin to the metabolite ratio, thus resulting in decreased reporting of adverse events when compared to patients taking comparable oral products. In addition, Anturool may also be more cosmetically appealing than patches and have less irritation and allergic reactions as well as comparable or decreased reporting of adverse events.

Background and Statistics

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OAB affects more than 20 million adults and is one of the fastest growing segments in the urology market. It is characterized by involuntary muscle contractions resulting in urine leakage. Symptoms include urinary frequency, urgency and urge incontinence. While OAB may occur at any age, it is most common among the elderly, affecting up to 61% of those over 65, particularly post-menopausal women. A recent SCRIIP Report showed the incontinence market growing at 40% per year.

Treatment currently consists of oral administration of compounds such as oxybutynin, tolteradine, darifenacin, solifenacin, and trospium each of which have significant side effects, including dry mouth (seen in 70% of patients), nausea, dry eyes, and constipation. It is estimated that half of the adults suffering from OAB either are too embarrassed to discuss their symptoms or are not aware that pharmacological treatment is available. It is estimated by Cowen & Co. in their March 2006 publication that just 16% of incontinence patients were compliant with their treatment in 2005 improving modestly to 18% in 2010.

### Summary of Clinical Data

In February 2006, the Company announced the results of its Phase II dose ranging study for its ATD oxybutynin based gel product called Anturool . The study was an open label, single period, randomized study using 48 healthy subjects and three different doses of Anturool over a 20 day period. Variables tested included accumulation of the dose, dose proportionality, decay of plasma levels, skin tolerability and other adverse events.

The overall conclusions of the study were positive. Dose proportionality occurred within the tested dosing range. A steady state was achieved after 3 applications (i.e., 3 days). Efficacy appeared comparable to oral products marketed. The incidences of dry mouth were minimal and similar to other transdermals while significantly improved over comparable oral medications. Additionally, skin tolerance (i.e. local skin irritation) was excellent.

A Phase III study has been preliminarily approved by the FDA and will include patients with urge and mixed urinary incontinence. The study will be a multi-center study over a 12 week period with Anturool applied once a day compared to a placebo.

### **Proprietary Rights**

When appropriate, the Company actively seeks protection for its products and proprietary information by means of U.S. and international patents and trademarks. The Company currently holds approximately 70 patents and has an additional 98 applications pending in the U.S. and other countries. Late in 2006 the Company 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. Our 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.

Some of the Company's technology is developed on its behalf by independent outside contractors. To protect the rights of its proprietary know-how and technology, Company policy requires all employees and consultants with access to proprietary information to execute confidentiality agreements prohibiting the disclosure of confidential information to anyone outside the Company. These agreements also require disclosure and assignment to the Company of discoveries and inventions made by such individuals while devoted to Company-sponsored activities. Companies with which Antares has entered into development agreements have the right to certain technology developed in connection with such agreements.

### **Manufacturing**

We do not have the resources, facilities or capabilities to commercially manufacture any of our product candidates. We have no current plans to establish a manufacturing facility. We expect that we will be dependent to a significant extent on contract manufacturers for commercial scale manufacturing of our product candidates in accordance with regulatory standards.

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Contract manufacturers may utilize their own technology, technology developed by us, or technology acquired or licensed from third parties. When contract manufacturers develop proprietary process technology and have ownership of the Drug Master File (DMF), our reliance on such contract manufacturers is increased, and we may have to obtain a license from such contract manufacturers to have our products manufactured by another party. Technology transfer from the original contract manufacturer may be required. Any such technology transfer may also require transfer of requisite data for regulatory purposes, including information contained in a proprietary DMF held by a contract manufacturer. FDA approval of the new manufacturer and manufacturing site would also be required.

We have not contracted with a commercial supplier of pharmaceutical chemicals, to supply us with active pharmaceutical ingredients of oxybutynin for Anturol in a manner that meets FDA requirements. We have contracted with Patheon, Inc. (Patheon), a manufacturing development company, to supply clinical quantities of Anturol gel in a manner that may meet FDA requirements. The FDA has not approved the manufacturing processes of Patheon at this time.

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The Company is responsible for U.S. device manufacturing in compliance with current Quality System Regulations ( QSR ) established by the Food and Drug Administration and by the centralized European regulatory authority (Medical Device Directive). Injector and disposable parts are manufactured by third-party suppliers and are assembled by a third-party supplier. Packaging is performed by a third-party supplier under the direction of the Company. Product release is performed by the Company.

The ATD Gel formulations for clinical studies have, in the past, been manufactured by contract under the Company's supervision. Early in 2005, Antares Pharma AG, our wholly owned subsidiary in Switzerland, received a GMP approval for the production and wholesaling of medicaments in small scale quantities.

### Marketing

The Company expects to currently market most of its products through other more substantial pharmaceutical and medical device companies while continuing direct-to-consumer marketing of its insulin injection devices and related disposable components in the U.S. In the future as the Company develops more products in niche therapeutic areas, it may decide to incorporate limited sales and marketing capabilities.

During 2006, 2005 and 2004, international revenue accounted for approximately 63%, 77% and 82% of total revenue, respectively. Europe accounted for 83%, 71% and 83% of international revenue in 2006, 2005 and 2004, respectively, with the remainder coming primarily from Asia. Ferring accounted for 39%, 48% and 47% of the Company's worldwide revenues in 2006, 2005 and 2004, respectively. BioSante Pharmaceuticals, Inc. accounted for 24%, 7% and 11% and JCR Pharmaceuticals, Co., Ltd. accounted for 4%, 12% and 6% of the Company's worldwide revenues in 2006, 2005 and 2004, respectively. Revenue from Ferring and JCR resulted from sales of injection devices and related disposable components for its hGH formulation. Revenue from BioSante resulted from license fees, development fees, milestone payments and clinical testing supplies for hormone replacement therapy transdermal gel formulations.

### Collaborative Arrangements and License Agreements

The following table describes significant existing pharmaceutical and device relationships, and license agreements.

<b>Partner</b>	<b>Compound/Product</b>	<b>Market Segment</b>	<b>Technology</b>
BioSante	Estradiol (Elestrin®)	Hormone replacement therapy  (North America, other countries)	ATD Gel
	Testosterone (Libi-Gel )	Female sexual dysfunction  (North America, other countries)	ATD Gel
Solvay	Estradiol/NETA	Hormone replacement therapy  (Worldwide)	ATD Gel
Undisclosed	Undisclosed	Central Nervous System	ATD Gel
	Development Agreement		

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Undisclosed	Undisclosed	Opioid dependence	ODT
Ferring	Development Agreement MJ-7 and undisclosed	Growth Hormone	Needle Free
Teva Pharmaceuticals, Ltd.	Undisclosed	(U.S. and Europe) Undisclosed	Device Needle Free
Eli Lilly and Company	MJ-7 and undisclosed	(United States) Diabetes and Obesity	Device Needle Free
JCR Pharmaceuticals Co., Ltd.	MJ-7	(Worldwide) Growth Hormone	Device Needle Free
SciGen Pte Ltd.	MJ-7	(Japan) Growth Hormone	Device Needle Free
Teva/Sicor	Undisclosed	(Asia/Pacific) Undisclosed	Device Undisclosed
Teva/Sicor	Undisclosed	(U.S. and Canada) Undisclosed	Disposable Device Undisclosed
		(United States)	Disposable Device

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This table summarizes agreements under which the Company's partners are selling products, conducting clinical evaluation, and performing development of the Company's products. For competitive reasons, the Company's partners may not divulge their name, the product name or the exact stage of clinical development.

In June 2000, the Company granted an exclusive license to BioSante to develop and commercialize three of the Company's gel technology products and one patch technology product for use in hormone replacement therapy in North America and other countries. Subsequently, the license for the patch technology product was returned to the Company in exchange for a fourth gel based product. BioSante paid the Company \$1 million upon execution of the agreement and is also required to pay the Company royalty payments once commercial sales of the products have begun. The royalty payments are based on a percentage of sales of the products and must be paid for a period of 10 years following the first commercial sale of the products, or when the last patent for the products expires, whichever is later. The agreement also provides for milestone payments to the Company upon the occurrence of certain events related to regulatory filings and approvals. In November 2006 BioSante entered into a sublicense and marketing agreement with Bradley Pharmaceuticals, Inc. for Elestrin® (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a payment to the Company of \$875,000. In December 2006 the FDA approved for marketing Elestrin® in the United States triggering payments to the Company totaling \$2.6 million, which will be received in 2007. In addition, the Company will receive royalties on sales of Elestrin® as well as potential sales-based milestone payments when marketed by Bradley.

In June 1999, the Company granted an exclusive license to Solvay for the Company's transdermal gel technology for delivery of an estradiol/progestin combination for hormone replacement therapy. The exclusive license applies to all countries and territories in the world, except for North America, Japan and Korea. The agreement contains a development plan under which the Company and Solvay collaborate to bring the product to market. Solvay must pay the Company a license fee of \$5 million in four separate payments, all of which are due upon completion of various phases of the development plan. To date, the Company has received \$1.75 million of this fee. Recently, development work performed by Solvay has been limited due to concerns about certain forms of hormone replacement therapy that have been debated in scientific literature. When and if commercial sale of the product begins, Solvay is required to, on a quarterly basis, pay the Company a royalty based on a percentage of sales. The royalty payments will be required for a period of 15 years or when the last patent for the product expires, whichever is later.

In August 2001, Solvay entered into an exclusive agreement with BioSante in which Solvay has sublicensed from BioSante the U.S. and Canadian rights to the Company's estrogen/progestin combination transdermal hormone replacement gel product, one of the drug-delivery products the Company previously licensed to BioSante. Under the terms of this license agreement between the Company and BioSante, the Company received a portion of the up front payment made by Solvay to BioSante. The Company is also entitled to a portion of any milestone payments or royalties BioSante receives from Solvay under the sublicense agreement.

In January 2003, the Company entered into a revised License Agreement with Ferring, under which the Company licensed certain of its intellectual property and extended the territories available to Ferring for use of certain of the Company's reusable needle-free injection devices to include all countries and territories in the world except Asia/Pacific. Specifically, the Company granted to Ferring an exclusive, royalty-bearing license, within a prescribed manufacturing territory, to utilize certain of the Company's reusable needle-free injector devices for the field of human growth hormone until the expiration of the last to expire of the patents in any country in the territory. The Company granted to Ferring similar non-exclusive rights outside of the prescribed manufacturing territory. In addition, the Company granted to Ferring a non-exclusive right to make and have made the equipment required to manufacture the licensed products, and an exclusive, royalty-free license in a prescribed territory to use and sell the licensed products under certain circumstances. The Company also granted to Ferring a right of first offer to obtain an exclusive worldwide license to manufacture and sell the Company's early version of a disposable mini-needle device in a specified field.

In September 2003, the Company entered into a Development and License Agreement (the "License Agreement") with Eli Lilly and Company. Under the License Agreement, the Company granted Lilly an exclusive license to certain of the Company's needle-free technology in the fields of diabetes and obesity.





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In 2004, JCR Pharmaceuticals Co., Ltd. initiated a campaign to broaden its marketing efforts for human growth hormone under a purchase agreement with our needle free injector, MJ-7. In 1999, SciGen Pte Ltd. began distribution in Asia of our needle free injector MJ-7 for human growth hormone.

In November 2005, the Company signed an agreement with Sicor Pharmaceuticals Inc., an affiliate of Teva Pharmaceutical Industries Ltd., under which Sicor is obligated to purchase all of its injection delivery device requirements from Antares for an undisclosed product to be marketed in the United States. Sicor also received an option for rights in other territories. The license agreement included, among other things, an upfront cash payment, milestone fees, a negotiated purchase price for each device sold, and royalties on sales of their product.

In July 2006, the Company entered into an exclusive License Development and Supply Agreement with Sicor Pharmaceuticals Inc., an affiliate of Teva Pharmaceutical Industries Ltd. Pursuant to the agreement, the affiliate is obligated to purchase all of its delivery device requirements from Antares for an undisclosed product to be marketed in the United States and Canada. Antares received an upfront cash payment, and will receive milestone fees, a negotiated purchase price for each device sold, as well as royalties on sales of their product.

In September 2006, the Company entered into a Supply Agreement with Teva Pharmaceutical Industries Ltd. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from Antares for an undisclosed product to be marketed in the United States. Antares received an upfront cash payment, and will receive milestone fees and a royalty payment on Teva's net sales, as well as a purchase price for each device sold.

Distribution/supply agreements are arrangements under which the Company's products are supplied to end-users through the distributor or supplier. The Company provides the distributor/supplier with injection devices and related disposable components, and the distributor/supplier often receives a margin on sales. The Company currently has a number of distribution/supply arrangements under which the distributors/suppliers sell the Company's injection devices and related disposable components for use with insulin.

### **Competition**

Competition in the pharmaceutical formulation sector is significant, mature and dominated by companies like ALZA Corporation, Elan Corporation plc, SkyePharma plc and Alkermes, Inc. Competition in the gel market includes companies like NexMed, Inc., Cellegy Pharmaceuticals, Inc., Bentley Pharmaceuticals, Inc., Novavax, Inc. and many others. Competition in the fast-melt market includes Eurand, Cardinal Health, Yamanouchi Pharmaceutical Co., Ltd. and many others. Competition in the disposable, single-use injector market includes, but is not limited to, OwenMumford Ltd., The Medical House and Pharma-Pen, Inc. (formerly Innoject, Inc.), while competition in the reusable needle-free injector market includes Bioject Medical Technologies Inc. and The Medical House.

Competition in the injectable drug delivery market is intensifying. The Company clearly faces competition from traditional needles and syringes as well as newer pen-like and sheathed needle syringes and other needle-free injection systems as well as alternative drug delivery methods including oral, transdermal and pulmonary delivery systems. Nevertheless, the majority of injections are still currently administered using needles. Because injections are typically only used when other drug delivery methods are not feasible, the needle-free injection systems may be made obsolete by the development or introduction of drugs or drug delivery methods which do not require injection for the treatment of conditions the Company has currently targeted. In addition, because the Company intends to, at least in part, enter into collaborative arrangements with pharmaceutical companies, the Company's competitive position will depend upon the competitive position of the pharmaceutical company with which it collaborates for each drug application.

### **Government Regulation**

We and our collaborative partners are subject to, and any potential products discovered, developed and manufactured by us or our collaborative partners must comply with, comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, and local entities regulate, among other things, the pre-clinical and clinical testing, safety, effectiveness, approval, manufacturing operations, quality, labeling, distribution, marketing, export, storage, record keeping, event reporting,

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advertising and promotion of pharmaceutical products and medical devices. Facilities and certain company records are also subject to inspections by the FDA and comparable authorities or their representatives. The FDA has broad discretion in enforcing the FD&C Act and the regulations thereunder, and noncompliance can result in a variety of regulatory steps ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal actions or penalties.

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. Many 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.

The process required by the FDA before a new drug (pharmaceutical product) or a new route of administration of a pharmaceutical product may be approved for marketing in the United States generally involves:

- § pre-clinical laboratory and animal tests;
- § submission to the FDA of an IND application, which must be in effect before clinical trials may begin;
- § adequate and well controlled human clinical trials to establish the safety and efficacy of the drug for its intended indication(s);
- § FDA compliance inspection and/or clearance of all manufacturers;
- § submission to the FDA of an NDA; and
- § FDA review of the NDA or product license application in order to determine, among other things, whether the drug is safe and effective for its intended uses.

Pre-clinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies, to assess the potential safety and efficacy of the product. Certain pre-clinical tests must comply with FDA regulations regarding current good laboratory practices. The results of the pre-clinical tests are submitted to the FDA as part of an IND, to support human clinical trials and are reviewed by the FDA, with patient safety as the primary objective, prior to the IND commencement of human clinical trials.

Clinical trials are conducted according to protocols that detail matters such as a description of the condition to be treated, the objectives of the study, a description of the patient population eligible for the study and the parameters to be used to monitor safety and efficacy. Each protocol must be submitted to the FDA as part of the IND. Protocols must be conducted in accordance with FDA regulations concerning good clinical practices to ensure the quality and integrity of clinical trial results and data. Failure to adhere to good clinical practices and the protocols may result in FDA rejection of clinical trial results and data, and may delay or prevent the FDA from approving the drug for commercial use.

Clinical trials are typically conducted in three sequential Phases, which may overlap. During Phase I, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, distribution, metabolism and excretion. Phase I studies are often conducted with healthy volunteers depending on the drug being tested; however, in oncology, Phase I trials are more often conducted in cancer patients. Phase II involves studies in a limited patient population, typically patients with the conditions needing treatment, to:

- § evaluate preliminarily the efficacy of the product for specific, targeted indications;
- § determine dosage tolerance and optimal dosage; and

§ identify possible adverse effects and safety risks.

