

ANTARES PHARMA INC
Form 10-K/A
August 24, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (D) OF
THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

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

Commission file number 0-20945

ANTARES PHARMA, INC.

(Exact name of registrant as specified in its charter)

Minnesota

41-1350192

State or other jurisdiction of incorporation or
organization

(I.R.S. Employer Identification Number)

707 Eagleview Boulevard, Suite 414, Exton, PA 19341
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code:

(610) 458-6200

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

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

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 an accelerated filer (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, 2004, was approximately \$25,682,223 (based upon the last reported sale price of \$0.89 per share on June 30, 2004, on the Over the Counter Market).

There were 40,493,606 shares of common stock outstanding as of March 1, 2005.

Explanatory Note

This Annual Report on Form 10-K/A is being filed principally to include in Exhibits 31.1 and 31.2 language which was previously inadvertently omitted therefrom.

PART I

Item 1. BUSINESS

Overview

Antares Pharma, Inc. (Antares or the Company) 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. These technologies are summarized and briefly described below.

Technology Platforms

Transdermal Drug Delivery

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 avoiding the initial gastrointestinal and liver uptake problems of some orally ingested drugs. The Company's gels consist of a hydro-alcoholic gel containing a combination of permeation enhancers to promote rapid drug absorption through the skin following application to the arms, shoulders, or abdomen. The Company's transdermal gel systems provide the options for delivery both systemically (penetrating into 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, effective on a sustained release basis over a 24-hour duration. The Company's gel systems, known as our Advanced Transdermal Delivery (ATD) gels are currently being developed in the following areas:

ATD Single Gels, which are being developed to incorporate hormonal formulations to deliver testosterone for the treatment of hypogonadism in men and low libido in women, as well as an estradiol gel to treat hot flashes and vaginal atrophy. The Company has also announced development results for the treatment of overactive bladder syndrome (OAB) with (AP-1034), its oxybutynin ATD gel.

2

ATD Combination Gels, Antares is currently developing two transdermal, combination gel products for hormone therapy (HT), one containing estradiol and testosterone and one containing estradiol with the progestin, norethindrone acetate.

The Company's licensee principally in North America, BioSante Pharmaceuticals, Inc. (BioSante) a developer of male and female HT products, recently announced successful Phase II results for LibiGel , a transdermal testosterone gel utilizing Antares' ATD gel for the treatment of female sexual dysfunction (FSD). Antares retains rights to the resulting clinical data of BioSante's LibiGel studies to enable the Company to file for approval to market in countries other than those licensed to BioSante. Antares is, therefore, exploring marketing alternatives for its own ATD testosterone gel product, possibly with marketing partners, in Europe and Japan. BioSante also has an estradiol gel (based on a license of Antares' ATD gel), known as Bio-E-Gel , currently in Phase III clinical trials in the U.S. Antares again retains rights to the resulting clinical data to enable it to file for approval to market in territories not licensed to BioSante. The Company has licensed a combination gel of estradiol and the progestin, norethindrone acetate, to BioSante and Solvay Pharmaceuticals B.V. (Solvay) for hormone therapy, under which Solvay is designing the Phase III clinical trials for the U.S. market. Another combination gel, estradiol and testosterone, has also been licensed to BioSante for development.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Antares has developed and licensed a topical ibuprofen gel, under non-royalty bearing agreements in 11 countries, including Russia, New Zealand, and Australia, and is exploring options for the Canadian and U.S. markets. This product or other nonsteroidal anti-inflammatory drugs (NSAIDs) in a gel form are being explored as an alternative that could benefit from the safety concerns related to cyclooxygenase 2 (COX-2) medications, such as Vioxx, and the resulting need for safe and effective pain medication alternatives.

Fast-Melt Oral Tablets

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 a key role in Antares' ability to target the pediatric market segment as well as the rapidly expanding geriatric market. Easy Tec tablets can be manufactured without specialized equipment and as the tablets are not effervescent (highly moisture sensitive), we believe it represents several significant processing and packaging advantages over conventional competitors. Our Easy Tec tablets may be of interest to pharmaceutical firms seeking line extensions in the marketplace and could also represent a key step in Antares' evolution into a specialty pharmaceutical company with its own products.

Injection Devices

Antares' injection device platform features three distinct products: reusable needle-free injectors, disposable mini-needle injectors, and its emerging 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® for use in more than 30 countries to deliver either insulin or human growth hormone (hGH). The Medi-Jector VISION employs a disposable plastic needle-free syringe, which offers high precision liquid medication delivery through an opening that is approximately half the diameter of a standard, 30-gauge needle. The product is available over-the-counter (OTC) or by prescription in the United States for use by patients with diabetes, and to date, we believe that more than 100 million such injections have been performed worldwide.

In September 2003, Antares entered into a collaborative agreement with Eli Lilly and Company (Lilly), under which Lilly has taken a license to develop and potentially market the Antares' reusable needle-free technology in the fields of diabetes and obesity and has an option to use the technology in one other smaller field on a worldwide basis. To date, most of the development activities under this agreement have been focused on improving the

3

Company's reusable needle-free injector and evaluating market opportunities. Lilly currently holds approximately 70% of the domestic insulin market.

Disposable mini-needle injectors (Vibex) employ the same basic technology developed for the Medi-Jector VISION. Combining a low-energy power 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 injection capabilities 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. Antares is also exploring opportunities to develop its own combination drug and device products incorporating the Vibex system.

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 method 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, Antares Pharma, Inc. (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. Upon consummation of the transaction, the acquired Permaterc subsidiaries were renamed Antares Pharma AG, Antares Pharma IPL AG and Permaterc NV. Prior to the closing of the business combination, the Company did not have sufficient funds to continue operating and had determined that it was necessary to, among other things, either raise more capital or merge with another biopharmaceutical company. Medi-Ject was a company focused on 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. Given that both groups were focused on delivering drugs across the skin, 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 shareholders. The transaction was accounted for as a reverse acquisition, as Permaterc's shareholders initially held approximately 67% of the outstanding stock of Antares. Accordingly, for accounting purposes, Permaterc is deemed to have acquired Medi-Ject. Upon completion of the transaction the Company's name was changed from Medi-Ject Corporation to Antares Pharma, Inc.

From inception as a combined business entity, the Company had fifty-three employees with thirty-five research and development personnel, engineers, formulation chemists and technicians, engaged in designing, formulating and developing new products for the pharmaceutical industry. As of March 1, 2005, the Company has twenty-seven full-time and four part-time employees.

The U.S. 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 without using a needle. The Company makes a small reusable spring-action device and the attached disposable plastic needle-free syringes to hold the drug, known as the Medi-Jector VISION®. Using an adapter, the liquid drug is drawn from a conventional vial into the 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 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 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 weighs five ounces. Today's insulin injector sells at a retail price of \$335 compared to \$799 eight years ago. The first growth hormone

4

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.

Antares is committed to other methods of drug delivery such as topical gel formulations. The Company believes that transdermal gels have advantages in cost, cosmetic elegance, ease of application and lack of irritancy compared with better-known transdermal patches and have applications in such therapeutic markets as hormone replacement therapy, osteoporosis therapy, cardiovascular therapy, pain management and central nervous system therapy. This drug delivery method is now a material part of the Company's business moving forward.

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 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 announced development results for AP-1034, its oxybutynin gel for OAB. The fast-melt tablet effort resulted in patents being issued in 2004 in the U.S. and Europe.

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 views pharmaceutical and biotechnology companies as 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

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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. Antares has also announced its plans to develop its own products using its gel and fast-melt technology platforms and is exploring developing its own combination drug and device products with its disposable mini-needle injection technology platform.

The Company is a Minnesota corporation incorporated in February 1979. Principal executive offices are located at 707 Eagleview Boulevard, Exton, Pennsylvania 19341; telephone (610) 458-6200. 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 previous experience in the industry, the Company believes the following significant trends in healthcare have important implications for the growth of its business.

After a drug loses patent protection, the branded version of the drug often faces competition from generic alternatives. It is 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 pharmaceutical manufacturers will continue to seek differentiating 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 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 against other major companies or generic competition.

The increasing trend of pharmaceutical companies marketing directly to consumers, as well as the recent 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 topical gels, fast-melt tablets and jet injection technologies meet these market needs.

5

The Company envisions its program with topical gel formulations as a second-generation technology, replacing the older transdermal patch products with more patient-friendly products. Topical gels offer patients more choices and added convenience with no compromise of efficacy. Although newer, 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 destroyed in the gastrointestinal tract and may only be administered through the skin, the lung or by injection. Pulmonary delivery is complex and has not yet been commercialized for therapeutic proteins intended for systemic delivery. Injection remains the mainstay of protein delivery. Therefore, 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 syringe needles require special and often costly disposal methods.

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, 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 an alternative 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 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. In the past, the Company had focused only upon the injection of medication in the home, but in 2000 the Company began to research the feasibility of using its devices for vaccines and new vaccine ingredients and is currently seeking collaboration with vaccine companies to support development of this application.

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

Drug delivery companies that compete with our technologies include Bioject Medical Technologies, Inc., Bentley Pharmaceuticals, Inc., Aradigm, Cellegy Pharmaceuticals, Inc., Cardinal Health, CIMA Laboratories, Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc. and Novavax, Inc., along with other companies. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing.

6

According to one industry publication, worldwide hormone replacement revenues, the initial focus of the Company's transdermal gel formulation program, were expected to grow to \$12.7 billion by 2005. Further growth in this sector may be achieved by the use of testosterone products in both male and female applications. 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 that affects an estimated 30-50% of women and for which no drug is currently approved in the U.S. Antares Pharma, along with its U.S. partner BioSante, has a testosterone product in clinical trial for FSD. 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. According to an industry report, 64.8% of treated menopausal women in France used either patch (44.7%) or gel (20.1%) therapy. It has also been suggested that the more physiological blood levels achieved when hormones are delivered across the skin may offer some advantage over oral therapy although currently there is no long-term evidence to support this contention. 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.

According to industry sources, oral drug delivery systems represented a \$28 billion worldwide market in 2002 with fast-dissolving dosage forms being in excess of \$1 billion of this market with a growth rate of more than 20% per year. There have been approximately 80 fast-dissolving dosage forms launched. This 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 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.

According to industry sources, an estimated 9 to 12 billion needles and syringes are sold annually worldwide. The Company believes that a significant portion of these 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 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. The Company's largest customer is a pharmaceutical company (Ferring BV), and one of the Company's major competitors, Bioject Medical Technologies, Inc., has a pharmaceutical company (Serono) as its largest customer. Greystone Associates (www.greystoneassociates.org) in 2003 estimated that the needle-free injection market in the U.S. would grow from \$10.2 million in 2002 to \$425 million by 2007, of which self-administration of insulin is expected to account for 54% of the total market. In 2003, Antares licensed its needle-free injection technology to Eli Lilly and Company for use in the fields of diabetes and obesity.

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 the delivery of insulin for patients with diabetes and human growth hormone for children with growth retardation. In the U.S., over 3.2 million people inject insulin for the treatment of diabetes, resulting in an estimated 2.3 billion injections annually, and 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. 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 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. It is estimated that there will be 190

7

biotechnology injectable drugs on the market in 2005, compared with 80 in 2000 and ten in 1990. 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® (Amgen, Wyeth) for treatment of rheumatoid arthritis, Aranesp® (Amgen) for treatment of anemia, Kineret® (Amgen) for rheumatoid arthritis, Forteo (Lilly) for treatment of osteoporosis, Intron® A (Schering Plough) and Roferon® (Roche) for hepatitis C, Lantus® (Aventis Pharma) for diabetes, Rebif® (Serono) for multiple sclerosis, Copaxone® (Teva) for multiple sclerosis and Gonal-F® for fertility treatment. 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 tablets (Easy Tec); disposable mini-needle injection systems (Vibex); and reusable needle-free injection systems (Medi-Jector VISION and Valeo).

Transdermal Drug Delivery

Transdermal drug delivery has emerged as a 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 are not 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 avoids 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 (Advanced Transdermal Delivery) 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. A summary of the benefits of transdermal gels is provided below.

Benefits of Transdermal Gels

- 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 Advanced Transdermal Delivery (ATD) System

Antares Advanced Transdermal Delivery (ATD) system has produced two transdermal drug delivery gels, both of which have demonstrated the ability to successfully penetrate 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 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 possess a distinct cosmetic advantage over other approaches. The following sections provide an overview of Antares ATD Single Gels and ATD Combination Gels.

ATD Single Drug Gels

Antares ATD single gels are single-drug transdermal gels that have demonstrated potential in a variety of therapeutic areas. Current ATD single drug gels in advanced development encompass a testosterone gel for men to treat hypogonadism, an estrogen gel for women to treat vasomotor symptoms associated with menopause, a low dose testosterone gel to treat low libido in women and an oxybutynin gel to treat overactive bladder syndrome (OAB). 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 several central nervous system (CNS) disorders, 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 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.

ATD Combination Drug Gels

Antares has also developed a transdermal combination gel product currently used in HT. This formulation has demonstrated the ability to deliver the following combinations of active agents as a means of HT, along with additional agents:

- Estradiol + Norethindrone Acetate;
- Estradiol + Testosterone;
- Estradiol + Levonorgestrel; and
- Ethinyl Estradiol + Levonorgestrel.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Currently the Company has ATD combination drug gels in advanced development with partners for HT including an estradiol/progestin combination product and estradiol/testosterone combination product.

Oral Delivery

Oral delivery remains the preferred method of dosage, with the majority of all drugs administered. Despite this method's widespread popularity, there remain limitations for those patients who have difficulty swallowing conventional oral dosage forms or where an underlying disease (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 any 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 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. Over 80 such products are currently marketed and generate sales in excess of \$1 billion per year with growth rates projected at 20% per year.

Antares Easy Tec Fast-Melt Technology

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 that no unique packaging requirements are necessary. The Company also believes that Easy Tec possesses several other key advantages over competing fast-melt technologies; all of these advantages are listed below.

10

Easy Tec Competitive Advantages

- High drug dose loading is possible
- Friability within pharmaceutical specifications
- No need for special packaging
- 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
- Low cost of goods
- Uses conventional manufacturing equipment
- No specific facility required, compared to effervescent products
- Compendial and CFR listed excipients

Fast-melt technology has proven attractive to customers in both OTC and prescription product fields. Current market leadership is held by Cardinal Health's Zydis technology followed by CIMA's (now part of Cephalon Inc. DuraSolv technology. Marketed products include those for CNS disorders (for example, Zyprexa Zydis® from Eli Lilly and Company), and several products aimed at the treatment of gastrointestinal disorders.

In addition to being easy to take, such products are perceived as being fast acting because of rapid dispersion in the mouth. 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 and plans on filing, to seek market approval, with the Food and Drug Administration (FDA) sometime in 2005.

Needle-Free Injection

Needle-free injection is an emerging form of parenteral drug delivery that is also gaining 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.

The future product portfolios of most pharmaceutical and biotechnology companies will contain a significant proportion of proteins and peptides derived from the so-called biotechnology revolution that began in the 1980s. This first generation of such products were bio-identical to natural proteins (for example, insulin and hGH) while future generations are expected to be novel macromolecules with construction based upon an understanding of specific targets supported by advanced research, such as that of the human genome project.

It is currently estimated that 350 biotechnology molecules are in clinical development. The most significant challenge beyond discovery of such molecules is how to effectively deliver them by means other than conventional injection technology. The majority of these molecules are not amenable to oral administration due to a combination of several factors, including breakdown in the gastrointestinal tract, fundamentally poor absorption, or high first pass metabolism. Many 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.

Improving patient comfort through needle-free injection increases compliance and mitigates the problem of daily injections. Needle-free delivery eliminates the risk of needlestick injuries as well, which occur approximately 800,000 times annually 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 Compliance Directive in November 1999 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.

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 of injection and the lack of requirement for needle disposal.

Status of Existing Needle-Free Injection Devices On the Market and In Development

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. In spite of the relative minor market penetration within this sector to date, in June 2003, Greystone Associates predicted that the needle-free injection market would grow from \$10.2 million in 2002 to \$425 million by 2007 with 54% of these sales being insulin-based.