Pivotal or Phase III adequate and well-controlled trials are undertaken in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for the purpose of registering the new drug. The

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FDA may suspend or terminate clinical trials at any point in this process if it concludes that patients are being exposed to an unacceptable health risk or if they decide it is unethical to continue the study. Results of pre-clinical and clinical trials must be summarized in comprehensive reports for the FDA. In addition, the results of Phase III studies are often subject to rigorous statistical analyses. This data may be presented in accordance with the guidelines for the International Committee of Harmonization that can facilitate registration in the United States, the EU and Japan.

FDA approval of our own and our collaborators' products is required before the products may be commercialized in the United States. FDA approval of an NDA will be based, among other factors, on the comprehensive reporting of clinical data, risk/benefit analysis, animal studies and manufacturing processes and facilities. The process of obtaining NDA approvals from the FDA can be costly and time consuming and may be affected by unanticipated delays.

Among the conditions for NDA approval is the requirement that the prospective manufacturer's procedures conform to current good manufacturing practices, which must be followed at all times. In complying with this requirement, manufacturers, including a drug sponsor's third-party contract manufacturer, must continue to expend time, money and effort in the area of production, quality assurance and quality control to ensure compliance. Domestic manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, compliance with current good manufacturing practices. To supply products for use in the United States, foreign manufacturing establishments also must comply with current good manufacturing practices and are subject to periodic inspection by the FDA or by regulatory authorities in certain countries under reciprocal agreements with the FDA.

A sNDA is a submission to an existing NDA that provides for changes to the NDA and therefore requires FDA approval. Changes to the NDA that require FDA approval are the subject of either the active ingredients, the drug product and/or the labeling. A supplement is required to fully describe the change. There are two types of sNDAs depending on the content and extent of the change. These two types are (i) supplements requiring FDA approval before the change is made and (ii) supplements for changes that may be made before FDA approval. Supplements to the labeling that change the Indication Section require prior FDA approval before the change can be made to the labeling, e.g. a new indication.

Both before and after market approval is obtained, a product, its manufacturer and the holder of the NDA for the product are subject to comprehensive regulatory oversight. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal of an approved product from the market and the imposition of criminal penalties against the manufacturer and NDA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

FDA approval is required before a generic equivalent can be marketed. We seek approval for such products by submitting an ANDA to the FDA. When processing an ANDA, the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. Bioequivalence compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of the active drug substance in the body are equivalent for the generic drug and the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

Before approving a product, the FDA also requires that our procedures and operations or those of our contracted manufacturer conform to Current Good Manufacturing Practice (cGMP) regulations, relating to good manufacturing practices as defined in the U.S. Code of Federal Regulations. We and our contracted manufacturer must follow the cGMP regulations at all times during the manufacture of our products. We will continue to spend significant time, money and effort in the areas of production and quality testing to help ensure full compliance with cGMP regulations and continued marketing of our products now or in the future.



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If the FDA believes a company is not in compliance with cGMP, sanctions may be imposed upon that company including:

- § withholding from the company new drug approvals as well as approvals for supplemental changes to existing applications;
- § preventing the company from receiving the necessary export licenses to export its products; and
- § classifying the company as an unacceptable supplier and thereby disqualifying the company from selling products to federal agencies.

The timing of final FDA approval of an ANDA depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods, during which the FDA may be prohibited from accepting applications for, or approving, generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, in certain circumstances the FDA may extend the exclusivity of a product by six months past the date of patent expiry if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension. The pediatric extension results from a 1997 law designed to reward branded pharmaceutical companies for conducting research on the effects of pharmaceutical products in the pediatric population. As a result, under certain circumstances, a branded company can obtain an additional six months of market exclusivity by performing pediatric research.

In May 1992, Congress enacted the Generic Drug Enforcement Act of 1992, which allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Drug Enforcement Act requires the FDA to not accept or review ANDAs for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Generic Drug Enforcement Act allows for civil penalties and withdrawal of previously approved applications. Neither we nor any of our employees have ever been subject to debarment.

Drug delivery systems such as injectors may be legally marketed as a medical device or may be evaluated as part of the drug approval process in connection with an NDA or a Product License Application ( PLA ). Combination drug/device products raise unique scientific, technical and regulatory issues. The FDA has established an Office of Combination Products to address the challenges associated with the premarket review and regulation of combination products. New drug/delivery combinations may require designation from the Office of Combination Products to determine assignment to the appropriate regulatory center. To the extent permitted under the FD&C Act and current FDA policy, the Company intends to seek the required approvals and clearance for the use of its new injectors, as modified for use in specific drug applications under the medical device provisions, rather than under the new drug provisions, of the FD&C Act.

Products regulated as medical devices can be commercially distributed in the United States if they have been found substantially equivalent to a marketed product or approved by the FDA, or have been exempted from the FD&C Act and regulations thereunder. Under Section 510(k) of the FD&C Act ( 510(k) notification ), certain products qualify for a pre-market notification ( PMN ) of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish in the PMN that the product to be marketed is substantially equivalent to another legally marketed product (that is, that it has the same intended use and that it is as safe and effective as a legally marketed device and does not raise questions of safety and effectiveness that are different from those associated with the legally marketed device). Marketing may commence when the FDA issues a letter finding substantial equivalence to such a legally marketed device. The FDA may require, in connection with a PMN, that it be provided with animal and/or human test results. If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a pre-market approval ( PMA ) application under Section 515 of the FD&C Act. A PMA must show that the device is safe and effective and is generally a much more complex submission than a 510(k) notification, typically requiring more extensive pre-filing testing and a longer FDA review process.

In addition to submission when a device is being introduced into the market for the first time, a PMN is also required when the manufacturer makes a change or modification to a previously marketed device that could





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significantly affect safety or effectiveness, or where there is a major change or modification in the intended use or in the manufacture of the device. When any change or modification is made in a device or its intended use, the manufacturer is expected to make the initial determination as to whether the change or modification is of a kind that would necessitate the filing of a new 510(k) notification. The *Medi-Jector VISION*<sup>®</sup> injection system is a legally marketed device under Section 510(k) of the FD&C Act. In the future the Company or its partners may submit 510(k) notifications with regard to further device design improvements and uses with additional drug therapies.

If the FDA concludes that any or all of the Company's new injectors must be handled under the new drug provisions of the FD&C Act, substantially greater regulatory requirements and approval times will be imposed. Use of a modified new product with a previously unapproved new drug likely will be handled as part of the NDA for the new drug itself. Under these circumstances, the device component will be handled as a drug accessory and will be approved, if ever, only when the NDA itself is approved. The Company's injectors may be required to be approved as a combination drug/device product under a supplemental NDA for use with previously approved drugs. Under these circumstances, the Company's device could be used with the drug only if and when the supplemental NDA is approved for this purpose. It is possible that, for some or even all drugs, the FDA may take the position that a drug-specific approval must be obtained through a full NDA or supplemental NDA before the device may be packaged and sold in combination with a particular drug.

To the extent that the Company's modified injectors are packaged with the drug, as part of a drug delivery system, the entire package may be subject to the requirements for drug/device combination products. These include drug manufacturing requirements, drug adverse reaction reporting requirements, and all of the restrictions that apply to drug labeling and advertising. In general, the drug requirements under the FD&C Act are more onerous than medical device requirements. These requirements could have a substantial adverse impact on the Company's ability to commercialize its products and its operations.

The FD&C Act also regulates quality control and manufacturing procedures by requiring the Company and its contract manufacturers to demonstrate compliance with the current Quality System Regulations (QSR). The FDA's interpretation and enforcement of these requirements have been increasingly strict in recent years and seem likely to be even more stringent in the future. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA and by conducting periodic FDA inspections of manufacturing facilities. If the inspector observes conditions that might violate the QSR, the manufacturer must correct those conditions or explain them satisfactorily. Failure to adhere to QSR requirements would cause the devices produced to be considered in violation of the FDA Act and subject to FDA enforcement action that might include physical removal of the devices from the marketplace.

The FDA's Medical Device Reporting Regulation requires companies to provide information to the FDA on the occurrence of any death or serious injuries alleged to have been associated with the use of their products, as well as any product malfunction that would likely cause or contribute to a death or serious injury if the malfunction were to recur. In addition, FDA regulations prohibit a device from being marketed for unapproved or uncleared indications. If the FDA believes that a company is not in compliance with these regulations, it could institute proceedings to detain or seize company products, issue a recall, seek injunctive relief or assess civil and criminal penalties against the company or its executive officers, directors or employees.

In addition to regulations enforced by the FDA, we must also comply with regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations.

In addition to regulations in the United States, we are subject to various foreign regulations governing clinical trials and the commercial sales and distribution of our products. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement and the regulatory approval process all vary greatly from country to country. Additionally, the time it takes to complete the approval process in foreign countries may be longer or shorter than that required for FDA approval. Foreign regulatory

approvals of our products are necessary whether or not we obtain FDA approval for such products. Finally, before a new drug may be exported from the United States, it must either be approved for

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marketing in the United States or meet the requirements of exportation of an unapproved drug under Section 802 of the Export Reform and Enhancement Act or comply with FDA regulations pertaining to INDs.

Under European Union regulatory systems, we are permitted to submit marketing authorizations under either a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all member states of the European Union. The decentralized procedure provides for mutual recognition of national approval decisions by permitting the holder of a national marketing authorization to submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

Sales of medical devices outside of the U.S. are subject to foreign legal and regulatory requirements. Certain of the Company's transdermal and injection systems have been approved for sale only in certain foreign jurisdictions. Legal restrictions on the sale of imported medical devices and products vary from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. Antares relies upon the companies marketing its injectors in foreign countries to obtain the necessary regulatory approvals for sales of the Company's products in those countries. Generally, products having an effective 510(k) clearance or PMA may be exported without further FDA authorization.

The Company has obtained ISO 13485: 2003 certification, the medical device industry standard for its quality systems. This certification shows that the Company's development and manufacturing comply with standards for quality assurance, design capability and manufacturing process control. Such certification, along with compliance with the European Medical Device Directive enables the Company to affix the CE Mark to current products and supply the device with a Declaration of Conformity. Semi-annual audits by the Company's notified body, British Standards Institute, are required to demonstrate continued compliance.

The Company has also received GMP approval from the Swiss Medical Institute for the production and wholesaling of medicaments, specifically related to its Advanced Transdermal Delivery (ATD) gels. This allows the Company to produce clinical trial materials and related packaging as well as production of intermediate products and end-user medicaments.

### **Employees**

We believe that our success is largely dependent upon our ability to attract and retain qualified personnel in the research, development, manufacturing, business development and commercialization fields. As of March 15, 2007, we had 27 full-time and 3 part-time employees worldwide, of whom 15 are in the United States. Of the 30 employees, 16 are primarily involved in research, development and manufacturing activities, 2 are primarily involved in business development and commercialization, with the remainder engaged in executive and administrative capacities. Although we believe that we are appropriately sized to focus on our mission, we intend to add personnel with specialized expertise, as needed.

We believe that we have been successful to date in attracting skilled and experienced scientific and business professionals. We consider our employee relations to be good, and none of our employees are represented by any labor union or other collective bargaining unit. However, competition for personnel is intense and we cannot assure that we will continue to be able to attract and retain personnel of high caliber.



*Item 1A. RISK FACTORS*

*The following risk factors contain important information about us and our business and should be read in their entirety. Additional risks and uncertainties not known to us or that we now believe to be not material could also impair our business. If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline and you could lose all of your investment. In this Section, the terms we and our refer to Antares Pharma, Inc.*

**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;
- § our ability to increase and continue to outsource manufacturing capacity to allow for new product introductions;

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- § 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

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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.

*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.*

We do not possess the capabilities, resources or facilities to manufacture Anturool, which is currently in development for over active bladder, or any other of our future drug candidates. We must contract with manufacturers to produce Anturool 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.



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We have not contracted with a commercial supplier of active pharmaceutical ingredients of oxybutynin for Anturol 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 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 .

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*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
- 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 progesterin because the study showed an increased risk of breast cancer, heart disease and

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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

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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 Anturool, 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 Anturool 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 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

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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

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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.

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*

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,



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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.

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. 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 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 Anturool is approved, we may be delayed in our marketing and the potential market value of Anturool 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

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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.

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 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.*

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The Company's business entails the risk of product liability claims. Although the Company has not experienced any material product liability claims to date, any such claims could have a material adverse impact on its business. The Company maintains product liability insurance with coverage of \$5 million per occurrence and an annual aggregate maximum of \$5 million. The Company evaluates its 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*

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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.

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 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.*

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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

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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;
- fines;
- 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 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

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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 March 15, 2007, approximately 18%) 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, five investors (Crestview Capital Master Fund, North Sound Funds, Perceptive Life Sciences Fund, SCO Capital Group and SDS Funds) own warrants that are, as of March 15, 2007, exercisable into an aggregate of 5,977,733 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 21%, and the five investors as a group would own, at a minimum, over 9% 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*

As of March 15, 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 21,400,000 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 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 March 15, 2007, our officers and directors beneficially owned an aggregate of approximately 15,500,000 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

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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.

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*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.

*Item 1B. UNRESOLVED STAFF COMMENTS*

None.

*Item 2. DESCRIPTION OF PROPERTY*

The Company leases approximately 7,000 square feet of office space in Ewing, New Jersey for its corporate headquarters facility. The lease will terminate in January 2012. The Company believes the facility will be sufficient to meet its requirements through the lease period at this location.

The Company leases approximately 9,300 square feet of office and laboratory space in Plymouth, a suburb of Minneapolis, Minnesota, and subleases approximately half of this space to another company. The lease will terminate in April 2011. The Company believes the facilities will be sufficient to meet its requirements through the lease period at this location.

The Company also leases approximately 650 square meters of facilities in Basel, Switzerland, for office space and formulation and analytical laboratories. The lease will terminate in September 2008. The Company believes the facilities will be sufficient to meet its requirements through the lease period at this location.

*Item 3. LEGAL PROCEEDINGS*

None.

*Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS*

None.



**PART II***Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.*

The Company's Common Stock trades on the American Stock Exchange under the symbol AIS. The following table sets forth the per share high and low closing sales prices of the Company's Common Stock, as reported by the American Stock Exchange, for each quarterly period during the two most recent fiscal years.

	<b>High</b>	<b>Low</b>
<b>2006:</b>		
First Quarter	\$ 1.89	\$ 1.10
Second Quarter	\$ 1.75	\$ 1.09
Third Quarter	\$ 1.35	\$ 0.86
Fourth Quarter	\$ 1.38	\$ 1.00
<b>2005:</b>		
First Quarter	\$ 1.46	\$ 0.88
Second Quarter	\$ 1.15	\$ 0.70
Third Quarter	\$ 1.22	\$ 0.78
Fourth Quarter	\$ 1.61	\$ 0.86

**Common Shareholders**

As of March 15, 2007, the Company had 136 shareholders of record of its common stock.

**Dividends**

The Company has not paid or declared any cash dividends on its common stock during the past nine years. The Company has no intention of paying cash dividends in the foreseeable future on common stock. The Company paid semi-annual dividends on Series A Convertible Preferred Stock ( Series A ) at an annual rate of 10%, payable on May 10 and November 10 each year. In June 2005, all of the Series A was converted into common stock. In addition to the stated 10% dividend, the Company had been obligated to pay income tax withholding on the dividend payment, which equates to an effective dividend rate of 14.2%. Such tax withholding payments have been reflected as dividends, to the extent they were non-recoverable. The Series A agreement had a provision that allowed the Company to pay the dividend by issuance of the same stock when funds were not available. The Company exercised this provision for ten of the last twelve dividend payments.

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Item 6. SELECTED FINANCIAL DATA

The following table summarizes certain selected financial data. The selected financial data is derived from, and is qualified by reference to, our financial statements accompanying this report (amounts expressed in thousands, except per share amounts).

	At December 31,				
	2006	2005	2004	2003	2002
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 2,706	\$ 2,718	\$ 1,652	\$ 1,929	\$ 268
Short-term investments	4,953	-	7,972	-	-
Working capital (deficit)	5,979	965	8,489	615	(2,972 )
Total assets	11,534	6,166	13,178	5,955	6,409
Long-term liabilities, less current maturities	3,556	3,062	3,339	3,558	1,247
Accumulated deficit	(99,322 )	(91,123 )	(82,575 )	(74,127 )	(41,166 )
Total stockholders' equity	5,080	757	8,189	307	655

	Year Ended December 31,				
	2006	2005	2004	2003	2002
<b>Statement of Operations Data:</b>					
Product sales	\$ 2,195	\$ 1,512	\$ 1,834	\$ 2,647	\$ 2,422
Development revenue	594	184	197	310	935
Licensing fees	1,254	374	635	695	639
Royalties	225	155	80	135	-
Revenues	4,268	2,225	2,746	3,787	3,996
Cost of revenues	1,556	1,137	1,372	2,008	2,574
Research and development (3)	3,778	3,677	2,870	2,389	3,331
Sales, marketing and business development	1,350	1,161	676	462	798
General and administrative (3) (4)	5,861	4,839	6,203	7,562	5,555
Goodwill impairment charge	-	-	-	-	2,000
Operating expenses	10,989	9,677	9,749	10,413	11,684
Operating loss	(8,277 )	(8,589 )	(8,375 )	(8,634 )	(10,262 )
Net other income (expense)	177	91	26	(24,184 )	(1,347 )
Net loss	(8,100 )	(8,498 )	(8,349 )	(32,818 )	(11,609 )
Deemed dividend to warrant holder	(99 )	-	-	-	-
Preferred stock dividends	-	(50 )	(100 )	(143 )	(100 )
Net loss applicable to common shares	\$ (8,199 )	\$ (8,548 )	\$ (8,449 )	\$ (32,961 )	\$ (11,709 )
Net loss per common share (1) (2)	\$ (0.16 )	\$ (0.21 )	\$ (0.23 )	\$ (2.18 )	\$ (1.22 )
Weighted average number of common shares	51,582	41,460	36,348	15,093	9,618

(1) Basic and diluted loss per share amounts are identical as the effect of potential common shares is anti-dilutive.

(2) The Company has not paid any dividends on its Common Stock since inception.

(3) In 2006 the Company reclassified expenses for quality and regulatory activities previously reported as general and administrative expenses to research and development expenses. The amounts of the reclassifications were \$268, \$234, \$280 and \$413 in 2005, 2004, 2003 and 2002, respectively.

(4) In 2006, 2004, 2003 and 2002 the Company recorded non-cash patent impairment charges of \$139, \$233, \$974 and \$435, respectively.





Item 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

*You should read the following discussion in conjunction with Item 1A. ( Risk Factors ) and our audited financial statements included elsewhere in this report. Some of the statements in the following discussion are forward-looking statements. See Special Note Regarding Forward-Looking Statements.*

**Overview**

The Company develops, produces and markets pharmaceutical delivery products, including transdermal gels, oral fast melting tablets and reusable needle-free and disposable mini-needle injector systems. In addition, the Company has several products and compound formulations under development. The Company has operating facilities in the U.S. and Switzerland. The U.S. operation develops reusable needle-free and disposable mini-needle injector systems and manufactures and markets reusable needle-free injection devices and related disposables. These operations, including all manufacturing and some U.S. administrative activities, are located in Minneapolis, Minnesota. The Company also has operations located in Basel, Switzerland, which consist of administration and facilities for the development of transdermal gels and oral fast melt tablet products. The Swiss operations focus principally on research, development and commercialization of pharmaceutical products and include a number of license agreements with pharmaceutical companies for the application of its drug delivery systems. The Company's corporate offices are located in Ewing, New Jersey.

The Company operates as a specialty pharmaceutical company in the broader pharmaceutical industry. Companies in this sector generally bring technology and know-how in the area of drug formulation and/or delivery to pharmaceutical product marketers through licensing and development agreements while actively pursuing development of its own products. The Company currently views pharmaceutical and biotechnology companies as primary customers. The Company has negotiated and executed licensing relationships in the growth hormone segment (reusable needle-free devices in Europe and Asia) and the transdermal gels segment (several development programs in place worldwide, including the United States and Europe). In addition, the Company continues to market reusable needle-free devices for the home or alternate site administration of insulin in the U.S. market through distributors, has granted a development license to its reusable needle-free technology in the diabetes and obesity fields to Eli Lilly and Company on a worldwide basis, and has licensed both disposable and reusable injection devices to Teva Pharmaceuticals for use in undisclosed fields and territories.

The Company is reporting a net loss of \$8,099,846 for the year ended December 31, 2006 and expects to report a net loss for the year ending December 31, 2007, as marketing and development costs related to bringing future generations of products to market continue. Long-term capital requirements will depend on numerous factors, including the status of collaborative arrangements and payments received under such arrangements, the progress of research and development programs, the receipt of revenues from sales of products and royalties and the ability to control costs.

## Critical Accounting Policies and Use of Estimates

In preparing the financial statements in conformity with U.S. generally accepted accounting principles (GAAP), management must make decisions that impact reported amounts and related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, management applies judgment based on its understanding and analysis of relevant circumstances. Note 2 to the consolidated financial statements provides a summary of the significant accounting policies followed in the preparation of the consolidated financial statements. The following accounting policies are considered by management to be the most critical to the presentation of the consolidated financial statements because they require the most difficult, subjective and complex judgments.

### *Revenue Recognition*

The majority of the Company's revenue relates to product sales for which revenue is recognized upon shipment, with limited judgment required related to product returns. Product sales are shipped FOB shipping point. The Company also enters into license arrangements that are often complex as they may involve a license, development and manufacturing components. Licensing revenue recognition requires significant management judgment to evaluate the effective terms of agreements, the Company's performance commitments and determination of fair value of the various deliverables under the arrangement. In December 2002, the Emerging Issues Task Force (EITF) issued EITF 00-21, *Revenue Arrangements with Multiple Deliverables*, which addresses certain aspects of revenue recognition for arrangements that include multiple revenue-generating activities. EITF 00-21 addresses when and, if so, how an arrangement involving multiple deliverables should be divided into separate units of accounting. In some arrangements, the different revenue-generating activities (deliverables) are sufficiently separable, and there exists sufficient evidence of their fair values to separately account for some or all of the deliverables (that is, there are separate units of accounting). In other arrangements, some or all of the deliverables are not independently functional, or there is not sufficient evidence of their fair values to account for them separately. The Company's ability to establish objective evidence of fair value for the deliverable portions of the contracts may significantly impact the time period over which revenues will be recognized. For instance, if there is no objective fair value of undelivered elements of a contract, then the Company may be required to treat a multi-deliverable contract as one unit of accounting, resulting in all revenue being deferred and recognized over the entire contract period. EITF 00-21 does not change otherwise applicable revenue recognition criteria. In arrangements where the deliverables cannot be separated, revenue related to up-front, time-based and performance-based payments is being recognized over the entire contract performance period. For major licensing contracts, this results in the deferral of significant revenue amounts (\$4,569,938 at December 31, 2006) where non-refundable cash payments have been received, but the revenue is not immediately recognized due to the long-term nature of the respective agreements. Subsequent factors affecting the initial estimate of the effective terms of agreements could either increase or decrease the period over which the deferred revenue is recognized.

In connection with a license agreement entered into with Eli Lilly and Company in 2003, the Company issued to Lilly a ten-year warrant to purchase 1,000,000 shares of the Company's common stock at an exercise price of \$3.776 per share. At the time of issue, the Company determined that the fair value of the warrant was \$2,943,739 using the Black Scholes option pricing model. EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*, requires that the value of the warrants be treated as a reduction in revenue. The fair value of the warrant was recorded to additional paid-in capital and to prepaid license discount, a contra equity account. The prepaid license discount will be reduced on a straight-line basis over the term of the agreement, offsetting revenue generated under the agreement. If during its periodic impairment assessment the Company concludes that the revenues from this arrangement will not exceed the costs, including prepaid license discount, part or all of the remaining prepaid license discount would be charged to operations at that time.

Due to the requirement to defer significant amounts of revenue and the extended period over which the revenue will be recognized, along with the requirement to amortize the prepaid license discount and certain deferred development costs over an extended period of time, revenue recognized and cost of sales may be materially different from cash flows.

On an overall basis, the Company's reported revenues can differ significantly from billings and/or accrued billings based on terms in agreements with customers. The table below is presented to help explain the impact of the



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deferral of revenue and amortization of prepaid license discount on reported revenues, and is not meant to be a substitute for accounting or presentation requirements under U.S. generally accepted accounting principles.

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Product sales	\$ 2,195,218	\$ 1,511,929	\$ 1,834,431
Development fees	785,720	214,210	445,625
Licensing fees and milestone payments	2,082,742	275,524	84,449
Royalties	140,110	105,276	-
Billings received and/or accrued per contract terms	5,203,790	2,106,939	2,364,505
Deferred billings received and/or accrued	(1,409,268 )	(360,949 )	(259,537 )
Deferred revenue recognized	670,126	675,005	837,238
Amortization of prepaid license discount	(196,249 )	(196,249 )	(196,250 )
Total revenue as reported	\$ 4,268,399	\$ 2,224,746	\$ 2,745,956

### *Valuation of Long-Lived and Intangible Assets and Goodwill*

Long-lived assets, including patent rights, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. This analysis can be very subjective as the Company relies upon signed distribution or license agreements with variable cash flows to substantiate the recoverability of long-lived assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

In the fourth quarter of each year the Company updated its long-range business plan. The Company then reviewed patent costs for impairment and identified patents related to products for which there were no signed distribution or license agreements or for which no revenues or cash flows were included in the business plan. In 2006 and 2004 the Company recognized impairment charges of \$138,632 and \$233,062, respectively, in general and administrative expenses, which represented the gross carrying amount, net of accumulated amortization, for the identified patents. After the impairment charge, the gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, were \$1,526,714 and \$713,122, respectively, at December 31, 2006. The Company's estimated aggregate patent amortization expense for the next five years is \$95,000 in 2007, \$90,000 in each of 2008, 2009 and 2010, and \$42,000 in 2011.

The Company evaluates the carrying value of goodwill during the fourth quarter of each year and between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying amount. Such circumstances could include, but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, (3) an adverse action or assessment by a regulator, or (4) a sustained significant drop in the Company's stock price. When evaluating whether goodwill is impaired, the Company compares the fair value of the Minnesota operations to the carrying amount, including goodwill. If the carrying amount of the Minnesota operations exceeds its fair value, then the amount of the impairment loss must be measured. The impairment loss would be calculated by comparing the implied fair value of goodwill to its carrying amount. In calculating the implied fair value of goodwill, the fair value of the Minnesota operations would be allocated to all of its other assets and liabilities based on their fair values. The excess of the fair value of the Minnesota operations over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. An impairment loss would be recognized when the carrying amount of goodwill exceeds its implied fair value. The Company's evaluation of goodwill completed during 2006, 2005 and 2004 resulted in no impairment losses.



## Results of Operations

*Years Ended December 31, 2006, 2005 and 2004*

### *Revenues*

Total revenue was \$4,268,399, \$2,224,746 and \$2,745,956 for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 was spread among all revenue categories, but was primarily due to increases in licensing revenue and product sales. The licensing revenue increase was mainly due to \$875,000 received under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc. The increase in product sales was mainly due to an increase in sales to the Company's major customer, Ferring. The decrease in 2005 resulted primarily from reductions in product sales to Ferring and reductions in licensing revenue, which was mainly due to the extension of revenue recognition periods of certain development and license agreements, resulting in the recognition of remaining deferred revenue over longer periods.

Product sales include sales of reusable needle-free injector devices, related parts, disposable components, and repairs. In 2006, 2005 and 2004, revenue from sales of needle-free injector devices totaled \$804,481, \$549,070 and \$621,518, respectively. Sales of disposable components in 2006, 2005 and 2004 totaled \$1,326,758, \$896,764 and \$1,143,071, respectively. The increase in device and disposable revenue in 2006 compared to 2005 was due mainly to an increase in sales to Ferring. This increase followed two years of decreasing sales that occurred while Ferring was working down high inventory levels they had accumulated in prior years.

Development revenue was \$593,797, \$183,760 and \$196,648 for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 was attributable to projects related to injector systems and transdermal gel technologies, but resulted primarily from one agreement related to use of the Company's proprietary ATD gel technology. In 2006 the Company also generated development fees of approximately \$217,000 in connection with an agreement related to its oral fast melting tablet technology, all of which was deferred and is expected to be recognized as revenue in 2007. In 2005 approximately half of the development revenue was generated from projects related to injector devices, with most of this coming from one-time projects. The remainder of the recognized development revenue in 2005 and substantially all of the recognized development revenue in 2004 was generated under licensing and development agreements related to use of the Company's transdermal gel technology. The Company also generated development fees of approximately \$260,000 in 2004 under a device development agreement, substantially all of which was deferred and is being recognized over the life of the associated agreement.

Licensing revenue was \$1,254,250, \$374,021 and \$634,542 for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 compared to 2005 was primarily due to \$875,000 received under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc. In November 2006 BioSante entered into a marketing agreement with Bradley Pharmaceuticals, Inc. for Elestrin® (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a payment to the Company of \$875,000. In December 2006 the FDA approved for marketing Elestrin® in the United States triggering payments to the Company totaling \$2.6 million, which will be received in 2007. In addition, the Company will receive royalties on sales of Elestrin® as well as potential sales-based milestone payments when marketed by Bradley. The decrease in 2005 compared to 2004 was primarily the result of a decrease in deferred revenue recognized due to an increase in the revenue recognition periods of two projects following an extension of the estimated project end dates.

Royalty revenue was \$225,134, \$155,036 and \$80,335 for the years ended December 31, 2006, 2005 and 2004, respectively. Royalty revenue has all been related to the Vision® reusable needle-free injection device, and has been generated primarily under the License Agreement with Ferring dated January 22, 2003, described in more detail in Note 9 to the Consolidated Financial Statements. Royalties from Ferring are earned on device sales and in 2006 and 2005 additional royalties were earned under a provision in the Ferring agreement triggered by the achievement of certain quality standards. The increase in 2006 was due to increases both in royalties earned from device sales and in the royalty earned under the quality standards provision. Even though device sales decreased in 2005 compared to 2004, the royalty revenue from Ferring increased,

which was mainly due to royalties earned under the quality standards provision. Royalties under the quality standards provision were not earned in 2004.

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### *Cost of Revenues*

The costs of product sales are primarily related to reusable injection devices and disposable components. Cost of sales as a percentage of product sales were 59%, 69% and 71% for the years ended December 31, 2006, 2005 and 2004, respectively. The decrease in 2006 was due to a combination of factors including a change in the mix of products sold and a higher sales volume absorbing a slightly decreased level of fixed overhead costs.

The cost of development revenue consists of labor costs, direct external costs and an allocation of certain overhead expenses based on actual costs and time spent in these revenue-generating activities. Cost of development revenue as a percentage of development revenue can fluctuate considerably between periods depending on the development projects in process. In some cases development projects are substantially labor based, resulting in relatively high margins, while in other cases development projects include a significant amount of external cost passed through to the customer at little or no markup, resulting in lower margins. Cost of development revenue as a percentage of development revenue was 44%, 51% and 34% for the years ended December 31, 2006, 2005 and 2004, respectively. The 2005 percentage was slightly higher than 2006 and 2004 due mainly to projects having more direct external costs that were billed to customers with little or no markup.

### *Research and Development*

Research and development expenses were \$3,778,469, \$3,677,015 and \$2,869,317 for the years ended December 31, 2006, 2005 and 2004, respectively. The overall increase in 2006 compared to 2005 was primarily due to an increase in stock based compensation expense of approximately \$128,000. The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development. The portion of expenses related to device development projects increased slightly in 2006 compared to 2005, but over 75% of the total research and development expenses in each year were generated in connection with development projects related to transdermal gels and oral fast melt tablet products. The increase in 2005 from 2004 was primarily due to development projects related to transdermal gels, including Phase II studies of Anturool, and oral fast melt tablet products and consisted mainly of increases in external costs for studies and analysis work around platform validation and proof-of-concept work.

### *Sales, Marketing and Business Development*

Sales, marketing and business development expenses were \$1,349,678, \$1,160,752 and \$675,878 for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 compared to 2005 was due mainly to an increase in professional services in connection with business development projects related to transdermal gels and oral fast melt tablets, along with an increase in stock based compensation expense of approximately \$80,000. The increase in 2005 compared to 2004 was due to increases in clinical studies related to injector devices and increases in business development activities which most directly impacted payroll, travel and professional services. The increases in payroll and travel expenses resulted primarily from the addition of a vice-president of corporate business development in February of 2005. The professional services increase was mainly due to the utilization of consultants for various sales and marketing and business development projects.

### *General and Administrative*

General and administrative expenses were \$5,861,111, \$4,839,408 and \$6,203,125 for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 compared to 2005 was due primarily to an increase in stock based compensation expense of approximately \$826,000, along with an increase in patent impairment charges of \$138,632. The decrease in 2005 compared to 2004 was due primarily to decreases in legal expenses of \$188,231 and professional services and investor relations expenses of \$872,662, along with a decrease in patent impairment charges from \$233,062 in 2004 to none in 2005. The patent impairment charges were recognized in connection with certain patents



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related to products for which there were no signed distribution or license agreements or for which no revenue or cash flows were projected in the Company's long-term business plan. The impairment charges represented the gross carrying amount net of accumulated amortization for the identified patents.

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*Other Income (Expense)*

Other income (expense), net, was \$176,983, \$91,218 and \$26,134 for the years ended December 31, 2006, 2005 and 2004, respectively. The increase in 2006 compared to 2005 was primarily due to an increase in interest income resulting from investment of the proceeds from the private placement of common stock in the first quarter of 2006, partially offset by an increase in foreign exchange losses related mainly to the impact of exchange rate fluctuations on liabilities due in foreign currencies. The increase in 2005 was primarily due to a reduction in interest expense in 2005 as compared to 2004.