Several other companies are actively developing disposable, needle-free devices, reflecting the interest in this sector. These companies include BioValve, Aradigm Corp., Visionary Medical Products and Crossject. None of the products from these companies have yet been commercialized, but such products, if and when commercialized, could compete with Antares injection devices systems and/or its next generation of injection devices, which are in various stages of development. Other companies, such as The Medical House and Bioject, have

products in the marketplace and currently compete with Antares.

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.

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 permits variable dosing at the time of administration and has a maximum dosage volume of 0.5 ml per injection in 0.01 ml increments. 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.

12

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

Insulin Delivery

The Medi-Jector VISION® is primarily used in the U.S. to provide a needle-free means of administering insulin to patients with diabetes. The potential market for insulin injector products is significant. The World Health Organization (WHO) estimated the worldwide prevalence of patients with diabetes to be more than 170 million in 2000, expected to increase to more than 360 million by 2030. Of this population, approximately 40%, or 68 million patients require insulin. Within the U.S., WHO estimated 17.7 million people with diabetes in 2000, and the Centers for Disease Control reported that approximately 18% of patients with diabetes (more than 3 million) used insulin in 2002.

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® 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.

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

In addition to the Medi-Jector VISION®, Antares is also developing a new 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 produced. The maximum dosage volume is 0.3 ml per injection in 0.01 ml increments. Medi-Jector Valeo has been licensed worldwide to Eli Lilly and Company for use with its portfolio of diabetes and anti-obesity products.

Vibex Pre-filled, Disposable Mini-Needle Injector

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Beyond Antares 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.

In order to minimize the anxiety and perceived pain associated with injection-based technologies, the Vibex disposable mini-needle injector features a protective collar that shields the needle from view. The 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 unique benefits of the Vibex disposable mini-needle product is provided below.

13

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 to the intradermal and 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 the individual administering the injection, and providing for a more comfortable means of vaccine delivery.

Patents

When appropriate, the Company actively seeks protection for its products and proprietary information by means of U.S. and international patents and trademarks. With the injection device technology, the Company currently holds 24 patents and has an additional 74 applications pending in the U.S. and other countries. With the Company's topical delivery technologies, it holds five patents, and an additional 30 applications in various countries are pending. The patents have expiration dates ranging from 2013 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. Ownership of intellectual property developed under the Lilly Development and License Agreement will be governed by U.S. laws of inventorship except that intellectual property relating to compounds, which is assigned to Lilly.

Manufacturing

The Company is responsible for a U.S. device manufacturing facility 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. Final quality control is performed by the Company.

The Company continues to have responsibility for the manufacturing of the product including the quality of all products and the release of all products produced by the supplier. The outsourcing agreement had an initial term of two years and continues with a six-month termination notice available to either party.

Manufacturing

The Company pays Becton Dickinson royalties on sales of plastic components of certain injector systems. Such royalties will continue until the expiration of the last patent covering such plastic components.

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.

Marketing

The Company expects to market most of its products through the existing distribution systems of pharmaceutical and medical device companies while continuing direct-to-consumer marketing of its insulin injection devices and related disposable elements in the U.S.

During 2004, 2003 and 2002, international revenue accounted for 82%, 77% and 59% of total revenue, respectively. Europe (primarily Germany) accounted for 83%, 95% and 96% of international revenue in 2004, 2003 and 2002, respectively, with the remainder coming primarily from Asia. Ferring accounted for 47%, 62% and 49% of the Company's worldwide revenues in 2004, 2003 and 2002, respectively. BioSante Pharmaceuticals, Inc. accounted for 11%, 14% and 30% of the Company's worldwide revenues in 2004, 2003 and 2002, respectively. Revenue from Ferring 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.

Transdermal Delivery Products

Over the short term, the majority of revenues generated from topical drug formulation will continue to be through the fees generated by licensing and development agreements.

The following table describes existing pharmaceutical relationships in the transdermal delivery sector.

Pharmaceutical Company Partner	Compound	Market Segment	Technology
Solvay	Estradiol/NETA	Hormone replacement therapy (Worldwide, excluding North America, Japan and Korea)	ATD Gel
Solvay (sublicense agreement through BioSante)	Estradiol/NETA	Hormone replacement therapy (North America)	ATD Gel
BioSante	Estradiol	Hormone replacement therapy	ATD Gel
BioSante	Testosterone	Male and female sexual dysfunction, Male hypogonadism (North America, other countries)	ATD Gel
BioSante	Estradiol/Testosterone	Combination of HT and FSD (North America, other countries)	ATD Gel

The agreements in the table are license agreements under which the Company's partners are conducting clinical evaluation and development of the Company's transdermal products. For competitive reasons, the Company's partners may not divulge the exact stage of clinical development. The Company's two major agreements are with Solvay Pharmaceuticals and BioSante Pharmaceuticals, Inc. Under the Company's June 1999 agreement with Solvay, 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. Once 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.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

In June 2000, the Company granted an exclusive license to BioSante to allow 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 August 2001, BioSante entered into an exclusive agreement with Solvay 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 which included a \$200,000 milestone payment in January of 2003.

Injection Devices

The Company markets needle-free injectors for insulin and growth hormone delivery through pharmaceutical companies and medical products distributors worldwide. Device and related disposable product sales in 2004 were approximately \$1.8 million. Historical product development alliances have generated licensing and development fees and eventually sales of product.

Ferring is selling human growth hormone throughout Europe with a marketing campaign tied to the Antares needle-free delivery system. Ferring has been successful in establishing a user base of more than 3,000 children for its drug using the Antares needle-free system. In the Netherlands, where Ferring enjoys its largest market share, we understand that 22% of children taking growth hormone use Antares injector. During the past six years, a Japanese pharmaceutical company, JCR, has distributed small numbers of growth hormone injectors to hospital-based physicians in Japan. In 2004, JCR initiated a larger scale campaign to broaden its marketing efforts with our injector. In 1999, SciGen Pte Ltd. began distribution in Asia of Antares growth hormone injectors along with its drug, and in 2004 Shreya Life Sciences initiated a test market evaluation that resulted in limited distribution in India with insulin.

The table below summarizes the Company's current collaborative and distribution/supply agreements in the injection device sector.

Company	Market
Eli Lilly and Company	Development and license agreement Needle-free delivery Diabetes and Obesity plus an option for another therapeutic market (worldwide)
Wal-Mart Stores, Inc.	Insulin Distribution (United States)
Ferring BV	Growth Hormone (Europe)
JCR Pharmaceuticals Co., Ltd.	Growth Hormone (Japan)
SciGen Pte Ltd.	Growth Hormone (Asia/Pacific)
drugstore.com	Insulin Distribution E-Commerce (United States)
Care Service, Inc. (Diabetic Express)	Insulin Distribution E-Commerce (United States/Canada)

16

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 three distribution/supply agreements under which the distributors/suppliers sell the Company's injection devices and related disposable components for use with insulin.

Under the Company's growth hormone agreements, the Company sells its injection devices to partners who manufacture and/or market human growth hormone directly. The partners then market the Company's devices with human growth hormone. The Company typically receives

benefits from these agreements in the form of manufacturing margins and royalties on end-sales of the partner's products.

On January 22, 2003, the Company entered into a 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, 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 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, perpetual, 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 AJ-1 device in a specified field.

Under the Company's December 1993 agreement with Ferring, the Company granted Ferring exclusive rights to use and market, throughout Europe and the former Soviet Union, the Company's reusable needle-free injection device for use with the administration of human growth hormone. Under the agreement, Ferring was required to pay the Company upon the occurrence of certain events, such as completion of certain clinical studies and receipt of regulatory approvals. The Company has received all such payments, and currently, the Company receives payments from Ferring for injectors and disposables supplied to Ferring. Unless Ferring exercises its option to renew the agreement for two-year periods, the agreement will terminate ten years following Ferring's receipt of technical and regulatory approvals to market the Company's injector devices in France, Germany, Italy and Spain. The last of such approvals was received December 1996. In 2004, 2003 and 2002, revenue from Ferring accounted for 62%, 82%, and 59%, respectively, of the Company's product sales. In 2004, revenue from JCR Pharmaceutical Co., Ltd and SciGen, Pte. Ltd. accounted for 9% and 13% of the Company's product sales, respectively, and in 2003 and 2002, revenue from these two companies accounted for 5% or less of product sales.

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, had been recorded as deferred revenue and will be credited against the royalties owed by Ferring, until such amount is exhausted. During 2004, \$80,335 of the deferred revenue royalty fee was recorded as revenue. 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.

Over the past few years, the Company has taken several steps to increase its U.S. insulin injector distribution. As a result, in March 2001, the Company granted non-exclusive U.S. distribution rights to Diabetic Express, a division of Care Services, Inc. Antares has concluded that the successful distribution of insulin devices will require additional physician support and the marketing power of a major insulin manufacturer. However, the Company's current effort will continue because its devices provide a vital service to certain patients and provide the Company with considerable information regarding the needs of people required to self-administer drugs by injection.

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 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, which option was extended on December 16, 2004, for a currently unnamed therapeutic area.

Competition

Competition in the pharmaceutical formulation sector is considerably large, 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. and Novavax, Inc. Competition in the fast-melt market includes Eurand, CIMA Labs, Inc., Cardinal Health and Yamanouchi Pharmaceutical Co., Ltd. Competition in the disposable, single-use injector market includes, but is not limited to, OwenMumford Ltd., The Medical House and Innoject, Inc., while competition in the reusable needle-free injector market includes Bioject Medical Technologies Inc. and The Medical House. Most of these companies have substantially greater capital resources, more experienced research teams, larger facilities and a broader range of products and technologies.

Competition in the injectable drug delivery market is intensifying. The Company faces competition from traditional needle syringes, 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 vast 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

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

companies, the Company's competitive position will depend upon the competitive position of the pharmaceutical company with which it collaborates for each drug application.

At least two companies currently sell injectors to the U.S. insulin market. Antares believes that it retained the largest market share in 2004, and competes on the basis of device size, price and ease of use. Equidyne, Inc. entered the worldwide insulin injector market in mid-2000 but was no longer operating in this area as of late 2003. Aradigm acquired the Weston medical injector technology and has financial resources to be a formidable competitor.

PowderMed Ltd (formerly Powderject Pharmaceuticals, plc), a British immunotherapeutics company, is developing a needle-free injection system based upon the principle of injecting a fine dry powder. Bioject and Powderject compete actively and successfully for licensing agreements with pharmaceutical manufacturers. Powderject has recently refocused exclusively on the use of its technology for vaccine delivery and licensed its technology for therapeutic applications to AlgoRx, a United States company.

The Company expects the needle-free injection market to expand, even though improvements continue to be made in needle syringes, including syringes with hidden needles and pen-like needle injectors. The Company expects to compete with existing needle injection methods as well as new delivery methods yet to be commercialized. For example, Nektar Therapeutics, in partnership with Pfizer, Inc. and Aventis Pharmaceuticals, has completed Phase III clinical testing of inhaled insulin that, if successful, could replace the use of injection for some patients, and in early March 2005, the companies announced the filing of a New Drug Application (NDA) in the U.S.

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, manufacture operations, quality, labeling, distribution, marketing, export, storage, record keeping, event reporting, advertising and promotion of pharmaceutical products and medical devices. Facilities and certain company records are also subject to FDA inspections. 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.

18

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.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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 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 vigorous statistical analysis. 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,

19

manufacturers, including a drug sponsor's third-party contract manufacturers, 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.

An 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.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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.

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.

We believe we are currently in compliance with cGMP regulations.

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

20

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 may not be commercially distributed in the United States unless they have been found substantially equivalent to a marketed product or approved by the FDA, unless otherwise exempted from the FD&C Act and regulations thereunder. There are two methods for obtaining such clearance or approvals. 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. The Company believes that injection systems, when indicated for use with drugs or biologicals approved by the FDA, will be regulated as medical devices and are eligible for clearance through the 510(k) notification process. There can be no assurance, however, that the FDA will not require a PMA in the future.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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 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*® 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

21

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 is 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.

In the European Union, a drug delivery device that is an integral combination with the drug to be delivered is considered part of the medicinal product and is regulated as a drug. Gels are drug delivery devices which are, therefore, regulated as drugs and must comply with the requirements described in the Council Directive 65/65/EEC.

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. For example, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, the privacy provisions of the Health Insurance Portability and Accountability Act, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements may apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. In addition, our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds the handling and disposal of which are governed by various state and federal 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 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. 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 9001:2000 qualification for its manufacturing systems. This certification shows that the Company's procedures and manufacturing facilities comply with standards for quality assurance, design capability and manufacturing process control. Such certification, along with European Medical Device Directive certification, evidences compliance with the requirements enabling the Company to affix the CE Mark to current products. The CE Mark denotes conformity with European standards for safety and allows certified devices to be placed on the market in all European Union countries. Semi-annual audits by the Company's notified body, British Standards Institute, are required to demonstrate continued compliance. The Company has initiated the revisions to its quality system to comply with ISO 13485:2003, the newly released medical device industry standard.

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) gel. This allows the Company to produce clinical trial materials and related packaging as well as production of intermediate products and end-user medicaments.

Forward Looking Statements

Antares and its representatives may from time to time make written or oral forward-looking statements with respect to its annual or long-term goals, including statements contained in its filings with the Securities and Exchange Commission and in reports to shareholders.

The words or phrases "will likely result," "are expected to," "will continue to," "is anticipated," "estimate," "project," "may," "should," "plans," "predicts," "intends," "potential or continue" or similar expressions identify forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical earnings and those presently anticipated or projected. Antares cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date made.

In connection with the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, Antares is identifying the important risk factors below that could affect its financial performance and could cause its actual results for future periods to differ materially from any opinions or statements expressed with respect to future periods in any current statements.

The Company undertakes no obligation to publicly revise any forward-looking statements to reflect future events or circumstances.

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 Business

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

We had working capital of \$8,489,253 at December 31, 2004, and \$615,371 at December 31, 2003. We incurred net losses of (\$8,348,532) and (\$32,817,964) in the fiscal years ended 2004 and 2003, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2004 of (\$82,575,151). 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 completed three private placements in February and March 2004 in which we received aggregate gross proceeds of \$15,120,000. We believe that the combination of these equity financings and projected product sales and product development and license revenues could provide us with sufficient funds to support operations for the near future. 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 and with the required quality;
- our ability to increase manufacturing capacity to allow for new product introductions;
- the level of product competition and of price competition;
- our ability to develop, maintain or acquire patent positions;
- our ability to develop additional commercial applications for our products;
- our limited regulatory and commercialization experience;
- our reliance on outside consultants as a virtual pharma company;
- 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 technologies to move into the marketplace. We may not make the correct choice of drug or technologies when combined with a drug, which may not be accepted by the marketplace as we expected or at all. FDA approval processes for the drugs and drugs with devices may be longer in time and/or more costly and/or require more extended clinical evaluation than anticipated. Funds required to bring our own products to market may be more than anticipated or may not be available at all. We have limited experience in development of compounds and in regulatory matters and bringing such products to market; therefore, we may experience difficulties in making this change or not be able to achieve the change at all.

24

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 fiscal 2004, we derived approximately 47%, 12% and 11% of our revenue, respectively, from the following three customers:

- Ferring BV
- Solvay Pharmaceuticals
- BioSante Pharmaceuticals, Inc.

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

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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

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

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

Our past assembly, testing and manufacturing experience for certain of our technologies has involved the assembly of products from machined stainless steel and composite components in limited quantities. Our planned future drug delivery technologies necessitate significant changes and additions to our manufacturing and assembly process to accommodate new components. These systems must be manufactured in compliance with regulatory requirements, in a timely manner and in sufficient quantities while maintaining quality and acceptable manufacturing costs. In the course of these changes and additions to our manufacturing and production methods, we may encounter difficulties, including problems involving yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment, component supplies and shortages of personnel, any of which could result in significant delays in production. Additionally, in February 2003, we entered into a manufacturing agreement under which a third party will assemble our MJ7 devices and certain related disposable component parts. There can be no assurance that 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 will also need to outsource manufacturing of our AJ products to third parties. Such products will be price sensitive and may be required to be manufactured in large quantities, and we have no assurance that this can be done.

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

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

advantages over alternative drug delivery systems or similar products from other companies;

25

demonstrated clinical efficacy, safety and enhanced patient compliance;
cost-effectiveness;
convenience and ease of use of injectors and transdermal gels; and
marketing and distribution support.

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

A 2002 National Institute of Health (NIH) study and the 2003 findings from the Million Women Study first launched in 1997 in the U.K. questioned the safety of hormone replacement therapy for menopausal women, and our female hormone replacement therapy business may suffer as a result

In July 2002, the NIH halted a long-term study, known as the Women's Health Initiative, being conducted on oral female hormone replacement therapy (HRT) using a combination of estradiol and progestin because the study showed an increased risk of breast cancer, heart disease and blood clots in women taking the combination therapy. The arm of the study using estrogen alone was stopped in March 2004 after

the NIH concluded that the benefits of estrogen did not outweigh the stroke risk for women in this trial. The halted study looked at only one brand of oral combined HRT and of estrogen, and there is no information on whether brands with different levels of hormones would carry the same risk. In January 2003, the FDA announced that it would require new warnings on the labels of HRT products, and it advised patients to consult with their physicians about whether to continue treatment with continuous combined HRT and to limit the period of use to that required to manage post-menopausal vasomotor symptoms only. Subsequently, additional analysis from the NIH study has suggested a slight increase in the risk of cognitive dysfunction developing in patients on long-term combined HRT. The Million Women Study, conducted in the U.K., confirmed that current and recent use of HRT increases a woman's chance of developing breast cancer and that the risk increased with duration of use. Other HRT studies have found potential links between HRT and an increased risk of dementia and asthma. These results and recommendations impacted the use of HRT, and product sales have diminished significantly. We cannot yet assess the impact any of the studies results may have on our contracts or on our partners' perspective of the market for transdermal gel products designed for HRT. We also cannot predict whether our alternative route of transdermal administration of HRT products will carry the same risk as the oral products used in the study.

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

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

We rely on third parties to supply components for our products, and any failure to retain relationships with these third parties could negatively impact our ability to manufacture our products

Certain of our technologies contain a number of customized components manufactured by various third parties. Regulatory requirements applicable to medical device 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.

26

We may be unable to successfully expand into new areas of drug delivery technology, which could negatively impact our business as a whole

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

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

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

As health insurance companies and other third-party payors increasingly challenge the products and services for which they will provide coverage, our individual consumers may not be able to receive adequate reimbursement or may be unable to afford to use our products, which could substantially reduce our revenues and negatively impact our business as a whole

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

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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.

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

One of our business pathways requires us to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use and marketing of drug delivery technologies with specific drug therapies. Under these arrangements, the partner company typically assists us in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. Our licensees may also be responsible for distribution and marketing of the technologies for these drug therapies either worldwide or in specific territories. We are currently a party to a number of such agreements, all of which are currently in varying stages of development. We may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product) and thus, would not receive the fees expected from such arrangements or related future royalties. Moreover,

27

there can be no assurance that we will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of our drug delivery technologies. In such event, our business, results of operations and financial condition could be adversely affected, and our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability. As a result of our collaborative agreements, we are dependent upon the development, data collection and marketing efforts of our licensees. The amount and timing of resources such licensees devote to these efforts are not within our control, and such licensees could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales of our drug delivery technology.

The failure of any of our third-party licensees to develop, obtain regulatory approvals for, market, distribute and sell our products as planned may result in us not meeting revenue and profit targets

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

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

Additional competitors in the needle-free injector market, some with greater resources and experience than us, may enter the market, as there is an increasing recognition of a need for less invasive methods of injecting drugs. Additionally, there is an ever increasing list of competitors in the oral disintegrating fast-melt tablet business. Similarly, several companies are competing in the transdermal gel market. Our success depends, in part, upon maintaining a competitive position in the development of products and technologies in rapidly evolving fields. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical company partners may choose to adopt the drug delivery technologies of our competitors. Drug delivery companies that compete with our technologies include Bioject Medical Technologies, Inc., Bentley Pharmaceuticals, Inc., Aradigm, Cellegy Pharmaceuticals, Inc., Cardinal Health, CIMA Laboratories, Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc. and Novavax, Inc., along with other companies. We also compete generally with

other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do, and, therefore, represent significant competition.

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

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

28

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.

Currently, we have been granted 29 patents and an additional 104 applications pending in the U.S. and other countries. Any patent applications we may have made or may make relating to inventions for our actual or potential products, processes and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for our inventions. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain their own patents that may have an adverse effect on our ability to conduct business, or are able to otherwise circumvent our patents. Further, we may not have the necessary financial resources to enforce or defend our patents or patent applications.

To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with employees, consultants and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully and independently develop the same or similar information.

Others may bring infringement claims against us, which could be time-consuming and expensive to defend

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

If the pharmaceutical companies to which we license our technologies lose their patent protection or face patent infringement claims for their drugs, we may not realize our revenue or profit plan

The drugs to which our drug delivery technologies are applied are generally the property of the pharmaceutical companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical companies or third parties. If those patents or other forms of protection expire, become ineffective or are subject to the control of third parties, sales of the drugs by the collaborating pharmaceutical company may be restricted or may cease. Our expected revenues, in that event, may not materialize or may decline.

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

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

Applicants for FDA approval often must submit extensive clinical data and supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new drug application also may cause delays or rejection of an approval. Even if the FDA approves a product, the approval may limit the uses or indications for which a product may be marketed, or may

29

require further studies. The FDA also can withdraw product clearances and approvals for failure to comply with regulatory requirements or if unforeseen problems follow initial marketing.

In other jurisdictions, we, and the pharmaceutical companies with whom we are developing technologies, must obtain required regulatory approvals from regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market the products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues may not materialize or may decline. We may not be able to obtain all necessary regulatory approvals. We may be required to incur significant costs in obtaining or maintaining regulatory approvals.

Our business could be harmed if we fail to comply with regulatory requirements and, as a result, are subject to sanctions

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

- warning letters;
- fines;
- product seizures or recalls;
- injunctions;
- refusals to permit products to be imported into or exported out of the applicable regulatory jurisdiction;
- total or partial suspension of production;
- withdrawals of previously approved marketing applications; or
- criminal prosecutions.

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

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

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

The testing, manufacturing and marketing of products utilizing our drug delivery technologies may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical companies with whom we are developing drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or may not be sufficient to reimburse us, for any expenses or

losses that may have been suffered. A successful product liability claim against us, if not covered by, or if in excess of our product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations. Adverse claim experience for our products or licensed technologies or medical device, pharmaceutical or insurance industry trends may make it difficult for us to obtain product liability insurance or we may be forced to pay very high premiums, and there can be no assurance that insurance coverage will continue to be available on commercially reasonable terms or at all.

30

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 and the United States. These geographic localities provide economically and politically stable environments in which to operate. However, in the future, we intend to introduce products through partnerships in other countries. As we expand our geographic market, we will face additional ongoing complexity to our business and may encounter the following additional risks:

- increased complexity and costs of managing international operations;
- protectionist laws and business practices that favor local companies;
- dependence on local vendors;
- multiple, conflicting and changing governmental laws and regulations;
- difficulties in enforcing our legal rights;
- reduced or limited protections of intellectual property rights; and
- political and economic instability.

A significant portion of our international revenues is denominated in foreign currencies. An increase in the value of the U.S. dollar relative to these currencies may make our products more expensive and, thus, less competitive in foreign markets.

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

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

Risks Related to our Common Stock

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

As a result of our reverse business combination with Permatec in January 2001 and subsequent additional debt and equity financings, Permatec Holding AG and its controlling shareholder, Dr. Jacques Gonella, own a substantial portion (as of March 1, 2005, approximately 23%) 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 84,500 shares of common stock. Additionally, five investors (North Sound Funds, Perceptive Life Sciences Fund, SCO Capital Group, SDS Funds and Xmark Funds) own Series D Convertible Preferred Stock and/or warrants or a combination thereof that are, as of March 1, 2005, convertible into or exercisable for an aggregate of 5,683,613 shares of our common stock. Some of these investors plus Atlas Equity also directly own an aggregate of approximately 4,438,800 shares of our common stock. If SDS converted all of the Series D stock and if Dr. Gonella and all of the above investors exercised all of the warrants or options owned by them, Dr. Gonella would own approximately 27%, and the six investors as a group would own approximately 20%, of our common stock.

31

Because the parties described above either currently own or could potentially own a large portion of our stock, they may be able to generally determine or they will be able to significantly influence the outcome of corporate actions requiring shareholder 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 articles of incorporation and bylaws; payment of dividends on our common stock; and acquisitions, sales of our assets, mergers or similar transactions, including transactions involving a change of control. As a result, some investors may be unwilling to purchase our common stock. In addition, if the demand for our common stock is reduced because of these shareholders' control of the Company, the price of our common stock could be materially depressed.

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

Several of our shareholders, including Dr. Gonella, whose sales are subject to volume limitations, Atlas Equity, the SDS funds, the North Sound funds and Perceptive Life Sciences Master Fund, own large blocks of our common stock or could own sizeable blocks of our common stock upon exercise or conversion of warrants or Series D stock. With the exception of a portion of the stock controlled by Dr. Gonella, the shares of our common stock owned by these shareholders (or issuable to them upon exercise or conversion of warrants, Series D stock or options) are registered. Future sales of large blocks of our common stock by any of the above investors could substantially depress our stock price.

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

As of March 1, 2005, we currently have warrants outstanding that are exercisable, at prices ranging from \$0.55 per share to \$29.55 per share, for an aggregate of 16,936,897 shares of our common stock. We also have options outstanding that are exercisable, at exercise prices ranging from \$0.70 to \$23.00 per share, for an aggregate of 3,499,495 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 warrants and the options are not registered and may be sold only if registered under the Securities Act of 1933, as amended, or sold in accordance with an applicable exemption from registration, such as Rule 144. The shares of common stock 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 1, 2005, our officers and directors beneficially owned an aggregate of 14,611,976 shares (or approximately 36%) of our common stock, including stock options exercisable within 60 days. If our officers and directors, or other shareholders, sell a substantial amount of our common stock, it could cause the market price of our common stock to decrease and could hamper our ability to raise capital through the sale of our equity securities.

We do not expect to pay dividends in the foreseeable future

We intend to retain any earnings in the foreseeable future for our continued growth and, thus, do not expect to declare or pay any cash dividends in the foreseeable future.

Anti-takeover effects of certain by-law provisions and Minnesota law could discourage, delay or prevent a change in control

Our articles of incorporation and bylaws along with Minnesota law could discourage, delay or prevent persons from acquiring or attempting to acquire us. Our articles of incorporation authorize our board of directors, without action by our shareholders, to designate and issue preferred stock in one or more series, with such rights, preferences and privileges as the board of directors shall determine. In addition, our bylaws grant our board of directors the authority to adopt, amend or repeal all or any of our bylaws, subject to the power of the shareholders to change or repeal the bylaws. In addition, our bylaws limit who may call meetings of our shareholders.

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

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 1, 2005, we had 27 full-time and 4 part-time employees worldwide, of whom 17 are in the United States. Of the 31 employees, 17 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.

EXECUTIVE OFFICERS OF THE REGISTRANT

Name	Age	Position
Jack E. Stover	51	President, Chief Executive Officer and Director
Lawrence M. Christian	62	Vice President - Finance, Secretary, and Chief Financial Officer
Dario Carrara, Ph.D.	41	Managing Director - Formulations Group
Peter Sadowski, Ph.D.	57	Vice President - Devices Group
James E. Hattersley	45	Vice President - Business Development

Jack E. Stover, joined Antares Pharma as President and Chief Operating Officer in July 2004. Effective September 1, 2004, he was appointed to the positions of Chief Executive Officer and Director. Prior to joining Antares Pharma, Mr. Stover was Executive Vice President and CFO of Sicom, Inc., a public injectable pharmaceuticals company that was acquired by Teva Pharmaceutical Industries Ltd. Prior to his time at Sicom, Mr. Stover held various senior management and operating roles with both proprietary pharmaceutical and global medical device companies and earlier was a partner with PricewaterhouseCoopers (formerly Coopers & Lybrand), where he headed their life sciences industry practice in New Jersey.

Lawrence M. Christian is currently Vice President Finance, Secretary and Chief Financial Officer. He joined the Company in March 1999 as Vice President, Finance & Administration, Secretary and Chief Financial Officer. Mr. Christian took early retirement from 3M after a 16-year career. Since 1996 Mr. Christian had been with 3M as Financial Director World-Wide Corporate R&D and Government Contracts and was involved in organizing new business venture units and commercialization of new technologies. Prior to 1996 Mr. Christian served as Financial Manager Government Contracts, European Controller and Division Controller within 3M. Prior to joining 3M in 1982, Mr. Christian was Vice President/CFO of APC Industries, Inc., a closely-held telecommunications manufacturing company in Texas.

Dario Carrara, Ph.D. is currently Managing Director Pharmaceutical Group, located in Basel, Switzerland. He served as General Manager of Permatest's Argentinean subsidiary from 1995 until its liquidation in 2000. Prior to joining Permatest, between 1986 and 1995, Dr. Carrara worked as Pharmaceutical Technology Manager for Laboratorios Beta, a pharmaceutical laboratory in Argentina that ranks among the top ten pharmaceutical companies in Argentina. Dr. Carrara has extensive experience in developing transdermal drug delivery devices. He earned a double degree in Pharmacy and Biochemistry, as well as a Ph.D. in Pharmaceutical Technology from the University of Buenos Aires.

33

Peter Sadowski, Ph.D., is currently Vice President Devices Group, located in Minneapolis, Minnesota. He joined the Company in March 1994 as Vice President, Product Development. He was promoted to Executive Vice President and Chief Technology Officer in 1999. From October 1992 to February 1994, Dr. Sadowski served as Manager, Product Development for GalaGen, Inc., a biopharmaceutical company. From 1988 to 1992, he was Vice President, Research and Development for American Biosystems, Inc., a medical device company. Dr. Sadowski holds a Ph.D. in microbiology.

James E. Hattersley joined Antares Pharma as Vice President, Business Development, in February 2005 and is located in Exton, Pennsylvania. Prior to joining Antares Pharma, Mr. Hattersley served as Senior Director of Business Development at Eurand, Inc., a global drug delivery and specialty pharma company. From 1998 to 2000, he was employed by Anesta Corp., and from 1995 to 1998, Mr. Hattersley was Director of Program Management for JAGO Pharma AG, which was acquired by SkyePharma. Mr. Hattersley also held technical positions at Abbott Laboratories, Syntex Research USA and Alza Corporation between 1986 and 1995. He holds an M.S. degree in biochemistry and an undergraduate degree in neurobiology from the University of California.

Liability Insurance

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 \$1 million per occurrence and an annual aggregate maximum of \$5 million. The Company evaluates its insurance requirements on an ongoing basis.

Item 2. DESCRIPTION OF PROPERTY.

The Company leases approximately 3,000 square feet of office space in Exton, Pennsylvania for its corporate headquarters facility. The lease terminated in November 2004 and continues on a month-to-month basis.

The Company leases approximately 9,300 square feet of office and laboratory space in Plymouth, a suburb of Minneapolis, Minnesota. 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

On September 25, 2003, Josephberg Grosz & Company (JGC) notified the Company that it intends to commence an arbitration action against the Company in New York State. The Company and JGC entered into a letter agreement on April 8, 2002. JGC claims that, pursuant to the letter agreement, the Company owes it seven percent of the proceeds received by the Company, as well as ten percent of various shares and securities issued by the Company, in connection with up to \$6 million in financing received by the Company since April 5, 2002. The Company disputes that it owes any amounts to JGC. The Company intends to vigorously defend this claim.

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

None.

PART II*Item 5. MARKET FOR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS.*

The Company's Common Stock began trading on the American Stock Exchange under the symbol AIS on September 23, 2004. Prior to that time, the Company's Common Stock traded on the Nasdaq Small Cap Market of the Nasdaq Stock Market from March 8, 1999 through June 30, 2003. Effective July 1, 2003, the Company's securities were delisted from The Nasdaq SmallCap Market and began trading on the Over-the-Counter Bulletin Board under the symbol ANTR.OB. Prior to the delisting, the Company's Common Stock had been traded under the symbol ANTR. The following table sets forth the per share high and low sales prices of the Company's Common Stock for each quarterly period during the two most recent fiscal years. Sale prices are as reported by the American Stock Exchange for the fourth quarter of 2004, both the American Stock Exchange and the Over-the-Counter Bulletin Board for the third quarter of 2004, the Over-the-Counter Bulletin Board for the third quarter of 2003 through the second quarter of 2004, and the Nasdaq Stock Market for the first two quarters of 2003.