**Liquidity and Capital Resources**

The Company has not historically generated, and does not currently generate, enough revenue to provide the cash needed to support its operations, and has continued to operate primarily by raising capital and incurring debt. In order to better position the Company to take advantage of potential growth opportunities and to fund future operations, the Company raised additional capital in the first quarter of 2006. The Company received net proceeds of \$9,782,055 in a private placement of its common stock in which a total of 8,770,000 shares of common stock were sold at a price of \$1.25 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 7,454,500 shares of common stock with an exercise price of \$1.50 per share. In 2006 the Company also received proceeds of \$1,335,086 in connection with warrant and stock option exercises which resulted in the issuance of 1,443,470 shares of common stock.

In February of 2007 the Company received gross proceeds of \$5,000,000 upon closing of the first tranche of a \$10,000,000 credit facility, to help fund additional working capital needs. A second tranche of \$5,000,000 is available after September 30, 2007 but before December 31, 2007 upon certain conditions. The per annum interest rate is equal to the sum of the yield for three-year US treasury bills as quoted by Bloomberg, plus 800 basis points calculated (i) in the case of the first tranche, on the business day prior to the first funding date and (ii) in the case of the second tranche, on the business day prior to the second funding date (as such term is defined in the Credit Agreement). In addition, once set, the applicable interest rate for each tranche will be fixed for the applicable term. The maturity date (i) with respect to the first tranche is forty-two months from the first funding date and (ii) with respect to the second tranche is thirty-six months from the second funding date. The credit agreement contains certain covenants and provisions that affect the Company, including, without limitation, covenants and provisions that:

restrict its ability to create or incur indebtedness (subject to enumerated exceptions);

restrict its ability to create or incur certain liens on its property (subject to enumerated exceptions);

in certain circumstances, require it to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least \$2,500,000;

in certain circumstances, restrict its ability to declare or pay any dividends on any shares of its capital stock, purchase or redeem any shares of its capital stock, return any capital to any holder of its equity securities or payment of certain bonuses;

restrict its ability to make certain investments.

In connection with the credit facility, the Company issued warrants to purchase a total of 640,000 shares of common stock at an exercise price of \$1.25, of which 240,000 will vest on the occurrence of the drawdown of the second tranche.

The Company believes that the combination of the recent debt and equity financings and projected product sales, product development, license revenues, milestone payments and royalties will provide sufficient funds to support operations for at least the next 12 months. During 2007, the Company believes capital expenditures may increase to over \$1.5 million primarily in connection with tooling and production equipment related to injection device deals. The Company does not currently have any bank credit lines. If the Company does need additional financing and is unable to obtain such financing when needed, or obtain it on favorable terms, the Company may be required to curtail development of new drug technologies, limit expansion of operations or accept financing terms that are not as attractive as the Company may desire.



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### *Net Cash Used in Operating Activities*

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, general and administrative costs, research and development projects and sales, marketing and business development activities. Net cash used in operating activities was \$6,118,050, \$7,218,529 and \$7,167,313 for the years ended December 31, 2006, 2005 and 2004, respectively. This was primarily the result of net losses of \$8,099,846, \$8,497,956 and \$8,348,532 in 2006, 2005 and 2004, respectively, adjusted by noncash expenses and changes in operating assets and liabilities.

Noncash expenses totaled \$1,798,524, \$695,967 and \$1,915,862 in 2006, 2005 and 2004, respectively. The increase in 2006 compared to 2005 was primarily the result of an increase in noncash stock-based compensation expense of nearly \$1.0 million, which was principally due to the adoption of SFAS No. 123R in 2006. The decrease in 2005 from 2004 was due mainly to decreases in patent rights impairment charges and stock-based compensation expense. Stock-based compensation expense in 2004 was higher due to more frequent utilization of common stock and warrants as compensation for external consultants.

In 2006, the change in operating assets and liabilities generated cash of \$183,272. This was primarily the net result of increases in accounts receivable of \$616,327 and deferred revenue of \$818,234. Both increases reflect the increase in revenue generating activity in 2006 compared to 2005. The accounts receivable increase was due to an increase in product sales activity, royalties and development revenue near the end of 2006 as compared to 2005. In 2006 the amount received from license fees, development fees and milestone payments increased compared to 2005, as did the portion of these payments that was deferred and is being recognized as revenue over various periods.

The change in operating assets and liabilities in 2005 generated cash of \$583,460. This resulted mainly from the increases in accounts payable and accrued expenses of \$501,614 and \$194,782, respectively. These increases were primarily due to increased research and development activities near the end of the year, particularly in connection with development projects related to transdermal gels, and increased accruals related to executive bonuses. Partially offsetting these increases was an increase in prepaid expenses and other assets, which utilized cash of \$210,753, and a decrease in deferred revenue of \$63,098. The increase in prepaid expenses and other assets was almost entirely due to payments made in connection with development projects related to transdermal gels. The reduction in deferred revenue was the result of recognizing as revenue amounts that had previously been deferred, which exceeded amounts deferred during the year totaling approximately \$610,000.

The change in operating assets and liabilities in 2004 utilized cash of \$734,643. This resulted primarily from decreases in deferred revenue and accrued expenses of \$577,700 and \$216,011, respectively, plus an increase in other assets of \$232,644, partially offset by decreases in accounts and other receivables of \$66,177 and inventory of \$133,064 and an increase in accounts payable of \$214,367. The decrease in deferred revenue was mainly due to the amortization of amounts deferred in prior years, partially offset by approximately \$250,000 of development fees deferred during the year. Related to the development fees deferred in 2004 were deferred costs that totaled approximately \$200,000, which is the primary reason other assets increased. Receivables decreased at the end of 2004 compared to 2003 mainly due to a reduction in billable development activity at the Antares/Switzerland operations. The decrease in inventory is mainly the result of the timing of purchases of finished goods from the third-party supplier versus shipments to customers. At the end of 2003 the Company had a large amount of finished goods in inventory that was shipped to a customer in early January 2004. The increase in accounts payable in 2004 compared to 2003 was mainly due to an increase in operating expense activity at the end of 2004 compared to 2003, particularly in the areas of research and development and business development.

### *Net Cash Provided by (Used in) Investing Activities*

Investing activities are comprised primarily of short-term investment purchases and maturities. All short-term investments are commercial paper or U.S. government agency discount notes that mature within six to ten months of purchase and are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. In 2006 and 2004 the use of cash to purchase securities exceeded cash generated from maturities by \$4,851,551 and \$7,889,565, respectively, due to the investment of excess funds from the private placements in

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each of those years. In 2005, maturities exceeded purchases by \$7,941,688, as cash was required to fund operations and was not available for reinvestment. Investing activities in 2006, 2005 and 2004 also included

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additions to patent rights of \$142,751, \$154,193 and \$76,193, respectively, and purchases of equipment, furniture and fixtures of \$35,703, \$89,651 and \$218,038, respectively. The 2004 purchases consisted primarily of furniture and office equipment in connection with the move of the Minnesota operations to new office and laboratory space, new disposable component tooling, and upgrades to computer hardware and software.

### *Net Cash Provided by Financing Activities*

Net cash provided by financing activities totaled \$11,117,141, \$619,700 and \$15,140,603 for the years ended December 31, 2006, 2005 and 2004, respectively. In 2006, the Company received \$1,335,086 from the exercise of warrants and stock options and received net proceeds of \$9,782,055 from the private placement of common stock in which a total of 8,770,000 shares of common stock were sold at a price of \$1.25 per share. In 2005, the Company received \$476,000 from the sale of common stock and \$193,700 from the exercise of warrants, which was partially offset by the payment of preferred stock dividends of \$50,000. In 2004, net cash provided by financing activities resulted primarily from net proceeds of \$13,753,400 from the private placement of common stock and proceeds of \$1,472,500 from the exercise of warrants, partially offset by principal payments on capital lease obligations of \$35,297 and payment of preferred stock dividends of \$50,000.

The Company's contractual cash obligations at December 31, 2006 are associated with operating leases and are summarized in the following table:

	<b>Payment Due by Period</b>				<b>After 5 years</b>
	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>4-5 years</b>	
Total contractual cash obligations	\$ 1,201,263	\$ 329,894	\$ 729,294	\$ 142,075	\$ -

### *Off Balance Sheet Arrangements*

The Company does not have any off-balance sheet arrangements, including any arrangements with any structured finance, special purpose or variable interest entities.

### **New Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123 (Revised 2004), Share-Based Payment. SFAS No. 123R is a revision of SFAS No. 123, Accounting for Stock-Based Compensation and supersedes APB Opinion No. 25, Accounting

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for Stock Issued to Employees and its related implementation guidance. Among other items, the standard requires that the compensation cost relating to share-based payment transactions be recognized in the consolidated statement of operations. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. As of January 1, 2006, the Company adopted the fair value method of accounting for employee stock compensation cost pursuant to SFAS No. 123R, which requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. Prior to January 1, 2006, the Company used the intrinsic value method under APB Opinion No. 25. Accordingly, compensation expense was recognized for restricted stock granted to employees, but was not recognized for employee stock options other than the intrinsic value of options when the exercise price of the options was below their fair value on the date of grant. The Company is using the modified prospective transition method in implementing SFAS No. 123R. Under that transition method, compensation cost recognized in 2006 includes: (1) compensation cost for all stock-based payments granted prior to, but not yet vested as of December 31, 2005, based on the grant date fair value calculated in accordance with the original provisions of SFAS No. 123, and (2) compensation cost for all stock-based payments granted subsequent to December 31, 2005, based on the grant-date fair value calculated in accordance with the provisions of SFAS No. 123R. In accordance with the modified prospective transition method, results for prior periods have not been restated and do not include the impact of SFAS No. 123R. As a result of adopting SFAS No. 123R, the Company's net loss for the year ended December 31, 2006 was approximately \$1,050,000 more than if it had continued to account for stock-based compensation under APB

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Opinion No. 25. Note 2 to the Consolidated Financial Statements contains pro forma disclosures regarding the effect on net loss and net loss per share as if the fair value method of accounting for stock-based compensation had been applied in the two years prior to adoption.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. This interpretation is effective beginning in fiscal year 2007. The Company does not believe the implementation of this standard will have a material impact on the consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* which is effective for fiscal years beginning after November 15, 2007 and for interim periods within those years. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. The Company is currently evaluating the potential impact of this statement on the consolidated financial statements.

In September 2006, the Staff of the SEC issued Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB No. 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year's financial statements are materially misstated. SAB No. 108 is effective for fiscal years ending after November 15, 2006. This bulletin did not have an impact on our consolidated financial statements.

### *Item 7(A). QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

The Company's primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of the Company's subsidiaries in Switzerland are translated into U.S. dollars for consolidation. The Company's exposure to foreign exchange rate fluctuations also arises from transferring funds to its Swiss subsidiaries in Swiss Francs. Most of the Company's sales and licensing fees are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. The effect of foreign exchange rate fluctuations on the Company's financial results for the years ended December 31, 2006, 2005 and 2004 was not material. Beginning in 2003 the Company also has exposure to exchange rate fluctuations between the Euro and the U.S. dollar. The licensing agreement entered into in January 2003 with Ferring, discussed in Note 9 to the Consolidated Financial Statements, established pricing in Euros for products sold under the existing supply agreement and for all royalties. In March 2007 the Company amended the 2003 agreement with Ferring to principally establish prices in U.S. dollars rather than Euros. The Company does not currently use derivative financial instruments to hedge against exchange rate risk. Because exposure increases as intercompany balances grow, the Company will continue to evaluate the need to initiate hedging programs to mitigate the impact of foreign exchange rate fluctuations on intercompany balances.

Typically, our short-term investments are commercial paper or U.S. government agency discount notes that mature within six to ten months of purchase. The market value of such investments fluctuates with current market interest rates. In general, as rates increase, the market value of a debt instrument is expected to decrease. The opposite is also true. To minimize such market risk, we have in the past and to the extent possible, will continue in the future, to hold such debt instruments to maturity at which time the debt instrument will be redeemed at its stated or face value. Due to the short duration and nature of these instruments, we do not believe that we have a material exposure to interest rate risk related to our investment portfolio.





Item 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.*

**ANTARES PHARMA, INC.**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders

Antares Pharma, Inc.:

We have audited the accompanying consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2006. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Antares Pharma, Inc. and subsidiaries as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123R, Share-Based Payment, on January 1, 2006.

/s/ KPMG LLP

Minneapolis, Minnesota

March 26, 2007

## ANTARES PHARMA, INC.

## CONSOLIDATED BALANCE SHEETS

	December 31, 2006	December 31, 2005
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 2,706,047	\$ 2,718,472
Short-term investments	4,953,421	-
Accounts receivable, less allowance for doubtful accounts of \$10,000 and \$20,800, respectively	855,866	223,944
Other receivables	55,794	48,185
Inventories	84,779	36,022
Prepaid expenses and other current assets	221,669	286,185
Total current assets	8,877,576	3,312,808
Equipment, furniture and fixtures, net	382,096	477,608
Patent rights, net	813,592	936,939
Goodwill	1,095,355	1,095,355
Other assets	365,864	343,654
Total Assets	\$ 11,534,483	\$ 6,166,364
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 813,014	\$ 945,028
Accrued expenses and other liabilities	1,071,086	798,468
Deferred revenue	1,014,337	604,143
Total current liabilities	2,898,437	2,347,639
Deferred revenue - long term	3,555,601	3,062,076
Total liabilities	6,454,038	5,409,715
Stockholders' Equity:		
Common Stock: \$0.01 par; authorized 100,000,000 shares; 53,319,622 and 43,019,486 issued and outstanding at December 31, 2006 and 2005, respectively	533,196	430,195
Additional paid-in capital	106,792,974	94,547,105
Prepaid license discount	(2,305,929 )	(2,502,178 )
Accumulated deficit	(99,322,453 )	(91,123,107 )
Accumulated other comprehensive loss	(617,343 )	(595,366 )
	5,080,445	756,649
Total Liabilities and Stockholders' Equity	\$ 11,534,483	\$ 6,166,364

See accompanying notes to consolidated financial statements.

## ANTARES PHARMA, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2006	2005	2004
Revenue:			
Product sales	\$ 2,195,218	\$ 1,511,929	\$ 1,834,431
Development revenue	593,797	183,760	196,648
Licensing revenue	1,254,250	374,021	634,542
Royalties	225,134	155,036	80,335
Total revenue	4,268,399	2,224,746	2,745,956
Cost of revenue:			
Cost of product sales	1,293,192	1,042,504	1,304,504
Cost of development revenue	262,778	94,241	67,798
Total cost of revenue	1,555,970	1,136,745	1,372,302
Gross profit	2,712,429	1,088,001	1,373,654
Operating expenses:			
Research and development	3,778,469	3,677,015	2,869,317
Sales, marketing and business development	1,349,678	1,160,752	675,878
General and administrative	5,861,111	4,839,408	6,203,125
	10,989,258	9,677,175	9,748,320
Operating loss	(8,276,829 )	(8,589,174 )	(8,374,666 )
Other income (expense):			
Interest income	353,236	128,832	120,292
Interest expense	(3,132 )	(576 )	(100,471 )
Foreign exchange losses	(128,268 )	(36,718 )	(6,849 )
Other, net	(44,853 )	(320 )	13,162
	176,983	91,218	26,134
Net loss	(8,099,846 )	(8,497,956 )	(8,348,532 )
Deemed dividend to warrant holders	(99,500 )	-	-
Preferred stock dividends	-	(50,000 )	(100,000 )
Net loss applicable to common shares	\$ (8,199,346 )	\$ (8,547,956 )	\$ (8,448,532 )
Basic and diluted net loss per common share	\$ (0.16 )	\$ (0.21 )	\$ (0.23 )
Basic and diluted weighted average common shares outstanding	51,582,111	41,459,533	36,347,892

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS**  
 Years Ended December 31, 2004, 2005 and 2006