	<u>High</u>	<u>Low</u>
2004:		
First Quarter	\$ 1.63	\$ 1.00
Second Quarter	1.50	0.78
Third Quarter	1.84	0.60
Fourth Quarter	1.61	0.92
2003:		
First Quarter	0.89	0.30
Second Quarter	2.38	0.36
Third Quarter	3.75	0.80
Fourth Quarter	1.95	1.01

Common Shareholders

As of March 1, 2005, the Company had 145 shareholders of record of its common stock, with another estimated 3,162 shareholders whose stock is held in nominee name.

Dividends

The Company has not paid or declared any cash dividends on its common stock during the past eight years. The Company has no intention of paying cash dividends in the foreseeable future on common stock. The Company is obligated to pay 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 addition to the stated 10% dividend, the Company has been historically obligated to pay foreign tax withholding on the dividend payment, which equates to an effective dividend rate of 14.2%. Such foreign tax withholding payments have been reflected as dividends, to the extent they are non-recoverable. The Series A agreement has a provision which allows the Company to pay the dividend by issuance of the same stock when funds are not available. The Company has exercised this provision for ten of the last eleven dividend payments.

Sales of Unregistered Securities

On October 15, 2004, the Company issued 5,000 shares of its common stock to Mark Wachs and Associates. The shares were issued as compensation pursuant to a public relations letter agreement. The issuance of the shares was exempt from registration under Section 4(2) of the Securities Act of 1933.

On December 30, 2004, the Company received proceeds of \$625,000 in connection with the issuance of 500,000 shares of common stock from the exercise of warrants. The issuance of the shares was exempt from registration under Section 4(2) of the Securities Act of 1933.

As compensation to non-employees for professional services, in November 2004 the Company issued warrants to purchase 150,000 shares of the Company's common stock. The warrants have exercise prices ranging from \$3.00 to

35

\$5.00 per share and expire five years after issuance. The issuance of the shares was exempt from registration under Section 4(2) of the Securities Act of 1933.

Item 6. SELECTED FINANCIAL DATA

SELECTED FINANCIAL DATA
(In thousands, except per share data)

	At December 31,				
	2004	2003	2002	2001	2000
Balance Sheet Data:					
Cash and cash equivalents	\$ 1,652	\$ 1,929	\$ 268	\$ 1,965	\$ 243
Short-term investments	7,972				
Working capital (deficit)	8,489	615	(2,972)	1,126	(2,440)
Total assets	13,178	5,955	6,409	11,128	6,975
Long-term liabilities, less current maturities	3,339	3,558	1,247	1,243	17,732
Accumulated deficit	(82,575)	(74,127)	(41,166)	(29,457)	(17,264)
Total shareholders' equity (deficit)	8,189	307	655	7,468	(13,862)
	Year Ended December 31,				
	2004	2003	2002	2001	2000
Statement of Operations Data:					
Product sales	\$ 1,834	\$ 2,647	\$ 2,422	\$ 2,016	\$
Development	197	310	935	754	

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Year Ended December 31,

Licensing	635	695	639	729	560
Royalties	80	135			
Revenues	2,746	3,787	3,996	3,499	560
Cost of sales	1,372	2,008	2,574	1,863	
Research and development (3)	3,547	3,494	3,654	4,504	939
Sales and marketing	676	462	798	1,343	1,157
General and administrative	5,526	6,457	5,232	5,359	2,102
Goodwill impairment charge			2,000		
Operating expenses	9,749	10,413	11,684	11,206	4,198
Net operating loss	(8,375)	(8,634)	(10,262)	(9,570)	(3,638)
Net other income (expense)	26	(24,184)	(1,347)	71	(563)
Income tax expense					
Loss before cumulative effect of change in accounting principle	(8,349)	(32,818)	(11,609)	(9,499)	(4,201)
Cumulative effect of change in accounting principle					(1,059)
Net loss	(8,349)	(32,818)	(11,609)	(9,499)	(5,260)
In-the-money conversion feature-preferred stock dividend				(5,314)	
Preferred stock dividends	(100)	(143)	(100)	(100)	
Net loss applicable to common shares	\$ (8,449)	\$ (32,961)	\$ (11,709)	\$ (14,913)	\$ (5,260)
Net loss per common share (1), (2)	\$ (0.23)	\$ (2.18)	\$ (1.22)	\$ (1.76)	\$ (1.22)
Weighted average number of common shares	36,348	15,093	9,618	8,495	4,326

(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 2001 the Company recorded a non-cash write-off of acquired in-process research and development of \$948,000. In 2004, 2003 and 2002 the Company recorded non-cash patent impairment charges of \$233,062, \$973,769 and \$435,035, respectively.

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

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 and are referred to as Antares/Minnesota. The Company also has operations located in Basel, Switzerland, which consists of administration and facilities for the research and development of transdermal gels and oral fast melt tablet products. The Swiss operations, referred to as Antares/Switzerland, focus on research, development and commercialization. Antares/Switzerland has signed a number of license agreements with pharmaceutical companies for the application of its drug delivery systems and began generating revenue in 1999 with the recognition of license revenues. The Company's corporate offices are located in Exton, Pennsylvania (near Philadelphia).

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 devices 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 hormone 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, and has licensed its reusable needle-free technology in the diabetes and obesity fields to Eli Lilly and Company on a worldwide basis.

The Company is reporting a net loss of \$8,348,532 for the year ending December 31, 2004 and expects to report a net loss for the year ending December 31, 2005, as marketing and development costs related to bringing future generations of products to market continue. Long-term capital requirements will depend on numerous factors, including the status of collaborative arrangements, the progress of research and development programs, the receipt of revenues from sales of products and the ability to control costs.

The Company has not historically, and does not currently, generate enough revenue to provide the cash needed to support its operations, and has continued to operate by raising capital and issuing 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 2004. The Company received net proceeds of \$13,753,400 in three private placements of its common stock in which a total of 15,120,000 shares of common stock were sold at a price of \$1.00 per share. Additionally, the Company issued five-year warrants to purchase an aggregate of 5,039,994 shares of common stock at an exercise price of \$1.25 per share. During 2004 the Company also received proceeds of \$1,472,500 in connection with the exercise of warrants for 3,480,500 shares of common stock.

The Company believes that the combination of these equity financings and projected product sales and product development and license revenues will provide sufficient funds to support operations through at least the next year. If the Company does need additional financing and we 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 or accept financing terms that are not as attractive as the Company may desire.

Results of Operations

Critical Accounting Policies and Use of Estimates

In preparing the financial statements in conformity with U.S. generally accepted accounting principles, 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 1 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 all of the Company's licensing and development contracts to this point, 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 (\$3,424,958 at December 31, 2004) 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.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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. 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 the Company concludes that the revenues from this arrangement will not exceed the costs, part or all of the remaining prepaid license discount may be charged to earnings 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 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.

38

	2004	2003	2002
Product sales	\$ 1,834,431	\$ 2,646,628	\$ 2,421,804
Development fees	445,625	365,387	935,324
Licensing fees and milestone payments	84,449	2,456,040	754,483
Royalties	80,335	134,937	
Billings received and/or accrued per contract terms	2,444,840	5,602,992	4,111,611
Deferred billings received and/or accrued	(259,537)	(2,458,559)	(793,719)
Deferred revenue recognized	756,903	691,473	677,869
Amortization of prepaid license discount	(196,250)	(49,062)	
Total revenue as reported	\$ 2,745,956	\$ 3,786,844	\$ 3,995,761

Valuation of Long-Lived and Intangible Assets and Goodwill

Long-lived assets, including patents, 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. 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.

The impairment analysis for patents can be very subjective as the Company relies upon signed distribution or license agreements with variable cash flows to substantiate the recoverability of these long-lived assets. In the fourth quarters of 2004, 2003 and 2002 the Company updated its long-range business plan. Certain capitalized patent costs were related to products for which there were no revenues or cash flows projected in the business plan or for which there were no signed distribution or license agreements. Therefore, the Company recognized an impairment charge of \$233,062, \$973,769 and \$435,035 in 2004, 2003 and 2002, respectively, in research and development expenses, which represented the carrying amount net of accumulated amortization for the identified patents. The Company's estimated aggregate patent amortization expense for the next five years is \$131,000 in 2005 and 2006, \$96,000 in 2007, and \$93,000 in 2008 and 2009.

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 2004 and 2003 resulted in no impairment losses.

In connection with the transitional goodwill impairment evaluation, SFAS 142 required the Company to perform an assessment of whether there was an indication that goodwill was impaired as of the January 1, 2002 adoption date. This analysis indicated that there was not a goodwill impairment upon adoption of SFAS No. 142. The Company's annual impairment analysis as of December 31, 2002 indicated a potential impairment charge due to a significant decline in the Company's stock price in the fourth quarter of 2002 and concerns about the continued existence of the Company due to continued net losses and negative cash flows from operations. After completion of the impairment analysis prescribed in SFAS No. 142, the Company recorded a goodwill impairment charge of \$2,000,000 in the fourth quarter of 2002.

Foreign Currency Translation

Revenues of the subsidiaries are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the U.S. parent. However, nearly all operating expenses, including labor, materials, leasing arrangements and other operating costs, are denominated in Swiss Francs. Additionally, bank accounts 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 European subsidiaries. The reporting currency for the Company is the United States Dollar (USD). The financial statements of the Company's three 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 shareholders' equity. Foreign currency transaction gains and losses are included in the statements of operations. The Company recorded in comprehensive loss a loss on foreign currency translation of \$42,642, \$116,999 and \$122,897 for 2004, 2003 and 2002, respectively. In 2004, 2003 and 2002, the USD weakened against the Swiss Franc, causing the losses from the Swiss subsidiaries, after translation to USD, to increase compared to what they would have been in prior years. The Company estimates that the weakening of the USD against the Swiss Franc has resulted in increased losses of approximately \$300,000, \$500,000 and \$250,000 in 2004, 2003 and 2002, respectively.

Accounting for Debt and Equity Instruments

During the first quarter of 2003, in connection with a restructuring of its 10% convertible debentures, the Company issued warrants to purchase common stock to the debenture holders. In the third quarter of 2003, the holders of the restructured debentures exchanged the remaining outstanding principal of such debentures for shares of the Company's Series D Convertible Preferred Stock. Also in the third quarter of 2003, the Company's largest shareholder converted debt owed to him by the Company into shares of the Company's common stock and warrants to purchase the Company's common stock. The Company also completed a private placement of its common stock and warrants in the third quarter of 2003 and first quarter of 2004. The accounting for debt and equity transactions is complex and requires the Company to make certain judgments regarding the proper accounting treatment of these instruments. The Company's significant judgments related to the capital restructuring transactions included:

- the accounting for one of the convertible debentures as an extinguishment and issuance of debt instruments and the other as a troubled debt restructuring;
- the determination of the fair values of the convertible debentures and the warrants issued with the transactions; and
- the classification of the warrants as liabilities.

The Company's significant judgments related to the debenture exchange transaction included the determination of the fair values of the Series D Convertible Preferred Stock and warrants issued in connection with the transaction. Significant judgments related to the private placement of common stock and warrants included the determination of the fair value of the warrants, the allocation of the proceeds between the common stock and the warrants, and the initial classification of the warrants as liabilities. In August and September of 2003, the Company modified the warrants issued in the above noted transactions resulting in the reclassification of the warrants from debt to equity.

Years Ended December 31, 2004, 2003 and 2002

Revenues

Revenues decreased by \$1,040,888, or 27%, to \$2,745,956 in 2004 from \$3,786,844 in 2003, and decreased \$208,917, or 5%, to \$3,786,844 in 2003 from \$3,995,761 in 2002. The decrease in 2004 resulted primarily from a reduction in sales to the Company's major customer, Ferring. The decrease in 2003 compared to 2002 was mainly due to reduced development revenue at the Antares/Switzerland operations, partially offset by an increase in sales to Ferring.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Antares/Minnesota product sales include sales of reusable needle-free injector devices, related parts, disposable components, and repairs. In 2004, 2003 and 2002, a total of 2,533, 3,384 and 4,966 devices, respectively, were sold at average prices of approximately \$245, \$231 and \$245, respectively. The average price increase in 2004 compared to 2003 was due mainly to the effect of the weakening of the USD to the Euro on the devices sold to Ferring. The decrease in 2003 compared to 2002 was due primarily to a reduction in the selling price to Ferring in 2003. Sales of disposable components in 2004, 2003 and 2002 totaled \$1,143,071, \$1,748,213 and \$1,033,635, respectively. The decrease in

40

sales of devices and disposable components in 2004 compared to 2003 was due primarily to a decrease in sales to Ferring, whose purchasing level in 2003 was impacted by their decision to convert their customers to the Company's most current device model, the Medi-Jector VISION®, from the earlier device model (the Choice) and by their increased purchases of product to sustain supply as the Company outsourced its assembly operations during 2003. The decrease in device sales in 2003 from 2002 was due to fewer sales to Ferring. In 2002 the Company sold both the Choice device and the Medi-Jector VISION® device to Ferring, who began purchasing the Medi-Jector VISION® device in anticipation of converting existing customers from the Choice device and in anticipation of launching the Medi-Jector VISION® device in new markets. The decrease in device sales in 2003 compared to 2002 was offset by an increase in sales of disposable components, which was primarily due to Ferring's supply building and conversion implementation efforts in 2003.

Development revenue decreased by \$113,387 in 2004 to \$196,648 from \$310,035 in 2003 and decreased by \$625,289 in 2003 from \$935,324 in 2002. Nearly all of the recognized development revenue has been generated under licensing and development agreements related to use of the Company's proprietary ATD gel technology in developing products for transdermal delivery of certain medications. The development revenue decreased in 2004 and 2003 as the product generating a substantial portion of the development revenue in 2002 moved past the primary major development stages and into clinical trial stages, which are being handled almost entirely by the licensee. 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 \$634,542, \$695,244 and \$638,633 in 2004, 2003 and 2002, respectively. The decrease of \$60,702 in 2004 compared to 2003 was due to an increase of \$147,188 in prepaid license discount amortization, partially offset by an increase in one time license fees of \$31,617 and an increase of \$54,869 in revenue recognized on previously deferred amounts. The increase in licensing revenue in 2003 compared to 2002 of \$56,611 was due to an increase of \$154,840 in revenue recognized on previously deferred amounts plus amortization of \$72,999 on deferred license fees received in 2003, partially offset by a decrease in one time license fees of \$122,166 and an increase in prepaid license discount amortization of \$49,062.

Royalty revenue was related to the sale of reusable needle-free injection devices to Ferring under the License Agreement dated January 22, 2003, described in more detail in Note 9 to the Consolidated Financial Statements. The reduction in royalty revenue from \$134,937 in 2003 to \$80,335 in 2004 was due to fewer device sales to Ferring in 2004.

Cost of Sales

The costs of product sales are primarily related to reusable injection devices and disposable components. Cost of sales as a percentage of product sales remained relatively constant in 2004 compared to 2003, decreasing 1% to 71% in 2004 from 72% in 2003. Cost of sales as a percentage of product sales decreased significantly in 2003 compared to 2002, decreasing by 23% to 72% in 2003 from 95% in 2002. In February 2003 the Company entered into a manufacturing agreement under which all assembly work previously performed in the Company's Minneapolis facility was to be outsourced. The transition of the assembly operations was completed by May of 2003. The 2003 decrease in cost of sales as a percentage of sales was due partially to the outsourcing, which has resulted in the elimination of excess capacity and has helped stabilize product costs. The 2003 decrease was also due to unexpected costs incurred in 2002 related to disposable component production and design issues, which resulted in an unusually high cost of sales percentage in that year.

The cost of development revenue consists of labor costs and an allocation of certain research and development expenses based on actual time spent in these revenue generating activities. Cost of development revenue as a percentage of development revenue was 34%, 29% and 29% in 2004, 2003 and 2002, respectively.

Research and Development

Research and development expenses increased by \$52,472, or 1%, to \$3,546,438 in 2004 from \$3,493,966 in 2003, and in 2003 decreased by \$160,367, or 4%, from \$3,654,333 in 2002. The increase in 2004 compared to 2003 was primarily due to increases in prototyping and tooling expenses in connection with device development projects and increases in expenses for studies and analysis work related to gel development projects. The increases were partially offset by decreased rent resulting from space reductions at both the Minnesota and Swiss facilities and by a decreased

patent impairment charge in 2004 compared to 2003. In the fourth quarter of 2004 the Company recorded a patent impairment charge of \$233,062 that was \$740,707 less than the 2003 fourth quarter patent impairment charge of \$973,769. The patent impairment charges were recognized in connection with certain patents related to products for which there were no signed distribution or license agreements or for which no revenue was included in the Company's long-term business plan that had been updated in the fourth quarter of each year. The impairment charges represented the gross carrying amount net of accumulated amortization for the identified patents. The decrease in research and development expenses in 2003 compared to 2002 was due primarily to a management decision to reduce overall research and development spending, which significantly impacted prototyping, tooling and clinical studies and which resulted in employee reductions in both locations, lowering payroll expenses. The decrease was also due to a reduction of \$120,000 in consulting expenses after a two-year consulting agreement ended in June of 2003. These reductions were partially offset by increased patent related expenses, including the patent impairment charge of \$973,769 in the fourth quarter of 2003.

Sales, Marketing and Business Development

Sales and marketing expenses increased by \$213,502, or 46%, to \$675,878 in 2004 from \$462,376 in 2003, and decreased in 2003 by \$335,279, or 42%, from \$797,655 in 2002. The increase in 2004 was primarily due to increases in travel and legal expenses related to business development activities and due to increased advertising and promotional activities related to the Medi-Jector VISION® device in the insulin market in the third and fourth quarters of 2004. The 2003 decrease was primarily due to payroll cost reductions, which accounted for 65% of the decrease in 2003, while the remainder of the decrease was derived mainly from reductions in travel costs and clinical trial expenses.

General and Administrative

General and administrative expenses decreased \$930,655, or 14%, to \$5,526,004 in 2004 from \$6,456,659 in 2003, and increased in 2003 by \$1,224,270, or 23%, from \$5,232,389 in 2002. The decrease in 2004 was primarily due to decreases in payroll, professional services and investor relations expenses, partially offset by increases in travel and insurance expenses. The payroll decrease was mainly due to the expiration of the employment agreement with Frank Pass, former CEO and director, at the end of 2003. The professional services and investor relations expenses decreased in 2004 primarily due to a decrease in the utilization of consulting services and the number of consulting agreements in 2004 compared to 2003. One agreement in particular, which was terminated in the first quarter of 2004, accounted for an expense decrease of \$516,299 from \$728,619 in 2003 to \$212,320 in 2004. In 2004 and 2003 a portion of the professional services and investor relations expenses were paid in common stock and warrants, resulting in non-cash expenses in each year of \$556,843 and \$1,563,041, respectively. In 2004 the Company issued 50,000 shares of common stock, recognizing expense of \$54,550 based on the market value of the stock on the dates the stock was issued, and issued warrants and options to purchase a total of 550,000 shares of common stock, which were recorded at a total value of \$502,293 using the Black Scholes option pricing model. In 2003, the Company issued 784,266 shares of common stock, recognizing expense of \$639,809 based on the market value of the stock on the dates the stock was issued, and issued warrants to purchase 1,050,000 shares of the Company's common stock which were recorded at a value of \$923,232 using the Black Scholes option pricing model. The increase in travel in 2004 of approximately \$140,000 was due primarily to increased travel by the Board of Directors, and the insurance expense increase of approximately \$76,000 was mainly due to increased Directors and Officers insurance coverage. In addition to increases in professional services and investor relations expenses in 2003 as compared to 2002, rent expense increased by approximately \$70,000 due primarily to a higher rent allocation to general and administrative expenses after the transition of the assembly operation was completed at the Antares/Minnesota location. The increases in 2003 were partially offset by decreases in payroll costs of approximately \$330,000 due to staff reductions, travel expenses of approximately \$60,000 and depreciation of approximately \$40,000. Excluding all stock-based noncash expenses, total general and administrative expenses increased in 2004 compared to 2003 by approximately \$75,000 and decreased in 2003 compared to 2002 by approximately \$125,000.

In 2004, the Company incurred approximately \$62,000 of professional fees and travel expenses in connection with documentation of internal controls over financial reporting in preparation for compliance with the requirements of Section 404 of the Sarbanes-Oxley Act.

Goodwill Impairment Charge

The Company had no impairment charges in 2004 or 2003, but recorded a \$2,000,000 impairment charge in the fourth quarter of 2002 related to the Minnesota operations reporting unit.

Other Income (Expense)

Other income (expense), net, changed to income of \$26,134 in 2004 from expense of (\$24,183,924) in 2003, and in 2003 increased from expense of (\$1,346,869) in 2002. The net decrease in other expenses of \$24,210,058 in 2004 compared to 2003 was mainly due to losses on debt

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

extinguishments, losses on conversions of debt to equity and losses on common stock warrants of \$885,770, \$16,283,677 and \$5,960,453, respectively, that occurred in 2003 but not in 2004. In addition, interest expense in 2004 was \$819,659 less than in 2003. The 2004 interest expense was mainly due to \$75,388 recognized in connection with warrants originally issued to convertible debenture holders that were exercised at a discounted exercise price. The 2003 interest expense consisted of discount amortization and interest accruals of \$389,443 and \$82,357, respectively, related to borrowings from the Company's largest shareholder, \$262,564 of debt issuance discount amortization, \$152,829 of interest related to convertible debentures, and \$32,937 of other interest. Also contributing to the change from net other expense in 2003 to net other income in 2004 was the increase in interest income in 2004 of \$103,751. This increase was due to the increase in cash and short-term investments that resulted from the private placement in the first quarter of 2004. The increase in expense of \$22,837,055 in 2003 compared to 2002 was primarily due to the losses on conversions of debt to equity, common stock warrants and debt extinguishments in amounts aggregating \$23,129,900. The loss on conversions of debt to equity represented the difference between the fair value of the preferred stock, common stock and warrants issued to the debt holders in excess of the carrying value of the debt on September 12, 2003, the date of the conversions. The losses on common stock warrants were the result of the warrants being classified as debt under EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock and a requirement to mark-to-market the warrants at each reporting period with changes in the warrant values being recorded in the consolidated statement of operations. The warrants were adjusted to their fair value at the end of each reporting period using the Black Scholes option pricing model, with the fair value increases being recorded as losses in the consolidated statement of operations and as increases in the debt on the consolidated balance sheets. The loss on debt extinguishments resulted from the debenture restructuring in January of 2003 and mainly represents the unamortized debt issuance discount related to the intrinsic value of the beneficial in-the-money conversion feature of the 10% debentures and unamortized debt issuance costs. Other expense in 2003 also includes an estimated \$156,759 of withholding taxes on foreign payments made in prior years. Partially offsetting the increases in other expenses in 2003 compared to 2002 was the decrease in interest expense from \$1,297,440 in 2002 to \$920,130 in 2003. Interest expense in 2002 consisted mainly of \$828,813 from amortization of a debt issuance discount related to the Company's 10% convertible debentures and of \$317,335 of amortization of deferred financing costs related to the 10% debentures and of interest on borrowings in the principal amount of \$2,700,000 in 2002 from the Company's largest shareholder.

Noncash other expenses significantly impacted the net loss and net loss per common share for 2003. The table below is presented to help explain the impact of the noncash other expenses on the net loss and net loss per common share for 2004, 2003 and 2002, and is not meant to be a substitute for accounting or presentation requirements under U.S. generally accepted accounting principles.

	For the Years Ended December 31,		
	2004	2003	2002
Noncash other expense items:			
Loss on debt extinguishments	\$	\$ (741,570)	\$
Loss on conversions of debt to equity		(16,283,677)	
Loss on common stock warrants		(5,960,453)	
Interest expense	(75,388)	(862,308)	(1,146,148)
Total noncash other expenses included in net loss in the consolidated statement of operations	\$ (75,388)	\$ (23,848,008)	\$ (1,146,148)
Impact of noncash other expenses on basic and diluted net loss per common share	\$	\$ (1.58)	\$ (0.12)

43

Liquidity and Capital Resources

Operating Activities

Net cash used in operating activities was \$7,167,313, \$3,553,323 and \$5,553,766 for the years ended December 31, 2004, 2003 and 2002, respectively. This was the result of net losses of \$8,348,532, \$32,817,964 and \$11,608,765 in 2004, 2003 and 2002, respectively, adjusted by noncash expenses and changes in operating assets and liabilities.

Noncash expenses totaled \$1,915,862 in 2004, consisting primarily of stock-based compensation of \$825,381, depreciation and amortization of \$580,080, patent rights impairment charge of \$233,062 and amortization of prepaid license discount of \$196,250. In 2003 noncash expenses totaled \$27,805,363, consisting of losses on conversions of debt to equity, common stock warrants and debt extinguishments in the amounts of \$16,283,677, \$5,960,453 and \$741,570, respectively, depreciation and amortization of \$845,234, noncash interest expense of \$862,308, stock-based compensation expense of \$1,965,165, patent rights impairment charge of \$973,769, loss on disposal and abandonment of assets of \$124,125 and amortization of prepaid license discount of \$49,062. The noncash expenses of \$4,878,602 in 2002 consisted primarily of

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

goodwill impairment charge of \$2,000,000, patent rights impairment charge of \$435,035, depreciation and amortization of \$907,131, noncash interest expense of \$1,146,148, and stock-based compensation expense of \$370,410. The depreciation and amortization decrease in 2004 from 2003 of \$265,154 is due primarily to production and office equipment that became fully depreciated early in 2004.

The change in operating assets and liabilities in 2004 utilized cash of \$717,592. 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.

In 2003 cash increased by \$1,459,278 as a result of the change in operating assets and liabilities. The increase was primarily due to an increase in deferred revenue of \$2,508,492, which was mainly due to license fees received in connection with new license agreements in 2003. The increase in 2003 was also due to a decrease in inventory of \$333,503 that was mainly due to the outsourcing of assembly operations to a third-party supplier that carries a large portion of the inventory previously carried by the Company. Partially offsetting the increase in deferred revenue and decrease in inventory were decreases in accounts payable and accrued expenses of \$355,359 and \$651,946, respectively, and an increase in accounts receivable of \$307,319. The decreases in accounts payable and accrued expenses were primarily the result of being more current on obligations at the end of 2003 due to the availability of funds as a result of cash raised in the private placements in July and cash received in connection with license agreements, compared to the end of 2002 when cash was not readily available. The increase in receivables at the end of 2003 compared to 2002 was mainly due to the timing of Ferring shipments from Antares/Minnesota.

Cash increased by \$1,176,397 as a result of the change in operating assets and liabilities in 2002. This increase was primarily due to reductions in receivables of \$654,266, increases in accrued expenses and deferred revenue of \$510,992 and \$348,090, respectively, offset by increased prepaid expenses and other assets of \$365,065. The decrease in receivables was primarily due to a reduction of approximately \$290,000 in VAT receivables and a reduction of approximately \$330,000 in receivables from BioSante due to a lower level of development activity. The increase in accrued expenses was mainly due to approximately \$500,000 of customer deposits received during 2002. The deferred revenue increase was due to approximately \$500,000 of milestone payments received in 2002 that were deferred. Prepaid expenses and other assets increased primarily in connection with deferred financing costs related to the issuance of convertible debentures in 2002.

44

Investing Activities

Net cash used in investing activities totaled \$8,183,796, \$169,847 and \$435,796 for the years ended December 31, 2004, 2003 and 2002, respectively. In 2004 the Company used proceeds from the private placement of common stock in the first quarter of the year to invest in short-term debt securities consisting of commercial paper and U.S. government agency discount notes. As a security matured it was usually reinvested in a new security, although at times a matured security was not reinvested but was used to fund operations. A total of \$12,000,000 of securities purchased with private placement funds or reinvested funds matured during 2004 and a total of \$19,889,565 of proceeds from the private placement or matured securities was used to acquire short-term securities in 2004. Purchases of equipment, furniture and fixtures utilized cash of \$218,038, \$1,160 and \$155,145 in 2004, 2003 and 2002, respectively. The 2004 purchases occurred mainly at the Antares/Minnesota operations and consisted primarily of furniture and office equipment in connection with the move to new office and laboratory space in April, new disposable component tooling expected to be in service in the first half of 2005, and upgrades to computer hardware and software. Capital spending in 2003 was essentially halted and in 2002 was related mainly to purchases of furniture and office equipment in connection with the opening of corporate offices in Exton, PA, along with smaller amounts for tooling improvement costs and computer related acquisitions. Capitalized spending related to patent development in 2004, 2003 and 2002 was \$76,193, \$168,687 and \$280,651, respectively. The Company expects capitalized patent development costs to decrease in the future, as a larger portion of these costs are expected to be expensed as they are incurred.

Financing Activities

The Company's contractual cash obligations at December 31, 2004 are associated with operating leases and are summarized in the following table:

Payment Due by Period

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Total contractual cash obligations	\$ 1,311,095	\$ 284,818	\$ 809,793	\$ 184,852	\$ 31,632

Net cash provided by financing activities totaled \$15,140,603, \$5,595,813 and \$4,571,212 for 2004, 2003 and 2002. 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. In 2003 the Company received net proceeds of \$3,930,000 from the sale of common stock and warrants in private placements in July, proceeds of \$16,249 from the exercise of stock options, proceeds from loans from a debenture holder of \$621,025, and \$1,600,000 in subordinated loans from shareholders. In 2003 the Company made principal payments on convertible debentures and capital lease obligations of \$464,000 and \$107,461, respectively. In 2002 net cash provided by financing activities was due to proceeds from subordinated loans from shareholders of \$2,700,000 and proceeds from issuance of convertible debentures of \$2,000,000, offset by principal payments on capital lease obligations of \$128,788.

In February and March 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 at a price of \$1.00 per share. The Company also issued five-year warrants to purchase an aggregate of 5,039,994 shares of common stock at an exercise price of \$1.25 per share.

During 2004 the Company received proceeds of \$1,472,500 in connection with the issuance of 3,480,500 shares of common stock resulting from the exercise of warrants. Of the shares issued, 2,932,500 were in connection with warrants exercised by holders of the Company's Series D Convertible Preferred Stock after the Company had offered, on December 30, 2003 when the availability of equity funds was unknown, 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.

On September 12, 2003, \$475,000 of the Company's 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures were converted into 949,998 shares of common stock. Also on

45

September 12, 2003, the holders of the Company's 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures (collectively, the Debentures) exchanged the outstanding \$1,218,743 aggregate principal and accrued interest of the Debentures for 243,749 shares of the Company's Series D Convertible Preferred Stock (the Series D Preferred). Each share of Series D Preferred 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. As a result, the Series D Preferred was convertible into the same number of shares of Common Stock as were the Debentures. In connection with the exchange of the Debentures for the Series D Preferred, the holders of the Debentures executed lien release letters terminating the security interest they held in the Company's assets. As consideration for the release of the security interest, the Company adjusted the exercise price of certain warrants issued to the holders of the Debentures on January 31, 2003 from \$0.55 per share to \$0.40 per share. These warrants were exercisable for an aggregate of 2,932,500 shares of Common Stock.

In July 2003 the Company received aggregate proceeds of \$4,000,000 in two separate private placements of its common stock. The Company issued 4,000,000 shares of its common stock at a price of \$1.00 per share and warrants to purchase 3,000,000 shares of common stock at an exercise price of \$1.25 per share. The warrants expire in July 2008. The warrants were subject to defined indemnifications if the underlying common shares were not fully tradable and the warrant holders incurred losses due to their inability to sell these shares. The Company analyzed the terms and conditions of the warrants and determined that the warrants should be classified as debt under EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock. As such, the Company was required to mark-to-market these warrants at each reporting period with changes in the warrant values being recorded in the consolidated statement of operations. The proceeds of \$4,000,000 were allocated between equity and debt based on the relative fair values of the common stock and the warrants on the dates of the private placements. The fair value of the common stock was based on the market price and the warrant fair values were calculated using the Black-Scholes option pricing model. The allocation resulted in an initial value assigned to the warrants of \$1,588,585. On September 30, 2003, certain terms and conditions of the warrant agreements were amended, causing the warrants to be classified as equity rather than as debt as of the date of the amendment and ending the requirement to adjust the market value of the warrants each reporting period. The warrants were adjusted to their fair value of \$4,254,211 on September 30, 2003, resulting in a loss of \$2,665,626 on these common stock warrants in 2003.