	Convertible Preferred Stock				Common Stock			Accumulated			Total Stockholders Equity
	Series A		Series D		Number of Shares	Amount	Additional Paid-In Capital	Prepaid License Discount	Other		
	Number of Shares	Amount	Number of Shares	Amount					Accumulated Deficit	Loss	
<b>December 31, 2003</b>	<b>1,450</b>	<b>\$ 15</b>	<b>243,749</b>	<b>\$ 2,437</b>	<b>19,831,200</b>	<b>198,313</b>	<b>\$ 77,747,461</b>	<b>\$ (2,894,677)</b>	<b>(\$ (74,126,611))</b>	<b>\$ 161,836</b>	<b>\$ 307,094</b>
Preferred Series D converted into common stock	-	-	(180,161)	(1,801)	1,801,610	18,016	(16,215)	-	-	-	-
Issuance of common stock in private placement	-	-	-	-	15,120,000	151,200	13,602,200	-	-	-	13,753,400
Exercise of warrants	-	-	-	-	3,480,500	34,805	1,513,083	-	-	-	1,547,888
Stock-based compensation	-	-	-	-	185,000	1,850	823,531	-	-	-	825,381
Amortization of prepaid license discount	-	-	-	-	-	-	-	196,250	-	-	196,250
Preferred stock dividends	50	-	-	-	-	-	50,000	-	(100,000)	-	(50,000)
Net loss	-	-	-	-	-	-	-	-	(8,348,532)	-	(8,348,532)
Translation adjustments	-	-	-	-	-	-	-	-	(42,642)	-	(42,642)
Comprehensive loss	-	-	-	-	-	-	-	-	-	-	(8,391,174)
<b>December 31, 2004</b>	<b>1,500</b>	<b>15</b>	<b>63,588</b>	<b>636</b>	<b>40,418,400</b>	<b>404,184</b>	<b>93,720,060</b>	<b>(2,698,427)</b>	<b>(\$ (82,575,151))</b>	<b>1662,478</b>	<b>8,188,839</b>
Preferred stock conversions	(1,500)	(15)	(63,588)	(636)	1,835,880	18,359	(17,708)	-	-	-	-
Issuance of common stock	-	-	-	-	400,000	4,000	472,000	-	-	-	476,000
Exercise of warrants	-	-	-	-	315,200	3,152	190,548	-	-	-	193,700
Stock-based compensation	-	-	-	-	50,000	500	182,205	-	-	-	182,705
Amortization of prepaid license discount	-	-	-	-	-	-	-	196,249	-	-	196,249
Preferred stock dividends	-	-	-	-	-	-	-	-	(50,000)	-	(50,000)
Net loss	-	-	-	-	-	-	-	-	(8,497,956)	-	(8,497,956)
Translation adjustments	-	-	-	-	-	-	-	-	67,112	-	67,112
Comprehensive loss	-	-	-	-	-	-	-	-	-	-	(8,430,844)
<b>December 31, 2005</b>	-	-	-	-	<b>43,019,480</b>	<b>430,195</b>	<b>94,547,105</b>	<b>(2,502,178)</b>	<b>(\$ (91,123,107))</b>	<b>1075,366</b>	<b>756,649</b>
Issuance of common stock in private placement	-	-	-	-	8,770,000	87,700	9,694,355	-	-	-	9,782,055
Exercise of warrants and options	-	-	-	-	1,443,470	14,435	1,320,651	-	-	-	1,335,086
Stock-based compensation	-	-	-	-	86,666	866	1,131,363	-	-	-	1,132,229
Amortization of prepaid license discount	-	-	-	-	-	-	-	196,249	-	-	196,249
Deemed dividend to warrant holder	-	-	-	-	-	-	99,500	-	(99,500)	-	-
Net loss	-	-	-	-	-	-	-	-	(8,099,846)	-	(8,099,846)
Translation adjustments	-	-	-	-	-	-	-	-	(21,977)	-	(21,977)
Comprehensive loss	-	-	-	-	-	-	-	-	-	-	(8,121,823)
<b>December 31, 2006</b>	-	<b>\$ -</b>	-	<b>\$ -</b>	<b>53,319,620</b>	<b>533,196</b>	<b>\$ 106,792,974</b>	<b>\$ (2,305,929)</b>	<b>(\$ (99,322,451))</b>	<b>151617,343</b>	<b>\$ 5,080,445</b>

See accompanying notes to consolidated financial statements.

## ANTARES PHARMA, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2006	2005	2004
Cash flows from operating activities:			
Net loss	\$ (8,099,846 )	\$ (8,497,956 )	\$ (8,348,532 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Patent rights impairment charge	138,632	-	233,062
Depreciation and amortization	297,375	317,013	580,080
Loss on disposal and abandonment of assets	-	-	5,701
Stock-based compensation expense	1,166,268	182,705	825,381
Noncash interest expense	-	-	75,388
Amortization of prepaid license discount	196,249	196,249	196,250
Changes in operating assets and liabilities:			
Accounts receivable	(616,327 )	48,710	200,855
Other receivables	(101,684 )	35,881	(134,678 )
Inventories	(48,757 )	56,322	133,064
Prepaid expenses and other current assets	114,446	(210,753 )	(16,873 )
Other assets	(13,038 )	20,002	(232,644 )
Accounts payable	(155,391 )	501,614	214,367
Accrued expenses and other current liabilities	185,789	194,782	(216,011 )
Due to related parties	-	-	(105,023 )
Deferred revenue	818,234	(63,098 )	(577,700 )
Net cash used in operating activities	(6,118,050 )	(7,218,529 )	(7,167,313 )
Cash flows from investing activities:			
Purchase of short-term investments	(10,694,799 )	(5,955,789 )	(19,889,565 )
Proceeds from maturity of short-term investments	5,843,248	13,897,477	12,000,000
Additions to patent rights	(142,751 )	(154,193 )	(76,193 )
Purchases of equipment, furniture and fixtures	(35,703 )	(89,651 )	(218,038 )
Net cash provided by (used in) investing activities	(5,030,005 )	7,697,844	(8,183,796 )
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	9,782,055	476,000	13,753,400
Proceeds from exercise of warrants and stock options	1,335,086	193,700	1,472,500
Principal payments on capital lease obligations	-	-	(35,297 )
Payment of preferred stock dividends	-	(50,000 )	(50,000 )
Net cash provided by financing activities	11,117,141	619,700	15,140,603
Effect of exchange rate changes on cash and cash equivalents	18,489	(32,951 )	(65,901 )
Net increase (decrease) in cash and cash equivalents	(12,425)	1,066,064	(276,407 )
Cash and cash equivalents:			
Beginning of year	2,718,472	1,652,408	1,928,815
End of year	\$ 2,706,047	\$ 2,718,472	\$ 1,652,408

See accompanying notes to consolidated financial statements.





**ANTARES PHARMA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Business**

Antares Pharma, Inc. ( Antares ) is a specialty drug delivery/pharmaceutical company utilizing its experience and expertise in drug delivery systems to enhance the performance of established and developing pharmaceuticals. The Company currently has three primary delivery platforms (1) transdermal gels, (2) fast-melt tablets, and (3) injection devices. The corporate headquarters are located in Ewing, New Jersey, with research and production facilities for the injection devices in Minneapolis, Minnesota, and research, development and commercialization facilities for the transdermal gels and fast-melt tablets in Basel, Switzerland.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying consolidated financial statements include the accounts of Antares Pharma, Inc. and its three wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

*Foreign Currency Translation*

The majority of the foreign subsidiaries revenues are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the U.S. parent. Nearly all operating expenses of the foreign subsidiaries, including labor, materials, leasing arrangements and other operating costs, are denominated in Swiss Francs. Additionally, bank accounts held by foreign subsidiaries are denominated in Swiss Francs, there is a low volume of intercompany transactions and there is not an extensive interrelationship between the operations of the subsidiaries and the parent company. As such, under Financial Accounting Standards Board Statement No. 52, *Foreign Currency Translation*, the Company has determined that the Swiss Franc is the functional currency for its three foreign subsidiaries. The reporting currency for the Company is the United States Dollar ( USD ). The financial statements of the Company's three foreign subsidiaries are translated into USD for consolidation purposes. All assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a separate component of stockholders' equity. Sales to certain customers by the U.S. parent are in currencies other than the U.S. dollar and are subject to foreign currency exchange rate fluctuations. Foreign currency transaction gains and losses are included in the statements of operations.

*Cash Equivalents*

The Company considers highly liquid debt instruments with original maturities of 90 days or less to be cash equivalents.

*Short-Term Investments*

All short-term investments are commercial paper or U.S. government agency discount notes that mature within one year of purchase and are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. At December 31, 2006 the securities had a fair value of \$4,951,654 and a carrying value of \$4,953,421. At December 31, 2005 there were no short-term investments.

*Inventories*

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out basis. Certain components of the Company's products are provided by a limited number of vendors, and the Company's production and assembly operations are outsourced to a third-party supplier. Disruption of supply from key vendors or the third-party supplier may have a material adverse impact on the Company's operations.

*Equipment, Furniture, and Fixtures*

Equipment, furniture, and fixtures are stated at cost and are depreciated using the straight-line method over their estimated useful lives ranging from three to ten years. Certain equipment and furniture held under capital leases is classified in equipment, furniture and fixtures and is amortized using the straight-line method over the lesser of the lease term or estimated useful life, and the related obligations are recorded as liabilities. Lease amortization is included in depreciation expense. Depreciation expense was \$144,225, \$192,869 and \$423,107 for the years ended December 31, 2006, 2005 and 2004, respectively.

*Goodwill*

The Company evaluates the carrying value of goodwill during the fourth quarter of each year and between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the Minnesota reporting unit below its carrying amount. Such circumstances could include, but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, (3) an adverse action or assessment by a regulator, or (4) a sustained significant drop in the Company's stock price. When evaluating whether goodwill is impaired, the Company compares the fair value of the Minnesota operations to the carrying amount, including goodwill. If the carrying amount of the Minnesota operations exceeds its fair value, then the amount of the impairment loss must be measured. The impairment loss would be calculated by comparing the implied fair value of goodwill to its carrying amount. In calculating the implied fair value of goodwill, the fair value of the Minnesota operations would be allocated to all of its other assets and liabilities based on their fair values. The excess of the fair value of the Minnesota operations over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. An impairment loss would be recognized when the carrying amount of goodwill exceeds its implied fair value. The Company's evaluation of goodwill completed during 2006, 2005 and 2004 resulted in no impairment losses.

*Patent Rights*

The Company capitalizes the cost of obtaining patent rights. These capitalized costs are being amortized on a straight-line basis over periods ranging from six to ten years beginning on the earlier of the date the patent is issued or the first commercial sale of product utilizing such patent rights. Amortization expense for the years ended December 31, 2006, 2005 and 2004 was \$153,150, \$129,349 and \$156,970, respectively.

*Impairment of Long-Lived Assets and Long-Lived Assets to Be Disposed Of*

Long-lived assets, including patent rights, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. This analysis can be very subjective as the Company relies upon signed distribution or license agreements with variable cash flows to substantiate the recoverability of long-lived assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

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In the fourth quarter of each year the Company updates its long-range business plan. The Company then reviews patent costs for impairment and identifies patents related to products for which there are no signed distribution or license agreements or for which no revenues or cash flows are included in the business plan. In 2006 and 2004 the Company recognized impairment charges of \$138,632 and \$233,062, respectively, in general and administrative expenses, which represented the gross carrying amount net of accumulated amortization for the identified patents. After the impairment charge, the gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, were \$1,526,714 and \$713,122, respectively, at December 31, 2006. The Company's estimated aggregate patent amortization expense for the next five years is \$95,000 in 2007, \$90,000 in each of 2008, 2009 and 2010, and \$42,000 in 2011.

*Fair Value of Financial Instruments*

All financial instruments are carried at amounts that approximate estimated fair value.

*Revenue Recognition*

The Company sells its proprietary reusable needle-free injectors and related disposable products through pharmaceutical and medical product distributors. The Company's reusable injectors and related disposable products are not interchangeable with any competitive products and must be used together. The Company recognizes revenue upon shipment when title transfers. The Company offers no price protection or return rights other than for customary warranty claims. Sales terms and pricing are governed by sales and distribution agreements.

The Company also records revenue from license fees, milestone payments and royalties. License fees and milestone payments received under contracts originating prior to June 15, 2003 are accounted for under the cumulative deferral method. This method defers milestone payments with amortization to income over the contract term on a straight-line basis commencing with the achievement of a contractual milestone. If the Company is required to refund any portion of a milestone payment, the milestone will not be amortized into revenue until the repayment obligation no longer exists.

The Company recognizes royalty revenues upon the sale of licensed products by the licensee. The Company occasionally receives payment of up-front royalty advances from licensees. Under the cumulative deferral method for contracts prior to June 15, 2003, if specific objective evidence of fair value exists, revenues from up-front royalty payments are deferred until earned through the sale of licensed product or the termination of the agreement based on the terms of the license. If specific objective evidence of fair value does not exist, revenues from up-front royalty payments are recognized using the cumulative deferral method.

In December 2002, the Emerging Issues Task Force ( EITF ) issued EITF 00-21 *Revenue Arrangements with Multiple Deliverables*. This Issue addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. In some arrangements, the different revenue-generating activities (deliverables) are sufficiently separable, and there exists sufficient evidence of their fair values to separately account for some or all of the deliverables (that is, there are separate units of accounting). In other arrangements, some or all of the deliverables are not independently functional, or there is not sufficient evidence of their fair values to account for them separately. This Issue addresses when and, if so, how an arrangement involving multiple deliverables should be divided into separate units of accounting. This Issue does not change otherwise applicable revenue recognition criteria.

Under EITF 00-21, an up-front license payment is evaluated to determine whether or not it meets the requirements to be considered a separate unit of accounting. If it meets the separation criteria it is recognized as revenue when received or over the development period if the license and development are a combined unit of accounting. If it does not meet the separation criteria, then an up-front payment is deferred and would be recognized consistent with the remaining deliverables.

If the Company earns development fees for time and material costs incurred in connection with a development agreement, the development fees will be recognized as revenue when earned if that portion of the agreement meets the separation criteria of EITF 00-21. If the separation criteria are not met, the development fees received would be recognized consistent with the remaining deliverables. Likewise, the labor and material

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costs related to the development fees are recognized as a cost of sales when incurred if the separation criteria are met, and are capitalized and amortized on a straight-line basis over the same period as the development fees if the criteria are not met.

In connection with a license agreement entered into with Eli Lilly and Company, the Company issued to Lilly a ten-year warrant to purchase 1,000,000 shares of the Company's common stock at an exercise price of \$3.776 per share. At the time of issue the Company determined that the fair value of the warrant was \$2,943,739 using the Black-Scholes option pricing model. EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*, requires that the value of the warrants be treated as a reduction in revenue. The fair value of the warrant was recorded to additional paid-in capital and to prepaid license discount, a

contra equity account. The prepaid license discount will be reduced on a straight-line basis over the term of the agreement, offsetting revenue generated under the agreement. If during its periodic impairment assessment the Company concludes that the revenues from this arrangement will not exceed the costs, including prepaid license discount, part or all of the remaining prepaid license discount would be charged to operations at that time.

#### *Stock-Based Compensation*

As of January 1, 2006, the Company adopted the fair value method of accounting for employee stock compensation cost pursuant to SFAS No. 123R, which requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. Prior to January 1, 2006, the Company used the intrinsic value method under APB Opinion No. 25. Accordingly, compensation expense was recognized for restricted stock granted to employees, but was not recognized for employee stock options other than the intrinsic value of options when the exercise price of the options was below their fair value on the date of grant. The Company is using the modified prospective transition method in implementing SFAS No. 123R. Under that transition method, for the portion of awards that vested in 2006, compensation cost recognized during the year includes: (1) compensation cost for all stock-based payments granted prior to, but not yet vested as of December 31, 2005, based on the grant date fair value calculated in accordance with the original provisions of SFAS No. 123, and (2) compensation cost for all stock-based payments granted subsequent to December 31, 2005, based on the grant-date fair value calculated in accordance with the provisions of SFAS No. 123R. In accordance with the modified prospective transition method, results for prior periods have not been restated and do not include the impact of SFAS No. 123R.

As a result of adopting SFAS No. 123R, the Company's net loss for the year ended December 31, 2006 was approximately \$1,050,000 more than if it had continued to account for stock-based compensation under APB Opinion No. 25.

Had compensation cost been determined based on the fair value at the grant date for stock options under SFAS No. 123R for the years ended December 31, 2005 and 2004, the net loss applicable to common shares and loss per common share would have increased to the pro-forma amounts shown below:

	<b>2005</b>	<b>2004</b>
Net loss applicable to common stockholders:		
As reported	\$ (8,547,956 )	\$ (8,448,532 )
Stock based employee compensation expense recognized	176,298	272,569
Fair-value method compensation expense	(1,069,103 )	(1,141,813 )
Pro Forma net loss	\$ (9,440,761 )	\$ (9,317,776 )
Basic and diluted net loss per common share:		
As reported	\$ (0.21 )	\$ (0.23 )
Stock based employee compensation expense recognized	-	-
Fair-value method compensation expense	(0.02 )	(0.03 )
Pro Forma net loss per common share	\$ (0.23 )	\$ (0.26 )

The Company accounts for stock-based instruments granted to nonemployees under the fair value method of SFAS 123R and Emerging Issues Task Force ( EITF ) 96-18 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. Under SFAS 123R, options granted to nonemployees are recorded at their fair value on the measurement date, which is typically the vesting date.