On February 7, 2003, the Company completed a restructuring of its 10% debentures previously sold to four primary investors. Specifically, as part of this restructuring, on January 24, 2003 and January 31, 2003, the Company borrowed an aggregate of \$621,025 from Xmark Funds.

The Company used the proceeds of these borrowings to repurchase \$464,000 principal amount of the 10% debentures previously sold to the two original 10% debenture holders who had converted \$536,000 of principal into common stock, and to pay a repurchase premium of \$144,200 and accrued interest of \$12,825. As additional repurchase compensation, the Company issued warrants to one of the two original 10% debenture holders and paid \$5,000, in lieu of warrants, to the other. The Company recognized a debt extinguishment loss of \$885,770 in 2003 related to these transactions. Thereafter, in exchange for the surrender and cancellation of the promissory notes, the Company issued to Xmark Funds 8% Senior Secured Convertible Debentures in the same principal amount of the promissory notes. The Company also exchanged Amended and Restated 8% Senior Secured Convertible Debentures for the remaining outstanding principal and accrued interest of \$955,000 and \$37,230, respectively, of the original 10% debentures. The aggregate principal amount of the 8% debentures was \$1,613,255. The 8% debentures contained terms similar to the 10% debentures, except that the 8% debentures included a fixed conversion price of \$.50 per share and an interest rate of 8% per annum. The 8% debentures were due March 31, 2004. Similar to the 10% debentures, the Company granted a senior security interest in substantially all of its assets to the holders of the 8% debentures. In connection with this restructuring, the Company also issued to the holders of the 8% debentures five-year warrants to purchase an aggregate of 2,932,500 shares of the Company's common stock at an exercise price of \$0.55 per share. The warrants were subject to defined indemnifications if the underlying common shares were not fully tradable and the warrant holders incurred losses due to their inability to sell these shares. The Company analyzed the terms and conditions of the warrants and determined that the warrants should be classified as debt under EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock. As such, the Company was required to mark-to-market these warrants at each reporting period with changes in the warrant values being recorded in the consolidated statement of operations. The warrants were recorded with an initial fair value on January 31, 2003 of \$1,142,442, determined using the Black Scholes option pricing model, and were adjusted to their fair value of \$4,437,269 at August 13, 2003, when certain terms and conditions of the warrant agreements were amended, causing the warrants to be classified as equity rather than as debt as of the date of the amendment and ending the requirement to adjust the market value of the warrants each reporting period. The Company recognized a loss \$3,294,827 on these common stock warrants in 2003.

46

The aggregate original principal amount of the 8% debentures of \$1,613,255 was held by two debenture holders in the amounts of \$469,513 and \$1,143,742, respectively. The Company analyzed each of the restructuring transactions for the two 8% debenture holders to determine the proper accounting treatment. The effective borrowing rate on \$469,513 of restructured debentures was determined to be less than the effective borrowing rate on the original debentures immediately prior to the restructuring. As a result, the Company determined that these debentures should be accounted for as a troubled debt restructuring. The net carrying value of these debentures at the time of the restructuring was reduced from \$140,659 to \$97,710 resulting in a debt discount of \$371,803 that was being amortized to interest expense through March 31, 2004 using the effective interest method. The unamortized discount was written off in connection with the conversions on September 12, 2003. The transaction related to the remaining \$1,143,742 was accounted for as a debt extinguishment under EITF 96-19. The restructured debentures were determined to be substantially different from the original debentures because the present value of the cash flows under the terms of the restructured debentures was more than 10 percent different from the present value of the remaining cash flows under the terms of the original debentures. The debentures were recorded at a fair value of \$1,276,339, and the premium of \$132,597 was being amortized monthly through March 31, 2004 using the effective interest method. The unamortized premium was written off in connection with the conversions on September 12, 2003.

Effective July 1, 2003, the Company's securities were delisted from The Nasdaq SmallCap Market and began trading on the Over-the-Counter (OTC) Bulletin Board under the symbol ANTR.OB, after the Nasdaq Listing Qualifications Panel determined to delist the Company's securities. The delisting from The Nasdaq SmallCap Market constituted an event of default under the restructured 8% debentures. However, the Company obtained letters from the debenture holders in which they agreed to forbear from exercising their rights and remedies with respect to such event of default, indicating they did not intend to accelerate the payment and other obligations of the Company under the debentures. The debenture holders reserved the right at any time to discontinue the forbearance and, among other things, to accelerate the payment and other obligations of the Company under the 8% debentures. If the debenture holders had decided to discontinue their forbearance, the debentures would have become due and payable at 130% of the outstanding principal and accrued interest. Because the debenture holders retained the right to discontinue the forbearance and this option was outside the control of the Company, the Company was required to record an expense and a liability of \$508,123 for the 30% penalty in future periods until the debentures were converted to common stock, at which time the liability was removed and offset against the loss on conversions of debt to equity.

In July 2002, the Company sold \$2,000,000 aggregate principal amount of its 10% debentures, with \$700,000 maturing on July 12, 2003, \$700,000 maturing on July 26, 2003 and \$600,000 maturing on October 15, 2003. The debentures were convertible into shares of the Company's common stock at a conversion price which was the lower of \$2.50 or 75% of the average of the three lowest intraday prices of the Company's common stock, as reported on the Nasdaq SmallCap Market, during the 20 trading days preceding the conversion date. From October 10, 2002 to January 17, 2003, three of the original four holders of the 10% debentures converted \$581,000 of principal into 1,777,992 shares of common stock at an average conversion price of approximately \$0.327 per share. Two of the original four holders accounted for the conversion of \$536,000 of principal into 1,660,863 shares of common stock.

New Accounting Pronouncements

In December 2004, the FASB issued FASB Statement No. 123R, *Share-Based Payment*. Among other items, the standard requires that the compensation cost relating to share-based payment transactions be recognized in the consolidated statement of operations. Note 1 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. The new standard is effective for the first interim or annual reporting period that begins after June 15, 2005. The Company expects to implement the new standard beginning with the third quarter of 2005, and to use the modified prospective transition method. Under this method, awards that are granted, modified, or settled after the date of adoption will be measured and accounted for in accordance with Statement 123R, and unvested equity awards granted prior to the effective date will continue to be accounted for in accordance with Statement 123 as they have been for purposes of pro forma disclosures, except that amounts will be recognized in the statement of operations.

47

Item 7(A). MARKET RISK ASSESSMENT

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, 2004, 2003 and 2002 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, establishes pricing in Euros for products sold under the existing supply agreement and for all royalties. 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.

48

Item 8. FINANCIAL STATEMENTS.

**ANTARES PHARMA, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Report of Independent Registered Public Accounting Firm	50
Consolidated Balance Sheets as of December 31, 2004 and 2003	51
Consolidated Statements of Operations for the Years Ended December 31, 2004, 2003 and 2002	52
Consolidated Statements of Shareholders' Equity and Comprehensive Loss for the Years Ended December 31, 2004, 2003 and 2002	53
Consolidated Statements of Cash Flows for the Years Ended December 31, 2004, 2003 and 2002	55
Notes to Consolidated Financial Statements	56

49

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, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

We conducted our audits in accordance with the standards of the Public Company 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, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Minneapolis, Minnesota
March 16, 2005

50

**ANTARES PHARMA, INC.
CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2004	2003
Assets		
Current Assets:		
Cash and cash equivalents	\$ 1,652,408	\$ 1,928,815
Short-term investments	7,971,625	
Accounts receivable, less allowance for doubtful accounts of \$22,500 and \$21,500, respectively	277,606	481,886
Other receivables	64,359	7,947
Inventories	92,344	225,408
Prepaid expenses and other assets	81,009	61,239
	<u>10,139,351</u>	<u>2,705,295</u>
Total current assets	10,139,351	2,705,295
Equipment, furniture and fixtures, net	611,920	801,369
Patent rights, net	947,459	1,214,356
Goodwill	1,095,355	1,095,355
Other assets	383,518	138,478
	<u>\$ 13,177,603</u>	<u>\$ 5,954,853</u>
Total Assets	\$ 13,177,603	\$ 5,954,853
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 476,509	\$ 253,336
Accrued expenses and other liabilities	626,583	827,676
Due to related parties		162,964
Capital lease obligations - current maturities		36,003
Deferred revenue	547,006	809,945
	<u>1,650,098</u>	<u>2,089,924</u>
Total current liabilities	1,650,098	2,089,924
Deferred revenue - long term	3,338,666	3,557,835
	<u>4,988,764</u>	<u>5,647,759</u>
Total liabilities	4,988,764	5,647,759

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

	<u>December 31,</u>	
Shareholders' Equity:		
Series A Convertible Preferred Stock: \$0.01 par; authorized 10,000 shares; 1,500 and 1,450 issued and outstanding at December 31, 2004 and 2003, respectively	15	15
Series D Convertible Preferred Stock: \$0.01 par; authorized 245,000 shares; 63,588 and 243,749 issued and outstanding at December 31, 2004 and 2003, respectively	636	2,437
Common Stock: \$0.01 par; authorized 100,000,000 shares; 40,418,406 and 19,831,296 issued and outstanding at December 31, 2004 and 2003, respectively	404,184	198,313
Additional paid-in capital	94,479,402	77,771,149
Prepaid license discount	(2,698,427)	(2,894,677)
Accumulated deficit	(82,575,151)	(74,126,619)
Deferred compensation	(759,342)	(23,688)
Accumulated other comprehensive loss	(662,478)	(619,836)
	<u>8,188,839</u>	<u>307,094</u>
Total Liabilities and Shareholders' Equity	\$ 13,177,603	\$ 5,954,853

See accompanying notes to consolidated financial statements.

51

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	<u>Years Ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Revenues:			
Product sales	\$ 1,834,431	\$ 2,646,628	\$ 2,421,804
Development revenue	196,648	310,035	935,324
Licensing fees	634,542	695,244	638,633
Royalties	80,335	134,937	
Total revenue	2,745,956	3,786,844	3,995,761
Cost of sales:			
Cost of product sales	1,304,504	1,917,647	2,301,994
Cost of development revenue	67,798	90,236	271,286
Total cost of sales	1,372,302	2,007,883	2,573,280
Gross margin	1,373,654	1,778,961	1,422,481
Operating expenses:			
Research and development	3,546,438	3,493,966	3,654,333
Sales, marketing and business development	675,878	462,376	797,655
General and administrative	5,526,004	6,456,659	5,232,389
Goodwill impairment charge			2,000,000
	<u>9,748,320</u>	<u>10,413,001</u>	<u>11,684,377</u>
Net operating loss	(8,374,666)	(8,634,040)	(10,261,896)

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

	Years Ended December 31,		
	2004	2003	2002
Other income (expense):			
Loss on debt extinguishments		(885,770)	
Loss on conversions of debt to equity		(16,283,677)	
Loss on common stock warrants		(5,960,453)	
Interest expense	(100,471)	(920,130)	(1,297,440)
Interest income	120,292	16,541	19,748
Foreign exchange gains (losses)	(6,849)	1,926	(68,395)
Other, net	13,162	(152,361)	(782)
	26,134	(24,183,924)	(1,346,869)
Net loss	(8,348,532)	(32,817,964)	(11,608,765)
Preferred stock dividends	(100,000)	(142,857)	(100,000)
Net loss applicable to common shares	\$ (8,448,532)	\$ (32,960,821)	\$ (11,708,765)
Basic and diluted net loss per common share	\$ (0.23)	\$ (2.18)	\$ (1.22)
Basic and diluted weighted average common shares outstanding	36,347,892	15,092,803	9,617,749

See accompanying notes to consolidated financial statements.

52

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS
Years Ended December 31, 2002, 2003 and 2004

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Prepaid License Discount	Accumulated Deficit	Deferred Compensation	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Series A	Series D	Number of Shares	Amount						
December 31,										
2001	1,250	\$ 13	\$ 9,161,188	\$ 91,612	\$ 37,464,531	\$ (29,457,033)	\$ (251,016)	\$ (379,940)	\$ 7,468,167	
Conversion of shareholder loans to equity			509,137	5,091	2,031,459					2,036,550
Preferred stock issued in lieu of dividends	100	1			99,999		(100,000)			
Stock-based compensation			158,810	1,588	321,158		113,664			436,410
Intrinsic value of beneficial con- version feature of convertible debentures					1,720,000					1,720,000
Issuance of										

**Convertible Preferred
Stock**

warrants in connection with convertible debentures				467,016					467,016
Convertible debentures converted into common stock			947,750	9,478	249,329				258,807
Net loss								(11,608,765)	(11,608,765)
Translation adjustments								(122,897)	(122,897)
Comprehensive loss									(11,731,662)
December 31, 2002	1,350	14	10,776,885	107,769	42,353,492	(41,165,798)	(137,352)	(502,837)	655,288

See accompanying notes to consolidated financial statements.

**ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS (CONTINUED)
Years Ended December 31, 2002, 2003 and 2004**

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Prepaid License Discount	Accumulated Deficit	Deferred Compensation	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Series A	Series D	Number of Shares	Amount						
December 31, 2002	1,350	14	10,776,885	107,769	42,353,492		(41,165,798)	(137,352)	(502,837)	655,288
Warrants issued with debt to shareholder					735,514					735,514
Conversion of shareholder loans to equity			2,398,635	23,986	12,294,909					12,318,530
Convertible debentures converted into common stock			1,831,110	18,311	594,518					612,939
Required intrinsic value of beneficial conversion of convertible debentures					(1,225,630)					(1,225,630)

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Convertible Preferred Stock

converted into Preferred Series D	243,749	2,437			7,084,211								7,086,
Issuance of common stock in private placement			4,000,000	40,000	2,301,414								2,341,
Stock-based compensation			814,266	8,143	1,881,357			113,664					2,003,
Exercise of stock options			10,400	104	16,146								16,
Preferred stock issued in lieu of dividends	100	1			99,999			(142,857)					(42,
Reclassification of warrants as equity from debt					8,691,480								8,691,
Prepaid license discount, net of amortization					2,943,739	(2,894,677)							49,
Net loss								(32,817,964)					(32,817,
Translation adjustments									(116,999)				(116,
Comprehensive loss													(32,934,
December 31, 2003	1,450	15	243,749	2,437	19,831,296	198,313	77,771,149	(2,894,677)	(74,126,619)	(23,688)	(619,836)		307,
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,
Stock-based compensation					185,000	1,850	1,559,185		(735,654)				825,
Exercise of warrants					3,480,500	34,805	1,513,083						1,547,
Preferred stock dividends	50						50,000		(100,000)				(50,
Amortization of prepaid license discount								196,250					196,
Net loss									(8,348,532)				(8,348,
Translation adjustments										(42,642)			(42,
Comprehensive loss													(8,391,

Convertible Preferred Stock

December 31,

2004	1,500	\$ 15	63,588	\$ 636	40,418,406	\$ 404,184	\$ 94,479,402	\$ (2,698,427)	\$ (82,575,151)	\$ (759,342)	\$ (662,478)	\$ 8,188,
------	-------	-------	--------	--------	------------	------------	---------------	----------------	-----------------	--------------	--------------	-----------

See accompanying notes to consolidated financial statements.