*Product Warranty*

The Company provides a warranty on its reusable needle-free injector devices. Warranty terms for devices sold to end-users by dealers and distributors are included in the device instruction manual included with each device sold. Warranty terms for devices sold to corporate customers who provide their own warranty terms to end-users are included in the contracts with the corporate customers. The Company is obligated to repair or replace, at the Company's option, a device found to be defective due to use of defective materials or faulty workmanship. The warranty does not apply to any product that has been used in violation of instructions as to the use of the product or to any product that has been neglected, altered, abused or used for a purpose other than the one for which it was manufactured. The warranty also does not apply to any damage or defect caused by unauthorized repair or the use of unauthorized parts. Warranty periods on devices range from 24 to 30 months from either the date of retail sale of the device by a dealer or distributor or the date of shipment to a customer if specified by contract. The Company recognizes the estimated cost of warranty obligations at the time the products are shipped based on historical claims incurred by the Company. Actual warranty claim costs could differ from these estimates. Warranty liability activity is as follows:

	<b>Balance at</b>			<b>Balance at</b>	
	<b>Beginning of</b>			<b>End of</b>	
	<b>Year</b>	<b>Provisions</b>	<b>Claims</b>		<b>Year</b>
2006	\$ 25,000	\$ 4,066	\$ (9,066	)	\$ 20,000
2005	\$ 30,000	\$ 6,212	\$ (11,212	)	\$ 25,000

*Research and Development*

Research and development costs are expensed as incurred.

*Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's significant accounting estimates relate to the revenue recognition periods for license revenues, product warranty accruals and determination of the fair value and recoverability of goodwill and patent rights. Actual results could differ from these estimates.

*Income Taxes*

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to historical net losses of the Company, a valuation allowance is established to offset the deferred tax asset.

*Net Loss Per Share*

Basic EPS is computed by dividing net income or loss available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS is computed similar to basic earnings per share except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of stock options, warrants, convertible debt or convertible preferred stock, if dilutive. The number of additional shares is calculated by assuming that outstanding stock options or warrants were exercised and that the proceeds from such exercise were used to acquire shares of common stock at the average market price during the reporting period. If the convertible preferred stock were dilutive, any applicable dividends would be removed and the shares issued would be assumed to be outstanding for the dilutive period. All potentially dilutive common shares were excluded from the calculation because they were anti-dilutive for all periods presented.

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Potentially dilutive securities at December 31, 2006, 2005 and 2004, excluded from dilutive loss per share as their effect is anti-dilutive, are as follows:

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Stock options and warrants	25,699,542	19,840,298	20,256,591
Potentially dilutive shares from Series D convertible preferred stock	-	-	635,880

### *Reclassifications*

Certain prior year amounts have been reclassified to conform to the current year presentation. These reclassifications did not impact previously reported net loss or net loss per share. In 2006 the Company reclassified expenses for quality and regulatory activities previously reported as general and administrative expenses to research and development expenses. The amounts of the reclassifications were \$267,529 and \$233,682 in 2005 and 2004, respectively.

### *New Accounting Pronouncements*

In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123 (Revised 2004), *Share-Based Payment*. SFAS No. 123R is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* and its related implementation guidance. Among other items, the standard requires that the compensation cost relating to share-based payment transactions be recognized in the consolidated statement of operations. SFAS No. 123R focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. As of January 1, 2006, the Company adopted the fair value method of accounting for employee stock compensation cost pursuant to SFAS No. 123R, which requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. Prior to January 1, 2006, the Company used the intrinsic value method under APB Opinion No. 25. Accordingly, compensation expense was recognized for restricted stock granted to employees, but was not recognized for employee stock options other than the intrinsic value of options when the exercise price of the options was below their fair value on the date of grant. The Company is using the modified prospective transition method in implementing SFAS No. 123R. Under that transition method, compensation cost recognized in 2006 includes: (1) compensation cost for all stock-based payments granted prior to, but not yet vested as of December 31, 2005, based on the grant date fair value calculated in accordance with the original provisions of SFAS No. 123, and (2) compensation cost for all stock-based payments granted subsequent to December 31, 2005, based on the grant-date fair value calculated in accordance with the provisions of SFAS No. 123R. In accordance with the modified prospective transition method, results for prior periods have not been restated and do not include the impact of SFAS No. 123R.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. This interpretation is effective beginning in fiscal year 2007. The Company does not believe the implementation of this standard will have a material impact on the consolidated financial statements.

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In September 2006, the FASB issued Statement of Financial Accounting Standards ( SFAS ) No. 157, Fair Value Measurements which is effective for fiscal years beginning after November 15, 2007 and for interim periods within those years. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. The Company is currently evaluating the potential impact of this statement on the consolidated financial statements.

In September 2006, the Staff of the SEC issued Staff Accounting Bulletin ( SAB ) No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. SAB No. 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year s financial statements are materially misstated. SAB No. 108 is effective for fiscal years ending after November 15, 2006. This bulletin did not have an impact on our consolidated financial statements.

### Liquidity

The Company has not historically generated, and does not currently generate, enough revenue to provide the cash needed to support its operations, and has continued to operate primarily by raising capital and incurring debt. In order to better position the Company to take advantage of potential growth opportunities and to fund future operations, the Company raised additional capital in the first quarter of 2006. The Company received net proceeds of \$9,782,055 in a private placement of its common stock in which a total of 8,770,000 shares of common stock were sold at a price of \$1.25 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 7,454,500 shares of common stock with an exercise price of \$1.50 per share. In 2006 the Company also received proceeds of \$1,335,086 in connection with warrant and stock option exercises which resulted in the issuance of 1,443,470 shares of common stock.

In February of 2007 the Company received gross proceeds of \$5,000,000 upon closing of the first tranche of a \$10,000,000 credit facility, to help fund additional working capital needs.

The Company believes that the combination of the recent debt and equity financings and projected product sales, product development, license revenues, milestone payments and royalties will provide sufficient funds to support operations for at least the next 12 months. During 2007, the Company believes capital expenditures may increase to over \$1.5 million primarily in connection with tooling and production equipment related to injection device deals. The Company does not currently have any bank credit lines. If the Company does need additional financing and is unable to obtain such financing when needed, or obtain it on favorable terms, the Company may be required to curtail development of new drug technologies, limit expansion of operations or accept financing terms that are not as attractive as the Company may desire.

### 3. Composition of Certain Financial Statement Captions

	December 31, 2006	December 31, 2005
Inventories:		
Raw material	\$ 16,828	\$ 22,854
Finished goods	67,951	13,168
	\$ 84,779	\$ 36,022
Equipment, furniture and fixtures:		
Furniture, fixtures and office equipment	\$ 1,233,538	\$ 1,161,004
Production equipment	2,130,992	2,068,887
Less accumulated depreciation	(2,982,434 )	(2,752,283 )
	\$ 382,096	\$ 477,608
Patent rights:		
Patent rights	\$ 1,526,714	\$ 1,493,069
Less accumulated amortization	(713,122 )	(556,130 )
	\$ 813,592	\$ 936,939
Accrued expenses and other liabilities:		

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Accrued employee compensation and benefits	\$ 660,248	\$ 371,033
Other liabilities	410,838	427,435
	\$ 1,071,086	\$ 798,468

#### 4. Leases

The Company has non-cancelable operating leases for its corporate headquarters facility in Ewing, New Jersey, its office, research and development facility in Minneapolis, MN and for its office and research facility in Basel, Switzerland. The leases require payment of all executory costs such as maintenance and property taxes. The Company also leases certain equipment and furniture under various operating leases.

Rent expense, net, incurred for the years ended December 31, 2006, 2005 and 2004 was \$352,473, \$375,090 and \$436,152, respectively.

Future minimum annual operating lease payments are as follows as of December 31, 2006:

	<b>Amount</b>
2007	\$ 329,894
2008	320,685
2009	209,806
2010	198,803
2011	133,580
Thereafter	8,495
Total future minimum lease payments	\$ 1,201,263

#### 5. Income Taxes

The Company incurred losses for both book and tax purposes in each of the years in the three-year period ended December 31, 2006, and, accordingly, no income taxes were provided. The Company was subject to taxes in both the U.S. and Switzerland in each of the years in the three-year period ended December 31, 2006. Effective tax rates differ from statutory income tax rates in the years ended December 31, 2006, 2005 and 2004 as follows:

	<b>2006</b>		<b>2005</b>		<b>2004</b>	
Statutory income tax rate	(34.0	)%	(34.0	)%	(34.0	)%
State income taxes, net of federal benefit	(0.7	)	(0.0	)	(0.0	)
Research and experimentation credit	(0.3	)	(0.8	)	0.1	
Valuation allowance increase	21.9		21.0		5.4	
Effect of foreign operations	13.1		12.8		8.1	
Expiration of net operating losses	0.8		0.2		3.0	
Intangibles impairment						
Foreign net operating loss carryforwards					15.7	
Other	(0.8	)	0.8		1.7	
	0.0	%	0.0	%	0.0	%





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Deferred tax assets as of December 31, 2006 and 2005 consist of the following:

	<b>2006</b>	<b>2005</b>
Net operating loss carryforward U.S.	\$ 15,251,000	\$ 14,753,000
Net operating loss carryforward Switzerland	3,862,000	2,875,000
Research and development tax credit carryforward	891,000	867,000
Deferred revenue	1,048,000	876,000
Depreciation and amortization	280,000	287,000
Other	1,256,000	873,000
	22,588,000	20,531,000
Less valuation allowance	(22,588,000 )	(20,531,000 )
	\$	\$

The valuation allowance for deferred tax assets as of December 31, 2006 and 2005 was \$22,588,000 and \$20,531,000, respectively. The net change in the total valuation allowance for the years ended December 31, 2006 and 2005 was an increase of \$2,057,000 and \$1,220,000, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Due to the uncertainty of realizing the deferred tax asset, management has recorded a valuation allowance against the entire deferred tax asset.

The Company has a U.S. federal net operating loss carryforward at December 31, 2006, of approximately \$42,000,000, which, subject to limitations of Internal Revenue Code Section 382, is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2007 through 2026, with approximately \$1,789,000 expiring over the next three years. Additionally, the Company has a research credit carryforward of approximately \$891,000. These credits expire in years 2008 through 2026.

The Company also has a Swiss net operating loss carryforward at December 31, 2006, of approximately \$28,600,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2007 through 2013, with approximately \$5,900,000 expiring over the next three years.

Utilization of U.S. net operating losses and tax credits of Antares Pharma, Inc. are subject to annual limitations under Internal Revenue Code Sections 382 and 383, respectively, as a result of significant changes in ownership, including the business combination with Permatec, private placements, warrant exercises and conversion of Series D Convertible Preferred Stock. Subsequent significant equity changes, including exercise of outstanding warrants, could further limit the utilization of the net operating losses and credits. The annual limitations have not yet been determined; however, when the annual limitations are determined, the gross deferred tax assets for the net operating losses and tax credits will be reduced with a reduction in the valuation allowance of a like amount.

### 6. Stockholders Equity

#### *Common Stock*

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In the first quarter of 2006, the Company received proceeds of \$9,782,055, which was net of offering costs of \$1,180,445, in a private placement of its common stock in which a total of 8,770,000 shares of common stock were sold at a price of \$1.25 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 7,454,500 shares of common stock with an exercise price of \$1.50 per share.

In November 2005, in connection with a License Development and Supply Agreement discussed further in Note 10, the Company sold 400,000 shares of its common stock at \$1.25 per share.

Warrant and stock option exercises during 2006 and 2005 resulted in proceeds of \$1,335,086 and \$193,700, respectively, and in the issuance of 1,517,020 and 315,200 shares of common stock, respectively. In connection with the exercise of 210,000 warrants, the Company agreed to issue new three-year warrants for the purchase of 105,000 shares of common stock with an exercise price of \$1.35. The new warrants were issued in 2006.

During the first quarter of 2004 the Company received net proceeds of \$13,753,400 in three private placements of its common stock. A total of 15,120,000 shares of common stock were sold to investors at a price of \$1.00 per share. The Company also issued to the investors five-year warrants to purchase an aggregate of 5,039,994 shares of common stock at an exercise price of \$1.25 per share. Additionally, warrants for the purchase of 1,612,000 shares of common stock at an exercise price of \$1.00 per share were issued to the placement agent as a commission.

During 2004 the Company received proceeds of \$1,472,500 in connection with the issuance of 3,480,500 shares of common stock from the exercise of warrants. Of the shares issued, 2,932,500 were in connection with warrants exercised after the Company had offered a 30% discount in the exercise price to holders of warrants with an exercise price of under \$1.00. In connection with the exercise of these warrants the Company recognized interest expense of \$75,388, which represents the difference between the fair values of the warrants on the exercise date before and after applying the discount. Fair value was determined using the Black-Scholes option pricing model.

During each of the years 2005 and 2004 a total of 50,000 shares of common stock were issued to consultants or professional services organizations as compensation for services rendered. The total value of the shares issued in each year was \$44,000 and \$54,550, respectively. In 2004 the Company issued 35,000 shares of common stock to directors at a value of \$30,300. Common stock values were based on the market price of the stock on the dates the shares were issued.

#### *Stock-Based Compensation to Chief Executive Officer*

Jack E. Stover was appointed President and Chief Operating Officer on July 22, 2004, and was appointed Chief Executive Officer on September 1, 2004. The terms of the employment agreement with Mr. Stover included the issuance of options to purchase 500,000 shares of common stock at \$0.70 per share and an additional issuance of options to purchase 40,000 shares of common stock in January of 2005, with all options vesting over four years. The employment agreement also included the issuance of 100,000 shares of common stock, of which 50,000 shares vested immediately and the remaining 50,000 shares vested on the first anniversary of his employment. In addition, Mr. Stover was granted 459,999 restricted shares that would vest upon attainment of certain criteria. The Company recorded compensation expense of \$35,000 related to the shares with immediate vesting and deferred compensation expense of \$35,000 related to the shares vesting over one year. The amounts recorded were based on the market value of the stock on the measurement date. The deferred compensation expense was recognized ratably over the one-year vesting period. Compensation expense of \$20,417 and \$14,583 was recognized in connection with these shares during the years ended December 31, 2005 and 2004, respectively. In the second quarter of 2006, Mr. Stover was awarded 86,666 shares of common stock after attainment of a triggering event defined in his employment agreement. He can earn up to an additional 373,333 shares of common stock upon the occurrence of various triggering events, which include attainment of specified gross revenue and market cap levels and achievements related to merger and acquisition based activities.

#### *Series A Convertible Preferred Stock*

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In June 2005, all 1,500 outstanding shares of Series A Convertible Preferred Stock ( Series A ) were converted into 1,200,000 shares of common stock. On November 10, 1998, the Company had sold 1,000 shares of Series A and warrants to purchase 56,000 shares of common stock to Elan International Services, Ltd., for total consideration of \$1,000,000. The Series A carried a 10% dividend which was payable semi-annually.

### *Series D Convertible Preferred Stock*

In June and September of 2005, the remaining 30,000 and 33,588 shares of Series D Preferred Stock, respectively, were converted into 300,000 and 335,880 shares of common stock. In August 2004, 180,161 shares of Series D Preferred Stock were converted into 1,801,610 shares of common stock. Each share of Series D Preferred

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was convertible into ten shares of the Company's Common Stock, resulting in an aggregate of 2,437,490 shares of Common Stock issuable upon conversion of the Series D Preferred.

### *Stock Options and Warrants*

The Company's stock option and equity incentive plans allow for the grants of options, restricted stock and/or performance awards to officers, directors, consultants and employees. Under the Company's recently adopted 2006 Equity Incentive Plan, the maximum number of shares of stock that may be granted to any one participant during a calendar year is 500,000 shares, and no more than 500,000 shares may be issued as restricted stock grants, restricted stock units and performance awards. Options to purchase shares of Common Stock are granted at exercise prices not less than 100% of fair market value on the dates of grant. The term of the options range from three to eleven years and they vest in varying periods. As of December 31, 2006, these plans had 3,745,242 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the plans as of December 31, 2006 and the changes during the year then ended is as follows:

	Number of Shares	Weighted Average Exercise Price (\$)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (\$)
Outstanding at December 31, 2005	3,255,901	1.76		
Granted/Issued	1,535,000	1.48		
Exercised	(3,333 )	1.32		
Cancelled	(360,809 )	2.00		
Outstanding at December 31, 2006	4,426,759	1.65	7.1	276,055
Exercisable at December 31, 2006	3,007,039	1.79	6.7	176,792

The intrinsic value of stock options exercised in the year ended December 31, 2006 was \$1,133. As of December 31, 2006, there was approximately \$1,300,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.1 years.

The per share weighted average fair value of options granted during 2006, 2005 and 2004 was estimated as \$1.35, \$1.25 and \$0.87, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock. The weighted average expected life is based on both historical and anticipated employee behavior.

	December 31, 2006		2005		2004	
Risk-free interest rate	4.5	%	3.9	%	3.7	%
Annualized volatility	126.0	%	131.0	%	124.0	%

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Weighted average expected life, in years	7.0		7.0		5.0	
Expected dividend yield	0.0	%	0.0	%	0.0	%

The employment agreements with the Chief Executive Officer, Chief Financial Officer and other members of executive management include stock-based incentives under which the executives could be awarded up to approximately 1,365,000 shares of common stock upon the occurrence of various triggering events. The Chief Executive Officer was awarded 86,666 of these shares in the second quarter of 2006 when one of the triggering events was reached. A total of approximately \$23,000 in compensation expense was recorded in 2006 in connection with these shares. The weighted average grant date fair value of the remaining awards considered probable of achievement was \$0.40 per share which resulted in a total fair value of \$80,000, of which approximately \$23,000 is expected to be recognized after December 31, 2006 over a weighted average period of 8 months.

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As compensation to non-employees for professional services, in 2006 and 2004 the Company issued options and warrants to purchase a total of 277,500 and 550,000 shares of the Company's common stock, respectively. The Company recorded these options and warrants at their fair values, using the Black-Scholes option pricing model, of \$116,909 and \$502,293 in 2006 and 2004, respectively. The options and warrants have exercise prices ranging from \$0.55 to \$5.00 per share and expire three to five years after issuance.

Certain warrants to acquire 8,097,640 shares of common stock at exercise prices ranging from \$1.00 to \$1.25 have full antidilution protection which reduces the exercise price of the warrants to the effective price paid or payable under new stock or stock equivalent issuances.

Stock option and warrant activity is summarized as follows:

	<b>Options</b>		<b>Warrants</b>	
	<b>Number of Shares</b>	<b>Weighted Average Price</b>	<b>Number of Shares</b>	<b>Weighted Average Price</b>
Outstanding at December 31, 2003	1,984,888	\$ 2.33	13,420,603	\$ 1.44
Granted/Issued	1,351,650	1.06	7,051,994	1.25
Exercised			(3,480,500 )	0.42
Cancelled	(62,044 )	2.00	(10,000 )	2.40
Outstanding at December 31, 2004	3,274,494	1.79	16,982,097	1.43
Granted/Issued	225,000	1.34		
Exercised			(315,200 )	0.61
Cancelled	(243,593 )	1.80	(82,500 )	2.37
Outstanding at December 31, 2005	3,255,901	1.76	16,584,397	1.44
Granted/Issued	1,535,000	1.48	7,659,500	1.49
Exercised	(3,333 )	1.32	(1,513,687 )	0.97
Cancelled	(360,809 )	2.00	(1,457,427 )	3.48
Outstanding at December 31, 2006	4,426,759	1.65	21,272,783	1.35

The following table summarizes information concerning currently outstanding and exercisable options and warrants by price range at December 31, 2006:

<b>Price Range Pursuant to Option Plans:</b>	<b>Outstanding</b>	<b>Weighted Average Remaining Life In Years</b>	<b>Weighted Average Exercise Price</b>	<b>Exercisable</b>	
	<b>Number of Shares Outstanding</b>			<b>Number Exercisable</b>	<b>Weighted Average Exercise Price</b>
\$ 0.70 to 0.96	533,000	7.5	\$ 0.71	334,474	\$ 0.71
1.01 to 1.56	2,645,550	7.5	1.42	1,424,356	1.40
1.77	930,000	6.7	1.77	930,000	1.77
4.56	311,609	4.0	4.56	311,609	4.56
9.05 to 15.65	<u>6,600</u>	1.1	11.12	<u>6,600</u>	11.12

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	<u>4,426,759</u>	7.1	1.65	<u>3,007,039</u>	1.79
<b>Warrants:</b>					
\$ 0.55 to 1.10	6,220,979	1.7	0.83	6,220,979	0.83
1.25	6,342,304	2.0	1.25	6,342,304	1.25
1.35 to 1.50	7,559,500	4.1	1.50	7,559,500	1.50
3.00 to 5.00	<u>1,150,000</u>	6.0	3.81	<u>1,150,000</u>	3.81
	<u>21,272,783</u>	2.9	1.35	<u>21,272,783</u>	1.35
<b>Total Options &amp; Warrants</b>					
	<u>25,699,542</u>	3.6	1.40	<u>24,279,822</u>	1.40

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## 7. Employee Savings Plan

The Company has an employee savings plan that covers all U.S. employees who have met minimum age and service requirements. Under the plan, eligible employees may contribute up to 50% of their compensation into the plan. At the discretion of the Board of Directors, the Company may contribute elective amounts to the plan, allocated in proportion to employee contributions to the plan, employee's salary, or both. For the years ended December 31, 2006, 2005 and 2004, the Company elected to make contributions to the plan totaling \$68,369, \$73,955 and \$65,571, respectively.

## 8. Supplemental Disclosures of Cash Flow Information

Cash paid for interest during the years ended December 31, 2006, 2005 and 2004 was \$3,132, \$576 and \$25,106, respectively.

## 9. License Agreements

### *Teva License Development and Supply Agreements*

In September 2006, the Company entered into a Supply Agreement with Teva Pharmaceutical Industries Ltd. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from Antares for an undisclosed product to be marketed in the United States. Antares received an upfront cash payment, and will receive milestone fees and a royalty payment on Teva's net sales, as well as a purchase price for each device sold. The upfront payment is being recognized as revenue over the development period. The milestone fees and royalties will be recognized as revenue when earned.

In July 2006, the Company entered into an exclusive License Development and Supply Agreement with an affiliate of Teva, Sicor Pharmaceuticals Inc. Pursuant to the agreement, the affiliate is obligated to purchase all of its delivery device requirements from Antares for an undisclosed product to be marketed in the United States and Canada. Antares received an upfront cash payment, and will receive milestone fees, a negotiated purchase price for each device sold, as well as royalties on sales of their product. Based on an analysis under EITF 00-21, the entire arrangement is considered a single unit of accounting. Therefore, payments received and development costs incurred will be deferred and will be recognized from the start of manufacturing through the end of the initial contract period.

In November 2005, the Company signed an agreement with an affiliate of Teva, Sicor Pharmaceuticals Inc., under which Sicor is obligated to purchase all of its injection delivery device requirements from Antares for an undisclosed product to be marketed in the United States. Sicor also received an option for rights in other territories. The license agreement included, among other things, an upfront cash payment, milestone fees, a negotiated purchase price for each device sold, and royalties on sales of their product. In addition, pursuant to a Stock Purchase Agreement, Sicor purchased 400,000 shares of Antares common stock at a per share price of \$1.25. Antares granted Sicor certain registration rights with respect to the purchased shares of common stock. Based on an analysis under EITF 00-21, the entire arrangement is considered a single unit of accounting. Therefore, payments received and development costs incurred will be deferred and will be recognized from the start of manufacturing through the end of the initial contract period.

### *Eli Lilly Development and License Agreement*

On September 12, 2003, the Company entered into a Development and License Agreement (the License Agreement ) with Eli Lilly and Company. Under the License Agreement, the Company granted Lilly an exclusive license to certain of the Company's reusable needle-free technology in the fields of diabetes and obesity. The Company also granted an option to Lilly to apply the technology in one additional therapeutic area. Additionally, the Company issued to Lilly a ten-year warrant to purchase shares of the Company's common stock. The Company granted Lilly certain registration rights with respect to the shares of common stock issuable upon exercise of the warrant. At the time of the grant, the Company determined that the fair value of the warrant was \$2,943,739 using the Black-Scholes option pricing model. The fair value of the warrant was recorded to additional paid in capital and to prepaid license discount, a contra equity account.

The Company analyzed this contract to determine the proper accounting treatment under EITF 00-21, discussed in Note 2. The Company reached the conclusion that although there are multiple deliverables in the contract, the entire contract must be accounted for as one unit of accounting. Therefore, all revenue will be deferred when billed under the contract terms and will be recognized into revenue on a straight-line basis over the remaining life of the contract. All related costs will also be deferred and recognized as expense over the remaining life of the contract on a straight-line basis. The prepaid license discount will be amortized against revenue on a straight-line basis over the life of the contract. If during its periodic impairment assessment the Company concludes that the revenues from this arrangement will not exceed the costs, including prepaid license discount, part or all of the remaining prepaid license discount would be charged to earnings at that time.

#### *Ferring License Agreement*

The Company entered into a License Agreement, dated January 22, 2003, with Ferring, under which the Company licensed certain of its intellectual property and extended the territories available to Ferring for use of certain of the Company's reusable needle-free injector devices. Specifically, the Company granted to Ferring an exclusive, perpetual, irrevocable, royalty-bearing license, within a prescribed manufacturing territory, to manufacture certain of the Company's reusable needle-free injector devices for the field of human growth hormone. The Company granted to Ferring similar non-exclusive rights outside of the prescribed manufacturing territory. In addition, the Company granted to Ferring a non-exclusive right to make and have made the equipment required to manufacture the licensed products, and an exclusive, perpetual, royalty-free license in a prescribed territory to use and sell the licensed products.

The Company also granted to Ferring a right of first offer to obtain an exclusive worldwide license to manufacture and sell the Company's AJ-1 device for the treatment of limited medical conditions.

As consideration for the license grants, Ferring paid the Company EUR500,000 (\$532,400) upon execution of the License Agreement, and paid an additional EUR1,000,000 (\$1,082,098) on February 24, 2003. Ferring will also pay the Company royalties for each device manufactured by or on behalf of Ferring, including devices manufactured by the Company. Beginning on January 1, 2004, EUR500,000 (\$541,049) of the license fee received on February 24, 2003, will be credited against the royalties owed by Ferring, until such amount is exhausted. These royalty obligations expire, on a country-by-country basis, when the respective patents for the products expire, despite the fact that the License Agreement does not itself expire until the last of such patents expires. The license fees have been deferred and are being recognized in income over the period from January 22, 2003 through expiration of the patents in December 2016.

The Company also agreed that it would enter into a third-party supply agreement to supply sufficient licensed products to meet the Company's obligations to Ferring under the License Agreement and under the parties' existing supply agreement.

In March 2007 the Company amended the agreement to include a next generation device and provided for payment principally in U.S. dollars rather than Euros.

#### *BioSante License Agreement*

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In June 2000, the Company entered into an exclusive agreement to license four applications of its drug-delivery technology to BioSante Pharmaceuticals, Inc. in the United States, Canada, China, Australia, New Zealand, South Africa, Israel, Mexico, Malaysia and Indonesia (collectively, the BioSante Territories ). The Company is required to transfer technology know-how to BioSante until each country's regulatory authorities approve the licensed product. BioSante will use the licensed technology for the development of hormone replacement therapy products. At the signing of the contract, BioSante made an upfront payment to the Company, a portion of which, per the terms of the contract, was used to partially offset a later payment made to the Company as a result of an upfront payment received by BioSante under a sublicense agreement. The initial upfront payment received by the Company was for the delivery of intellectual property to BioSante.

The Company will receive payments upon the achievement of certain milestones and will receive from BioSante a royalty from the sale of licensed products. The Company will also receive a portion of any sublicense fees received by BioSante.

Under the cumulative deferral method, the Company ratably recognizes revenue related to milestone payments from the date of achievement of the milestone through the estimated date of receipt of final regulatory approval in the BioSante Territory. The Company is recognizing the initial milestone payment in revenue over a 129-month period. All other milestone payments will be recognized ratably on a product-by-product basis from the date the milestone payment is earned and all repayment obligations have been satisfied until the receipt of final regulatory approval in the BioSante Territory for each respective product. It is expected that these milestones will be earned at various dates from January 2005 to March 2011 and will be recognized as revenue over periods of up to 75 months.

In November 2006 BioSante entered into a sublicense and marketing agreement with Bradley Pharmaceuticals, Inc. for Elestrin<sup>®</sup> (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a payment to the Company of \$875,000. In December 2006 the FDA approved for marketing Elestrin<sup>®</sup> in the United States triggering payments to the Company totaling \$2.6 million, which will be received in 2007. In addition, the Company will receive royalties on sales of Elestrin<sup>®</sup> as well as potential sales-based milestone payments when marketed by Bradley. Because final regulatory approval for this product was obtained by BioSante and Antares has no further obligations in connection with this product, the sublicense payment of \$875,000 was recognized as revenue in 2006. Further sublicense payments and royalties will be recognized as revenue when due and payable.

In August 2001, BioSante entered into an exclusive agreement with Solvay in which Solvay has sublicensed from BioSante the U.S. and Canadian rights to an estrogen/progestogen combination transdermal hormone replacement gel product, one of the four drug-delivery products the Company has licensed to BioSante. Under the terms of the license agreement between the Company and BioSante, the Company received a portion of the up front payment made by Solvay to BioSante, net of the portion of the initial up front payment the Company received from BioSante intended to offset sublicense up front payments. The Company is also entitled to a portion of any milestone payments or royalties BioSante receives from Solvay under the sublicense agreement. The Company is recognizing the payment received from BioSante in revenue over an 108-month period. The Company received a \$200,000 milestone payment in January of 2003 and is recognizing revenue over a period of 91 months. All other milestone payments will be recognized ratably from the date the milestone payment is earned until the receipt of final regulatory approval in the U.S. and Canada.

#### *Solvay License Agreement*

In June 1999, the Company entered into an exclusive agreement to license one application of its gel based drug-delivery technology to Solvay Pharmaceuticals in all countries except the United States, Canada, Japan and Korea (collectively, the Solvay Territories). The Company is required to transfer technology know-how and to provide developmental assistance to Solvay until each country's applicable regulatory authorities approve the licensed product. Solvay will reimburse the Company for all technical assistance provided during Solvay's development. Solvay will use the licensed technology for the development of a hormone replacement therapy gel. The license agreement requires Solvay to pay the Company milestone payments of \$1,000,000 upon signing of the license, \$1,000,000 upon the start of Phase IIb/III clinical trials, as defined in the agreement, \$1,000,000 upon the first submission by Solvay to regulatory authorities in the Solvay Territories, and \$2,000,000 upon the first completed registration in either Germany, France or the United Kingdom. The Company will receive from Solvay a 5% royalty from the sale of licensed products. In 2002 the agreement was amended to change the terms associated with the second \$1,000,000 milestone payment, resulting in a payment of \$500,000 received in 2002, and two \$250,000 payments to be received upon satisfaction of certain conditions. Recently, development work performed by Solvay has been limited due to concerns about certain forms of hormone replacement therapy that have been debated in scientific literature.

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Under the cumulative deferral method, the Company ratably recognizes revenue related to milestone payments from the date of achievement of the milestone through the estimated date of the first completed registration in Germany, France or the United Kingdom. The Company is recognizing the first \$1,000,000 milestone payment over a period of 133 months, the \$500,000 received in 2002 over 99 months, and will recognize the two \$250,000

payments and the third \$1,000,000 payment from the date the milestone is earned until the estimated date of the first completed registration.

## 10. Segment Information and Significant Customers

The Company has one operating segment, drug delivery, which includes the development of drug delivery transdermal and transmucosal pharmaceutical products and drug delivery injection devices and supplies.

The geographic distributions of the Company's identifiable assets and revenues are summarized in the following tables:

The Company has operating assets located in two countries as follows:

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Switzerland	\$ 1,655,869	\$ 1,339,101
United States of America	9,878,614	4,827,263
	<b>\$ 11,534,483</b>	<b>\$ 6,166,364</b>

Revenues by customer location are summarized as follows:

	<b>For the Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
United States of America	\$ 1,939,802	\$ 511,567	\$ 491,014
Europe	1,856,847	1,215,814	1,866,359
Other	471,750	497,365	388,583
	<b>\$ 4,268,399</b>	<b>\$ 2,224,746</b>	<b>\$ 2,745,956</b>

The following summarizes significant customers comprising 10% or more of total revenue for the years ended December 31:

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Ferring	\$ 1,660,016	\$ 1,065,835	\$ 1,299,469
BioSante	1,038,339	161,021	289,031
JCR	163,193	258,949	161,097
Solvay	67,535	140,963	334,276

The following summarizes significant customers comprising 10% or more of outstanding accounts receivable as of December 31:

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	<b>2006</b>	<b>2005</b>
Ferring	\$ 273,381	\$ 65,304
Undisclosed	214,967	
Teva	155,083	
SciGen, Ltd.	72,852	56,118
Undisclosed		58,823



**11. Quarterly Financial Data (unaudited)**

	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
<b>2006:</b>				
Total revenues	\$ 636,660	\$ 859,095	\$ 756,624	\$ 2,016,020
Gross profit	315,172	427,871	436,926	1,532,460
Net loss applicable to common shares (2)	(2,404,014 )	(2,456,744 )	(1,924,867 )	(1,413,721 )
Net loss per common share (2)	(.05 )	(.05 )	(.04 )	(.03 )
Weighted average shares (1)	46,972,487	52,961,664	53,094,622	53,214,459
<b>2005:</b>				
Total revenues	\$ 554,385	\$ 492,425	\$ 443,978	\$ 733,958
Gross profit	246,897	224,100	144,096	472,908
Net loss applicable to common shares (2)	(2,272,872 )	(2,377,729 )	(1,976,629 )	(1,920,726 )
Net loss per common share (2)	(.06 )	(.06 )	(.05 )	(.05 )
Weighted average shares (1)	40,457,850	40,539,760	42,171,329	42,637,420

- (1) Loss per Common Share is computed based upon the weighted average number of shares outstanding during each period. Basic and diluted loss per share amounts are identical as the effect of potential Common Shares is anti-dilutive.
- (2) The net loss applicable to common shares and net loss per common share include a deemed dividend to warrant holders of \$99,500 in the first quarter of 2006 and preferred stock dividends of \$50,000 in the second quarter of 2005.