54

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	\$ (8,348,532)	\$ (32,817,964)	\$ (11,608,765)
Adjustments to reconcile net loss to net cash used in operating activities:			
Goodwill impairment charge			2,000,000
Patent rights impairment charge	233,062	973,769	435,035
Depreciation and amortization	580,080	845,234	907,131
Loss on disposal and abandonment of assets	5,701	124,125	19,878
Stock-based compensation expense	825,381	1,965,165	370,410
Noncash interest expense	75,388	862,308	1,146,148
Loss on conversions of debt to equity		16,283,677	
Loss on debt extinguishments		741,570	
Losses on common stock warrants		5,960,453	
Amortization of prepaid license discount	196,250	49,062	
Changes in operating assets and liabilities:			
Accounts receivable	200,855	(307,319)	360,895
Other receivables	(134,678)	30,342	293,371
Inventories	133,064	333,503	96,780
Prepaid expenses and other assets	(16,873)	(19,935)	(365,065)
Accounts payable	214,367	(355,359)	(29,099)
Accrued expenses and other	(216,011)	(651,946)	510,992
Due to related parties	(105,023)	(30,929)	(49,800)
Deferred revenue	(577,700)	2,508,492	348,090
Other	(232,644)	(47,571)	10,233
Net cash used in operating activities	(7,167,313)	(3,553,323)	(5,553,766)
Cash flows from investing activities:			
Purchases of equipment, furniture and fixtures	(218,038)	(1,160)	(155,145)
Additions to patent rights	(76,193)	(168,687)	(280,651)
Purchase of short-term investments	(19,889,565)		
Proceeds from maturity of short-term investments	12,000,000		
Net cash used in investing activities	(8,183,796)	(169,847)	(435,796)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	13,753,400	2,357,663	
Proceeds from exercise of warrants	1,472,500		
Proceeds from sales of warrants		1,588,586	
Proceeds from subordinated loans from shareholders		1,600,000	2,700,000
Proceeds from issuance of convertible debentures		621,025	2,000,000
Principal payments on convertible debentures		(464,000)	
Principal payments on capital lease obligations	(35,297)	(107,461)	(128,788)
Payment of preferred stock dividends	(50,000)		

	Years Ended December 31,		
	2004	2003	2002
Net cash provided by financing activities	15,140,603	5,595,813	4,571,212
Effect of exchange rate changes on cash and cash equivalents	(65,901)	(211,773)	(278,794)
Net increase (decrease) in cash and cash equivalents	(276,407)	1,660,870	(1,697,144)
Cash and cash equivalents:			
Beginning of year	1,928,815	267,945	1,965,089
End of year	\$ 1,652,408	\$ 1,928,815	\$ 267,945

See accompanying notes to consolidated financial statements.

55

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2004, 2003 and 2002

1. Description of Business and Summary of Significant Accounting Policies

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 Exton, Pennsylvania, with research and production facilities in Minneapolis, Minnesota, and research, development and commercialization facilities in Basel, Switzerland. As discussed in Note 10, in 2003 the Company outsourced all assembly work previously performed at its Minneapolis facility to a third-party supplier.

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

Sales transactions of foreign subsidiaries are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the U.S. parent. However, nearly all operating expenses, including labor, materials, leasing arrangements and other operating costs, are denominated in Swiss Francs. Additionally, bank accounts 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 subsidiaries. The reporting currency for the Company is the United States Dollar (USD). The financial statements of the Company's three 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 shareholders' 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 four to six 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. The securities are carried at their amortized cost. At December 31, 2004 the securities have a fair value of \$7,968,203 and a carrying value of \$7,971,625.

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 as discussed in Note 10 the Company's production and assembly operations have been transferred 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.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

1. Description of Business and Summary of Significant Accounting Policies (Continued)

Deferred Financing Costs

The Company capitalized costs associated with the issuance of its 10% debentures. These costs were being amortized to interest expense using the effective-interest method over the twelve-month period of the debentures, or the unamortized balance was recorded to additional-paid-in-capital on a pro rata basis as an offset against net proceeds upon conversion of the debentures to common stock. As further described in Note 3, the 10% debentures were restructured and exchanged in January 2003 for 8% debentures. As a result of the debenture restructuring, approximately \$223,223 of the deferred financing costs of \$454,910 at December 31, 2002 was recognized as part of the loss on debt extinguishments. The remaining balance was recognized as interest expense, recorded as part of debt discount on the 8% debentures, or was recorded to additional-paid-in-capital as an offset against net proceeds upon conversion of the debentures to common stock.

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 for 2004, 2003 and 2002 was \$423,107, \$667,050 and \$727,705, 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 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 2004 and 2003 resulted in no impairment losses.

In connection with the transitional goodwill impairment evaluation, SFAS 142 required the Company to perform an assessment of whether there was an indication that goodwill was impaired as of the January 1, 2002 adoption date. This analysis indicated that there was not a goodwill impairment upon adoption of SFAS No. 142. The Company's annual impairment analysis as of December 31, 2002 indicated a potential impairment charge due to a significant decline in the Company's stock price in the fourth quarter of 2002 and concerns about the continued existence of the Company due to continued net losses and negative cash flows from operations. After completion of the impairment analysis prescribed in SFAS No. 142, the Company recorded a goodwill impairment charge of \$2,000,000 in the fourth quarter of 2002.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

1. Description of Business and Summary of Significant Accounting Policies (Continued)

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.

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.

In the fourth quarters of 2004 and 2003 the Company updated its long-range business plan. The Company then reviewed patent costs for impairment and identified certain 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. Therefore, in 2004 and 2003 the Company recognized impairment charges of \$233,062 and \$973,769, respectively, in research and development expenses, which represented the gross carrying amount net of accumulated amortization for the identified patents. After the impairment charges, the gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, were \$1,382,595 and \$435,136, respectively, at December 31, 2004 and were \$1,756,711 and \$542,355, respectively, at December 31, 2003. The Company's estimated aggregate amortization expense for the next five years is \$131,000 in 2005 and 2006, \$96,000 in 2007, and \$93,000 in 2008 and 2009.

The Company's goodwill impairment analysis as of December 31, 2002 indicated that the Company's goodwill might be impaired which required the Company to assess the recoverability of its capitalized patent portfolio costs and other long-lived assets as of December 31, 2002. As a result of this analysis, the Company recognized an impairment charge related to its patent portfolio of \$435,035 in research and development expenses for the year ended December 31, 2002. The analysis of patent costs was performed by management based on values provided through third-party corporate development activities.

Accounting for Debt and Equity Instruments

During the first quarter of 2003, in connection with a restructuring of its 10% convertible debentures, the Company issued warrants to purchase common stock to the debenture holders. In the third quarter of 2003, the holders of the restructured debentures exchanged the remaining outstanding principal of such debentures for shares of the Company's Series D Convertible Preferred Stock. Also in the third quarter of 2003, the Company's largest shareholder converted debt owed to him by the Company into shares of the Company's common stock and warrants to purchase the Company's common stock. The Company also completed a private placement of its common stock and warrants in the third quarter of 2003 and the first quarter of 2004. The accounting for debt and equity transactions is complex and requires the Company to make certain judgments regarding the proper accounting treatment of these instruments. The Company's significant judgments related to the capital restructuring transactions included:

- the accounting for one of the convertible debentures as an extinguishment and issuance of debt instruments and the other as a troubled debt restructuring;
- the determination of the fair values of the convertible debentures and the warrants issued with the transactions; and

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

1. Description of Business and Summary of Significant Accounting Policies (Continued)

the classification of the warrants as liabilities.

The Company's significant judgments related to the debenture exchange transaction included the determination of the fair values of the Series D Convertible Preferred Stock and warrants issued in connection with the transaction. Significant judgments related to the private placement of common stock and warrants included the determination of the fair value of the warrants, the allocation of the proceeds between the common stock and the warrants, and the initial classification of the warrants as liabilities. In August and September of 2003, the Company modified the warrants issued in the above noted transactions resulting in the reclassification of the warrants from debt to equity.

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 using the percentage of completion or 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. This Issue was applicable for the Company effective June 15, 2003 and was applied to the license agreement with Eli Lilly and Company, discussed further in Note 9.

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, but if it does not meet the separation criteria, then an up-front payment is deferred and amortized into revenues on a straight-line basis.

1. Description of Business and Summary of Significant Accounting Policies (Continued)

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 will be amortized into revenues on a straight-line basis. Likewise, the labor and material 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.

As discussed in Note 6, 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. 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 the Company concludes that the revenues from this arrangement will not exceed the costs, part or all of the remaining prepaid license discount may be charged to earnings at that time.

Stock-Based Compensation

The Company applies Accounting Principles Board, Opinion 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for stock plans. Accordingly, compensation expense has not been recognized for stock-based compensation plans other than when the exercise price of stock options was below the fair value of the options on the date of grant. In September 2003 the Company issued stock options to employees at \$1.77 per share when the fair value of the stock was \$2.20 per share. In 2004 and 2003 the Company recognized compensation expense of \$165,192 and \$249,640, respectively, in connection with the employee stock options granted in September 2003. Had compensation cost been determined based on the fair value at the grant date for all stock options under SFAS No. 123, *Accounting and Disclosure of Stock-Based Compensation*, the net loss and loss per share would have increased to the pro-forma amounts shown below:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net loss applicable to common shareholders:			
As reported	\$ (8,448,532)	\$ (32,960,821)	\$ (11,708,765)
Add intrinsic value of stock options granted	165,192	249,460	
Deduct fair-value method compensation expense	(1,203,327)	(1,318,030)	(389,722)
Pro Forma net loss	<u>\$ (9,486,667)</u>	<u>\$ (34,029,391)</u>	<u>\$ (12,098,487)</u>
Basic and diluted net loss per common share:			
As reported	\$ (0.23)	\$ (2.18)	\$ (1.22)
Add intrinsic value of stock options granted		0.02	
Deduct fair-value method compensation expense	(0.03)	(0.09)	(0.04)
Pro Forma net loss per common share	<u>\$ (0.26)</u>	<u>\$ (2.25)</u>	<u>\$ (1.26)</u>

The per share weighted-average fair value of stock based awards granted during 2004, 2003 and 2002 was estimated as \$0.87, \$1.93 and \$3.66 respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Risk-free interest rate	3.7%	3.1%	4.5%
Annualized volatility	124.0%	140.0%	134.0%
Weighted average expected life, in years	5.0	5.0	5.0
Expected dividend yield	0.0%	0.0%	0.0%

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

1. Description of Business and Summary of Significant Accounting Policies (Continued)

The Company accounts for stock-based instruments granted to nonemployees under the fair value method of SFAS 123 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 123, 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 12 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:

	Balance at Beginning of Year	Warranty Provisions	Warranty Claims	Balance at End of Year
2004	\$ 50,000	\$ (13,542)	\$ (6,458)	\$ 30,000
2003	\$ 179,000	\$ (25,859)	\$ (103,141)	\$ 50,000

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.

1. Description of Business and Summary of Significant Accounting Policies (Continued)

Net Loss Per Share

Basic EPS is computed by dividing net income or loss available to common shareholders 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 debentures had been dilutive, the associated interest expense and amortization of deferred financing costs, net of taxes, would have been removed from operations and the shares issued would have been assumed outstanding for the dilutive period. Likewise, 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.

Potentially dilutive securities at December 31, 2004, 2003 and 2002, excluded from dilutive loss per share as their effect is anti-dilutive, are as follows:

	2004	2003	2002
Stock options and warrants	20,256,591	15,405,491	1,878,288
Principal of convertible debentures	\$	\$	\$ 1,624,346
Potentially dilutive shares from Series D convertible preferred stock	635,880	2,437,490	

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.

New Accounting Pronouncements

In December 2004, the FASB issued FASB Statement No. 123R, *Share-Based Payment*. Among other items, the standard requires that the compensation cost relating to share-based payment transactions be recognized in the consolidated statement of operations. Note 1 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. The new standard is effective for the first interim or annual reporting period that begins after June 15, 2005. The Company expects to implement the new standard beginning with the third quarter of 2005, and to use the modified prospective transition method. Under this method, awards that are granted, modified, or settled after the date of adoption will be measured and accounted for in accordance with Statement 123R, and unvested equity awards granted prior to the effective date will continue to be accounted for in accordance with Statement 123 as they have been for purposes of pro forma disclosures, except that amounts will be recognized in the statement of operations.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

2. Composition of Certain Financial Statement Captions

	December 31,	
	2004	2003
Inventories:		
Raw material	\$ 32,335	\$ 40,420
Finished goods	60,009	184,988
	\$ 92,344	\$ 225,408

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

December 31,

Equipment, furniture and fixtures:

Furniture, fixtures and office equipment	\$ 1,250,751	\$ 1,376,022
Production equipment	2,183,026	1,836,608
Less accumulated depreciation	(2,821,857)	(2,411,261)
	<u>\$ 611,920</u>	<u>\$ 801,369</u>

Patent rights:

Patent rights	\$ 1,382,595	\$ 1,756,711
Less accumulated amortization	(435,136)	(542,355)
	<u>\$ 947,459</u>	<u>\$ 1,214,356</u>

Goodwill:

Goodwill	\$ 1,470,807	\$ 1,470,807
Less accumulated amortization	(375,452)	(375,452)
	<u>\$ 1,095,355</u>	<u>\$ 1,095,355</u>

Accrued expenses and other liabilities:

Retirement benefits	\$ 100,000	\$ 150,000
Estimated withholding tax due on foreign payments		199,616
Other liabilities	526,583	478,060
	<u>\$ 626,583</u>	<u>\$ 827,676</u>

3. Convertible Debentures

In July 2002, the Company sold \$2,000,000 aggregate principal amount of its 10% debentures, with \$700,000 maturing on July 12, 2003, \$700,000 maturing on July 26, 2003 and \$600,000 maturing on October 15, 2003. The debentures were convertible into shares of the Company's common stock at a conversion price which is the lower of \$2.50 or 75% of the average of the three lowest intraday prices of the Company's common stock, as reported on the Nasdaq SmallCap Market, during the 20 trading days preceding the conversion date. From October 10, 2002 to January 17, 2003, three of the original four holders of the 10% debentures converted \$581,000 of principal into 1,777,992 shares of common stock at an average conversion price of approximately \$0.327 per share. Two of the original four holders accounted for the conversion of \$536,000 of principal into 1,660,863 shares of common stock. As a result of the Company's low common stock price, the 10% debentures became highly dilutive to the Company's current common shareholders.

To reduce the risk of substantial dilution to common shareholders in the near-term, on February 7, 2003, the Company completed a restructuring of its 10% debentures previously sold to four primary investors. Specifically, as part of this restructuring, on January 24, 2003 and January 31, 2003, the Company borrowed an aggregate of \$621,025 from Xmark Funds. The Company used the proceeds of these borrowings to repurchase \$464,000 principal amount of the 10% debentures previously sold to the two original 10% debenture holders who had converted \$536,000 of principal into common stock, and to pay a repurchase premium of \$144,200 and accrued interest of \$12,825. As additional repurchase compensation, the Company issued warrants to one of the two original 10% debenture holders and paid \$5,000, in lieu of warrants, to the other. The Company recognized a debt extinguishment loss of \$885,770 related to these transactions. Thereafter, in exchange for the surrender and cancellation of the promissory notes, the Company issued to Xmark Funds 8% Senior Secured Convertible Debentures in the same principal amount of the promissory notes. The Company also exchanged Amended and Restated 8% Senior Secured Convertible Debentures for the remaining outstanding principal and accrued interest of \$955,000 and \$37,230, respectively, of the original 10% debentures. The aggregate principal amount of the 8% debentures was \$1,613,255. The 8% debentures contained terms similar to the 10% debentures, except that the 8%

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

3. Convertible Debentures (Continued)

debentures included a fixed conversion price of \$.50 per share and an interest rate of 8% per annum. The 8% debentures were due March 31, 2004. Similar to the 10% debentures, the Company granted a senior security interest in substantially all of its assets to the holders of the 8% debentures. In connection with this restructuring, the Company also issued to the holders of the 8% debentures five-year warrants to purchase an aggregate of 2,932,500 shares of the Company's common stock at an exercise price of \$0.55 per share.