**12. Subsequent Event**

In February of 2007 the Company 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. The per annum interest rate is equal to the sum of the yield for three-year US treasury bills as quoted by Bloomberg, plus 800 basis points calculated (i) in the case of the first tranche, on the business day prior to the first funding date and (ii) in the case of the second tranche, on the business day prior to the second funding date (as such term is defined in the Credit Agreement). In addition, once set, the applicable interest rate for each tranche will be fixed for the applicable term. The maturity date (i) with respect to the first tranche is forty-two months from the first funding date and (ii) with respect to the second tranche is thirty-six months from the second funding date. The Company has pledged certain property as collateral, including all intellectual property. The credit agreement contains certain covenants and provisions that affect the Company, including, without limitation, covenants and provisions that:

restrict its ability to create or incur indebtedness (subject to enumerated exceptions);

restrict its ability to create or incur certain liens on its property (subject to enumerated exceptions);

in certain circumstances, require it to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least \$2,500,000;

in certain circumstances, restrict its ability to declare or pay any dividends on any shares of its capital stock, purchase or redeem any shares of its capital stock, return any capital to any holder of its equity securities or payment of certain bonuses;

restrict its ability to make certain investments.

In connection with the credit facility, the Company issued warrants to purchase a total of 640,000 shares of common stock at an exercise price of \$1.25, of which 240,000 will vest on the occurrence of the drawdown of the second tranche.



*Item 9 CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None

*Item 9A. CONTROLS AND PROCEDURES*

Disclosure Controls and Procedures.

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and is accumulated and communicated to management, including the Company's principal executive and principal financial officers, or person performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting.

There have not been any changes in the Company's internal control over financial reporting during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

*Item 9B. OTHER INFORMATION*

None

**PART III**

*Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Information required by this item concerning directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

Information required by this item concerning executive officers will be set forth under the caption "Executive Officers of the Company" in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the United States Securities Exchange Act of 1934, as amended, will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

Information required by this item concerning the audit committee of the Company, the audit committee financial expert of the Company and any material changes to the way in which security holders may recommend nominees to the Company's Board of Directors will be set forth under the caption "Corporate Governance" in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

The Board of Directors adopted a Code of Business Conduct and Ethics that is applicable to all employees and directors. We will provide copies of our Code of Business Conduct and Ethics without charge upon request. To obtain a copy, please send your written request to Antares Pharma, Inc., 250 Phillips Boulevard, Suite 290, Ewing, NJ 08618, Attn: Corporate Secretary. With respect to any amendments or waivers of this Code of Business Conduct and Ethics (to the extent applicable to the Company's chief executive officer, principal accounting officer or controller, or persons performing similar functions) the Company intends to either post such amendments or waivers on its website, [www.antaresspharma.com](http://www.antaresspharma.com), or disclose such amendments or waivers pursuant to a Current Report on Form 8-K.

*Item 11. EXECUTIVE COMPENSATION*

Information required by this item will be set forth under the caption "Executive Compensation" in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

*Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

Information required by this item concerning ownership will be set forth under the caption "Security Ownership of Certain Beneficial Owners and Management" in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

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The following table provides information for our equity compensation plans as of December 31, 2006:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans  (excluding shares reflected in the first column)
Equity compensation plans approved by security holders	4,426,759	\$ 1.65	3,745,242
Equity compensation plans not approved by security holders (1)	705,000	1.76	
Total	5,131,759	\$ 1.67	3,745,242

(1) Includes shares underlying warrants granted to various consultants as compensation for professional services.

*Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

Information required by this item will be set forth under the captions *Certain Relationships and Related Transactions* and *Corporate Governance* in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

*Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES*

Information required by this item will be set forth under the caption *Ratification of Selection of Independent Registered Public Accountants* in our definitive proxy statement for our 2007 annual meeting, and is incorporated herein by reference.

**PART IV**

*Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

(a) The following documents are filed as part of this report:

(1) Financial Statements - see Part II

(2) Financial Statement Schedules

Report of Independent Registered Public Accounting Firm on Financial Statement Schedule.

Schedule II Valuation and Qualifying Accounts.

All other schedules have been omitted because they are not applicable, are immaterial or are not required because the information is included in the financial statements or the notes thereto.

(3) Item 601 Exhibits - see list of Exhibits below

(b) Exhibits

The following is a list of exhibits filed as part of this annual report on Form 10-K.

Exhibit No.	Description
3.1	Certificate of Incorporation (Filed as an exhibit to Schedule 14A on March 18, 2005 and incorporated herein by reference.)
3.2	Bylaws (Filed as an exhibit to Schedule 14A on March 18, 2005 and incorporated herein by reference.)
4.1	Form of Certificate for Common Stock (Filed as an exhibit to Form S-1 on October 1, 1996 and incorporated herein by reference.)
4.2	Registration Rights Agreement with Permatec Holding AG dated January 31, 2001 (Filed as Exhibit 10.2 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
4.3	Securities Purchase Agreement dated July 7, 2003 (Filed as exhibit 10.48 to Form 8-K on July 9, 2003 and incorporated by reference.)
4.4	Form of Registration Rights Agreement dated July 7, 2003 (Filed as exhibit 10.49 to Form 8-K on July 9, 2003 and incorporated by reference.)
4.5	Voting Agreement, dated July 7, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P. and XMark Fund, Ltd. (Filed as exhibit 10.50 to Form 8-K on July 9, 2003 and incorporated by reference.)
4.6	Form of Warrant, dated July 7, 2003 (Filed as exhibit 10.51 to Form 8-K on July 9, 2003 and incorporated by reference.)
4.7	

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- Form of Securities Purchase Agreement dated July 17, 2003 (Filed as exhibit 10.52 to Form 8-K on July 22, 2003 and incorporated herein by reference.)
- 4.8 Form of Registration Rights Agreement dated July 17, 2003 (Filed as exhibit 10.53 to Form 8-K on July 22, 2003 and incorporated herein by reference.)
- 4.9 Form of Warrant, dated July 17, 2003 (Filed as exhibit 10.54 to Form 8-K on July 22, 2003 and incorporated herein by reference.)
- 4.10 Warrant Agreement with Eli Lilly and Company dated September 12, 2003 (Filed as exhibit 10.60 to Form 8-K on September 18, 2003 and incorporated herein by reference.)
- 4.11 Registration Rights Agreement with Eli Lilly and Company dated September 12, 2003 (Filed as exhibit 10.61 to Form 8-K on September 18, 2003 and incorporated herein by reference.)
- 4.12 Form of Securities Purchase Agreement dated February 10, 2004 (Filed as exhibit 10.62 to Form 8-K on February 10, 2004 and incorporated herein by reference.)
- 4.13 Form of Registration Rights Agreement, dated February 10, 2004 (Filed as exhibit 10.63 to Form 8-K on February 10, 2004 and incorporated herein by reference.)



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- 4.14 Form of Warrant Agreement, dated February 10, 2004 (Filed as exhibit 10.64 to Form 8-K on February 10, 2004 and incorporated herein by reference.)
- 4.15 Stock Purchase Agreement with Sicor Pharmaceuticals, Inc., dated November 23, 2005 (Filed as exhibit 10.55 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
- 4.16 Form of Common Stock and Warrant Purchase Agreement, dated February 27, 2006 (Filed as exhibit 10.57 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
- 4.17 Form of Investors Rights Agreement, dated March 2, 2006 (Filed as exhibit 10.58 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
- 4.18 Form of Common Stock Purchase Warrant, dated March 2, 2006 (Filed as exhibit 10.59 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
- 4.19 Form of Common Stock Purchase Warrant and Related Schedule of Holders and Other Terms (Filed as exhibit 4.7 to Form S-3/A Registration Statement on May 16, 2006 and incorporated herein by reference.)
- 4.20 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.)
- 4.21 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.)
- 4.22 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.)
- 4.23 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.)
- 10.0 Stock Purchase Agreement with Permaterc Holding AG, Permaterc Pharma AG, Permaterc Technologie AG and Permaterc NV with First and Second Amendments  
  
dated July 14, 2000 (Filed as an exhibit to Schedule 14A on December 28, 2000 and incorporated herein by reference.)
- 10.1 Third Amendment to Stock Purchase Agreement, dated January 31, 2001 (Filed as exhibit 10.1 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
- 10.2\* Agreement with Becton Dickinson dated January 1, 1999 (Filed as exhibit 10.24 to Form 10-K for the year ended December 31, 1998 and incorporated herein by reference.)
- 10.3+ 1993 Stock Option Plan (Filed as an exhibit to Form S-1 on October 1, 1996 and incorporated herein by reference.)
- 10.4+ Form of incentive stock option agreement for use with 1993 Stock Option Plan (Filed as an exhibit to Form S-1 on October 1, 1996 and incorporated herein by reference.)
- 10.5+ Form of non-qualified stock option agreement for use with 1993 Stock Option Plan (Filed as an exhibit to Form S-1 on October 1, 1996 and incorporated herein by reference.)
- 10.6+ 1996 Stock Option Plan, with form of stock option agreement (Filed as an exhibit to Form S-1 on October 1, 1996 and incorporated herein by reference.)
- 10.7 Amended and Restated 2001 Stock Option Plan for Non-Employee Directors and Consultants (Filed as exhibit 10.24 to Form S-8 Registration Statement on December 15, 2003.)
- 10.8 Amended and Restated 2001 Incentive Stock Option Plan for Employees (Filed as exhibit 10.25 to Form S-8 Registration Statement on December 15, 2003.)
- 10.9\* License Agreement with Solvay Pharmaceuticals BV, dated June 9, 1999 (Filed as exhibit 10.33 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)



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- 10.10\* License Agreement with BioSante Pharmaceuticals, Inc., dated June 13, 2000 (Filed as exhibit 10.34 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
- 10.11\* Amendment No. 1 to License Agreement with BioSante Pharmaceuticals, Inc., dated May 20, 2001 (Filed as exhibit 10.35 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
- 10.12\* Amendment No. 2 to License Agreement with BioSante Pharmaceuticals, Inc., dated July 5, 2001 (Filed as exhibit 10.36 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
- 10.13\* Amendment No. 3 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 28, 2001 (Filed as exhibit 10.37 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
- 10.14\* Amendment No. 4 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 8, 2002 (Filed as exhibit 10.38 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
- 10.15\* License Agreement between Antares Pharma, Inc. and Ferring, dated January 21, 2003 (Filed as exhibit 10.47 to Form 8-K on February 20, 2003 and incorporated herein by reference.)
- 10.16 Securities and Exchange Agreement, dated September 12, 2003 (Filed as exhibit 10.57 to Form 8-K on September 15, 2003 and incorporated herein by reference.)
- 10.17\* Development and License Agreement, dated September 12, 2003, with Eli Lilly and Company (Filed as exhibit 10.59 to Form 8-K on September 18, 2003 and incorporated herein by reference.)
- 10.18 Office lease with The Trustees Under the Will and of the Estate of James Campbell, Deceased, dated February 19, 2004 (Filed as exhibit 10.65 to Form 10-K for the year ended December 31, 2003 and incorporated herein by reference.)
- 10.19 Form of Indemnification Agreement, dated January 2, 2004, between Antares Pharma, Inc. and each of its directors and executive officers (Filed as exhibit 10.66 to Form 10-K for the year ended December 31, 2003 and incorporated herein by reference.)
- 10.20+ Employment Agreement, dated July 22, 2004, with Jack E. Stover (Filed as exhibit 10.0 to Form 10-Q for the quarter ended September 30, 2004 and incorporated herein by reference.)
- 10.21\* Development Supply Agreement, dated June 22, 2005 (Filed as exhibit 10.0 to Form 10-Q for the quarter ended June 30, 2005 and incorporated herein by reference.)
- 10.22\* License Development and Supply Agreement with Sicor Pharmaceuticals, Inc., dated November 23, 2005 (Filed as exhibit 10.54 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
- 10.23+ Senior Management Agreement by and between Antares Pharma, Inc. and Robert F. Apple, dated February 9, 2006 (Filed as exhibit 10.1 to Form 8-K on February 14, 2006 and incorporated herein by reference.)
- 10.24+ 2006 Equity Incentive Plan (Filed as exhibit 10.1 to Form 8-K on May 9, 2006 and incorporated herein by reference.)
- 10.25 Lease Agreement, dated as of May 15, 2006, between the Company and 250 Phillips Associates LLC (Filed as exhibit 10.2 to Form 10-Q for the quarter ended June 30, 2006 and incorporated herein by reference.)
- 10.26+ Employment agreement with Peter Sadowski, Ph.D., dated October 13, 2006 (Filed as exhibit 10.1 to Form 8-K on October 16, 2006 and incorporated herein by reference.)
- 10.27+ Employment agreement with Dario Carrara, dated October 13, 2006 (Filed as exhibit 10.2 to Form 8-K on October 16, 2006 and incorporated herein by reference.)
- 10.28+ Employment Agreement, dated February 14, 2005, with James Hattersley (Filed as exhibit 10.1 to Form 8-K on February 15, 2005 and incorporated herein by reference.)
- 10.29+ Amendment No. 1 to Employment agreement with James Hattersley, dated October 13, 2006 (Filed as exhibit 10.3 to Form 8-K on October 16, 2006 and incorporated herein by reference.)
- 14.1 Code of Business Conduct and Ethics (Filed as exhibit 14.1 to Form 10-K for the year ended December 31, 2003 and incorporated herein by reference.)
- 21.1 Subsidiaries of the Registrant
- 23.1 Consent of Independent Registered Public Accounting Firm (KPMG LLP)



31.1	Section 302 CEO Certification
31.2	Section 302 CFO Certification
32.1	Section 906 CEO Certification
32.2	Section 906 CFO Certification

- \* Confidential portions of this document have been redacted and have been separately filed with the Securities and Exchange Commission.
- + Indicates management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized, in the City of Ewing, State of New Jersey, on March 27, 2007.

**ANTARES PHARMA, INC.**

/s/ Jack E. Stover  
Jack E. Stover  
President and Chief Executive Officer

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities indicated on March 27, 2007.

**Signature**

**Title**

/s/Jack E. Stover  
Jack E. Stover

President, Chief Executive Officer and Director  
(principal executive officer)

/s/Robert F. Apple  
Robert F. Apple

Senior Vice President and Chief Financial Officer  
(principal financial and accounting officer)

/s/Dr. Jacques Gonella  
Dr. Jacques Gonella

Director, Chairman of the Board

/s/Thomas J. Garrity  
Thomas J. Garrity

Director

/s/Anton Gueth  
Anton Gueth

Director

/s/Dr. Rajesh Shrotriya  
Dr. Rajesh Shrotriya

Director

/s/Dr. Paul Wotton

Director

Dr. Paul Wotton

/s/Dr. Leonard Jacob  
Dr. Leonard Jacob

Director

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**Report of Independent Registered Public Accounting Firm on Financial Statement Schedule**

The Board of Directors and Shareholders

Antares Pharma, Inc.:

Under the date of March 26, 2007, we reported on the consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2006, as included in Antares Pharma, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2006. In connection with our audits of the aforementioned consolidated financial statements, we also audited the related consolidated financial statement schedule as listed in the accompanying index. This consolidated financial statement schedule is the responsibility of Antares Pharma, Inc.'s management. Our responsibility is to express an opinion on this consolidated financial statement schedule based on our audits.

In our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

Our report on the consolidated financial statements refers to the Company's adoption of the provisions of Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment, on January 1, 2006.

/s/ KPMG LLP

Minneapolis, Minnesota

March 26, 2007





## Antares Pharma, Inc.

## Schedule II

## Valuation and Qualifying Accounts

For the Years Ended December 31, 2006, 2005 and 2004

Description	Balance at Beginning of Year	Charged to Costs and Expenses	Deductions	Balance at End of Year
Year Ended December 31, 2006 Allowance for doubtful accounts (Deducted from accounts receivable)	\$ 20,800	\$ -	\$ 10,800	\$ 10,000
Year Ended December 31, 2005 Allowance for doubtful accounts (Deducted from accounts receivable)	22,500	6,173	7,873	20,800
Year Ended December 31, 2004 Allowance for doubtful accounts (Deducted from accounts receivable)	21,500	1,000	-	22,500