The aggregate original principal amount of the 8% debentures of \$1,613,255 was held by two debenture holders in the amounts of \$469,513 and \$1,143,742, respectively. The Company analyzed each of the restructuring transactions for the two 8% debenture holders to determine the proper accounting treatment. The effective borrowing rate on \$469,513 of restructured debentures was determined to be less than the effective borrowing rate on the original debentures immediately prior to the restructuring. As a result, the Company determined that these debentures should be accounted for as a troubled debt restructuring. The net carrying value of these debentures at the time of the restructuring was reduced from \$140,659 to \$97,710 resulting in a debt discount of \$371,803 that was being amortized to interest expense through March 31, 2004 using the effective interest method. The unamortized discount was written off in connection with the conversions on September 12, 2003. The transaction related to the remaining \$1,143,742 was accounted for as a debt extinguishment under EITF 96-19. The restructured debentures were determined to be substantially different from the original debentures because the present value of the cash flows under the terms of the restructured debentures was more than 10 percent different from the present value of the remaining cash flows under the terms of the original debentures. The debentures were recorded at a fair value of \$1,276,339, and the premium of \$132,597 was being amortized monthly through March 31, 2004 using the effective interest method. The unamortized premium was written off in connection with the conversions on September 12, 2003. In connection with both transactions, the Company issued warrants to acquire 2,932,500 shares of common stock. The Company determined that the fair value of these warrants was \$1,142,442 using the Black Scholes option pricing model. As further discussed in Note 6, these common stock warrants were initially classified as debt for accounting purposes.

Effective July 1, 2003, the Company's securities were delisted from The Nasdaq SmallCap Market and began trading on the Over-the-Counter ("OTC") Bulletin Board under the symbol "ANTR.OB," after the Nasdaq Listing Qualifications Panel determined to delist the Company's securities. The delisting from The Nasdaq SmallCap Market constituted an event of default under the restructured 8% debentures. However, the Company obtained letters from the debenture holders in which they agreed to forbear from exercising their rights and remedies with respect to such event of default, indicating they did not intend to accelerate the payment and other obligations of the Company under the debentures. The debenture holders reserved the right at any time to discontinue the forbearance and, among other things, to accelerate the payment and other obligations of the Company under the 8% debentures. If the debenture holders had decided to discontinue their forbearance, the debentures would have become due and payable at 130% of the outstanding principal and accrued interest. Because the debenture holders retained the right to discontinue the forbearance and this option was outside the control of the Company, the Company was required to record an expense and a liability of \$508,123 for the 30% penalty in future periods until the debentures were converted to common stock, at which time the liability was removed and offset against the loss on conversions of debt to equity.

On September 12, 2003, \$475,000 of the Company's 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures were converted into 949,998 shares of common stock.

On September 12, 2003, the holders of the Company's 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures (collectively, the "Debentures") exchanged the outstanding \$1,218,743 aggregate principal and accrued interest of the Debentures for 243,749 shares of the Company's Series D Convertible Preferred Stock (the "Series D Preferred"). Each share of Series D Preferred is currently 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. As a result, the Series D Preferred is

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

3. Convertible Debentures (Continued)

convertible into the same number of shares of Common Stock as were the Debentures. In connection with the exchange of the Debentures for the Series D Preferred, the holders of the Debentures executed lien release letters terminating the security interest they held in the Company's assets. As consideration for the release of the security interest, the Company adjusted the exercise price of certain warrants issued to the holders of the Debentures on January 31, 2003 from \$0.55 per share to \$0.40 per share. These warrants are exercisable for an aggregate of 2,932,500 shares of

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Common Stock and are redeemable at the option of the Company upon the achievement of certain milestones set forth in the warrants. In connection with the exchange of the Debentures for the Series D Preferred and the reduction in the warrant exercise price, the Company recognized a loss on conversion of \$6,017,346 during the quarter ended September 30, 2003. The loss consists of the fair value of the Series D Preferred plus the increase in fair value of the warrants due to the reduction in the exercise price, less the carrying value of the Debentures. The carrying value of the Debentures included the aggregate principal and accrued interest less unamortized discount and premium.

4. Leases

The Company has non-cancelable operating leases for its office, research and manufacturing facility in Minneapolis, MN, for office space in Exton, PA, 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. The cost of equipment and furniture under capital leases at December 31, 2003 was \$191,881 and accumulated amortization was \$153,289. The Company's capital lease was fully repaid in 2004.

Rent expense incurred for the years ended December 31, 2004, 2003 and 2002 was \$436,152, \$670,650 and \$559,512, respectively.

Future minimum annual operating lease payments are as follows as of December 31, 2004:

	Amount
2005	\$ 282,168
2006	284,946
2007	286,334
2008	238,513
2009	91,191
Thereafter	125,293
	\$ 1,308,445

65

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

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, 2004, 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, 2004. Effective tax rates differ from statutory income tax rates in the years ended December 31, 2004, 2003 and 2002 as follows:

	2004	2003	2002
Statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(0.0)	(0.0)	(0.0)
Research and experimentation credit	0.1	(0.3)	(0.3)
Intangibles impairment		1.0	7.1
Valuation allowance increase	5.4	4.1	7.5
Expiration of net operating losses	3.0	1.7	7.3
Foreign net operating loss carryforwards	15.7		
Effect of foreign operations	8.1	2.3	12.3
Losses from various financing transactions		25.0	
Other	1.7	0.2	0.1
	0.0%	0.0%	0.0%

Deferred tax assets as of December 31, 2004 and 2003 consist of the following:

5. Income Taxes

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

	2004	2003
Net operating loss carryforward - U.S.	\$ 13,924,000	\$ 13,296,000
Net operating loss carryforward - Switzerland	2,414,000	2,665,000
Research and development costs and tax credit carryforward	796,000	808,000
Deferred revenue	964,000	1,038,000
Depreciation and amortization	418,000	66,000
Other	795,000	732,000
	19,311,000	18,605,000
Less valuation allowance	(19,311,000)	(18,605,000)
	\$	\$

The valuation allowance for deferred tax assets as of December 31, 2004 and 2003 was \$19,311,000 and \$18,605,000, respectively. The net change in the total valuation allowance for the years ended December 31, 2004 and 2003 was an increase of \$706,000 and \$1,783,000, 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 placed a valuation allowance against the entire deferred tax asset.

The Company has a U.S. federal net operating loss carryforward at December 31, 2004, of approximately \$38,000,000, 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 2005 through 2024, with approximately \$437,000 expiring over the next three years. Additionally, the Company has a research credit carryforward of approximately \$796,000. These credits expire in years 2008 through 2024.

66

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

5. Income Taxes (Continued)

The Company also has a Swiss net operating loss carryforward at December 31, 2004, of approximately \$17,800,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2006 through 2011, with approximately \$1,800,000 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. Shareholders Equity

Common Stock

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

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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.

On September 12, 2003, \$475,000 of the Company's 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures were converted into 949,998 shares of common stock.

As discussed in Note 13, on September 12, 2003, principal of \$2,300,000 and accrued interest of \$98,635 due to the Company's largest shareholder, Dr. Jacques Gonella, was converted into 2,398,635 shares of common stock and warrants to acquire 1,798,976 shares of common stock with an exercise price of \$1.25 per share. The common stock and warrants issued in this exchange aggregated \$12,318,895, resulting in a charge to earnings of \$10,266,331. On June 10, 2002, Dr. Gonella converted principal and interest of \$2,036,550, loaned to the Company under a Term Note agreement, into 509,137 shares of common stock at \$4.00 per share, the market price of the Company's stock on that date.

In July 2003 the Company received aggregate proceeds of \$4,000,000 in two separate private placements of its common stock. The Company issued 4,000,000 shares of its common stock at a price of \$1.00 per share and warrants to purchase 3,000,000 shares of common stock at an exercise price of \$1.25 per share. The warrants expire in July 2008. The proceeds of the private placements were allocated to the common stock and warrants based on their relative fair values. An aggregate of \$2,411,414 was allocated to the common shares and \$1,588,586 to the common stock warrants issued in the transaction.

In January of 2003, \$198,250 of the Company's 10% debentures was converted into 881,112 shares of common stock. As of December 31, 2002, \$382,750 of the 10% debentures and accrued interest of \$17,085 had been converted into 947,750 shares of common stock.

67

ANTARES PHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued) December 31, 2004, 2003 and 2002

6. Shareholders Equity (Continued)

During 2004, 2003 and 2002, a total of 50,000, 784,266 and 118,810 shares of common stock, respectively, were issued to consultants or professional services organizations as compensation for services rendered. The total value of the shares issued was \$54,550, \$677,809 and \$304,300, respectively. In 2004 and 2003 the Company issued 35,000 and 30,000 shares of common stock, respectively, to directors at a value of \$30,300 and \$39,000, respectively. 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, upon the resignation of Roger G. Harrison, Ph.D. 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 will become fully vested on the first anniversary of his employment. 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 is being recognized ratably over the one-year vesting period. Compensation expense of \$14,583 was recognized in connection with these shares during the year ended December 31, 2004. Mr. Stover can earn up to an additional 459,999 shares of common stock upon the occurrence of various triggering events. The Company will begin recognizing expense in connection with these additional shares when it becomes probable that a triggering event will be reached.

Roger G. Harrison, Ph.D., was appointed Chief Executive Officer of Antares Pharma, Inc., effective March 12, 2001. Under the terms of the employment agreement with Dr. Harrison, the Company issued 88,000 restricted shares of common stock with a three-year vesting period that became fully vested on March 12, 2004. The Company had recorded deferred compensation expense of \$341,000, the aggregate market value of the 88,000 shares at the measurement date. Compensation expense was recognized ratably over the three-year vesting period. Compensation expense of \$23,688, \$113,664 and \$113,664 was recognized in connection with these shares during the years ended December 31, 2004, 2003 and 2002, respectively. Dr. Harrison resigned as Chief Executive Officer effective September 1, 2004, and on that date entered into an agreement with the Company under which he will provide consulting services.

Series A Convertible Preferred Stock

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

On November 10, 1998, the Company sold 1,000 shares of Series A Convertible Preferred Stock (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 carries a 10% dividend which is payable semi-annually. The Series A is redeemable at the Company's option at any time and is convertible into common stock for sixty days following the 10th anniversary of the date of issuance at the lower of \$7.50 per share or 95% of the market price of the Common Stock. The warrants to purchase Common Stock may be exercised at any time prior to November 10, 2005, at a price of \$1.29 per share.

Convertible Debentures Beneficial Conversion Feature

As discussed in Note 3, on July 12, 2002 the Company entered into a Securities Purchase Agreement for the sale and purchase of up to \$2,000,000 aggregate principal amount of the Company's 10% Convertible Debentures. As the per share conversion price of the debentures was substantially lower than the market price of the common stock on the date the debentures were sold, the Company recorded a debt issuance discount of \$1,720,000 in 2002 for the intrinsic value of the beneficial in-the-money conversion feature of the debentures. Interest expense of \$606,456 was

68

ANTARES PHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued) December 31, 2004, 2003 and 2002

6. Shareholders' Equity (Continued)

recorded as amortization of the \$1,720,000 of debt issuance discount over the original one year redemption period, and an additional \$222,357 of the debt issuance discount was recorded as interest expense due to conversions of the 10% debentures to common stock. When the debentures were restructured in February 2003, the intrinsic value of the beneficial in-the-money conversion feature for the remaining debentures on the date of the restructuring was \$1,225,630. This amount exceeded the remaining debt issuance discount from the intrinsic value of the beneficial in-the-money conversion feature when the debentures were originally sold. In accordance with applicable accounting literature the entire amount of the intrinsic value of the beneficial conversion feature on the date of the restructuring was deemed to have been reacquired by the Company and was recorded as a reduction to additional paid-in capital.

Series D Convertible Preferred Stock

As discussed in Note 3, on September 12, 2003, the holders of the Company's 8% Senior Secured Convertible Debentures and Amended and Restated 8% Senior Secured Convertible Debentures exchanged the outstanding \$1,218,743 aggregate principal and accrued interest of these Debentures for 243,749 shares of the Company's Series D Convertible Preferred Stock. Each share of Series D Preferred 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. In August 2004, 180,161 shares of Series D Preferred Stock were converted into 1,801,610 shares of common stock.

Stock Options and Warrants

The Company's stock option plans allow for the grants of options to officers, directors, consultants and employees to purchase shares of Common Stock at exercise prices not less than 100% of fair market value on the dates of grant. The term of the options is either ten or eleven years and they vest in varying periods. As of December 31, 2004, these plans had 2,636,147 shares available for grant.

As compensation to non-employees for professional services, in 2004 the Company issued options and warrants to purchase 150,000 and 400,000 shares of the Company's common stock, respectively, and in 2003 issued warrants to purchase 1,050,000 shares of the Company's common stock. The Company recognized expense related to these options and warrants of \$502,293 and \$923,232 in 2004 and 2003, 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.

The warrants to purchase 3,000,000 shares of common stock issued in the private placement in July 2003 were subject to defined indemnifications if the underlying common shares were not fully tradable and the warrant holders incurred losses due to their inability to sell these shares. The Company analyzed the terms and conditions of the warrants and determined that the warrants should be classified as debt under EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock. As such, the Company was required to mark-to-market these warrants at each reporting period with changes in the warrant values being recorded in the consolidated statement of operations. The proceeds of \$4,000,000 were allocated between equity and debt based on the relative fair values of the common stock and the warrants on the dates of the private placements. The fair value of the common stock was based on the market price and the warrant fair values were calculated using the Black-Scholes option pricing model. The allocation resulted in an initial value assigned to the warrants of \$1,588,585. On September 30, 2003, certain terms and conditions of the warrant agreements were amended, causing the warrants to be classified as equity rather than as debt as of the date of the amendment and ending the requirement to adjust the market value of the warrants

6. Shareholders' Equity (Continued)

61

each reporting period. The warrants were adjusted to their fair value of \$4,254,211 on September 30, 2003, resulting in a loss of \$2,665,626 on these common stock warrants in 2003.

In July 2003 the Company issued warrants to purchase 100,000 shares of the Company's common stock as compensation for agent services related to the private placement in July 2003. The warrants are exercisable at \$1.25 per share and expire in 2008.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

6. Shareholders' Equity (Continued)

As discussed in Note 13, during 2003 the Company issued warrants to Jacques Gonella, its largest shareholder, for the purchase of 2,400,000 shares of common stock at an exercise price of \$0.55 per share in connection with Term Notes totaling \$1,600,000 and for the purchase of 1,798,976 shares of common stock at an exercise price of \$1.25 per share in connection with the conversion of Term Notes to common stock.

In connection with the debenture restructuring transactions completed in February 2003 discussed in Note 3, the Company issued to the holders of the 8% debentures five-year warrants to purchase an aggregate of 2,932,500 shares of the Company's common stock at an exercise price of \$0.55 per share, which was subsequently reduced to \$0.40 per share. The warrants were subject to defined indemnifications if the underlying common shares were not fully tradable and the warrant holders incurred losses due to their inability to sell these shares. The Company analyzed the terms and conditions of the warrants and determined that the warrants should be classified as debt under EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock. As such, the Company was required to mark-to-market these warrants at each reporting period with changes in the warrant values being recorded in the consolidated statement of operations. The warrants were recorded with an initial fair value on January 31, 2003 of \$1,142,442, determined using the Black Scholes option pricing model, and were adjusted to their fair value of \$4,437,269 at August 13, 2003, when certain terms and conditions of the warrant agreements were amended, causing the warrants to be classified as equity rather than as debt as of the date of the amendment and ending the requirement to adjust the market value of the warrants each reporting period. The Company recognized a loss \$3,294,827 on these common stock warrants in 2003.

As discussed in Note 9, 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. The Company granted Lilly certain registration rights with respect to the shares of common stock issuable upon exercise of the warrant. 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 prepaid license discount will be reduced on a straight-line basis over the term of the agreement, offsetting revenue generated under the agreement.

Warrants were issued in connection with debt financing, financial consulting and technology procurement during 1996 through 2002. The terms of the warrants do not exceed ten years and vest in varying periods. Under the terms of an equity advisor agreement in connection with the Company's 10% Convertible Debentures, the Company issued in July and October 2002, warrants to purchase an aggregate of 112,000 and 48,000 shares, respectively, valued at \$412,117 and \$54,899, respectively, which were recorded to deferred financing costs. During 2002 the deferred financing costs were being amortized to interest expense over the one-year life of the debentures. As debentures were converted to common stock, the unamortized portion of the allocated deferred financing costs was recorded to additional paid in capital. As discussed in Note 3, a restructuring of the Company's 10% debentures was completed on February 7, 2003, and as a result the remaining unamortized deferred financing costs were recognized as interest expense in the first quarter of 2003.

A majority of the Company's warrants have either weighted average or full antidilution protection, which may increase the number of shares issuable under the warrants and/or reduce their effective exercise price if the Company were to sell or issue stock, warrants, options or convertible instruments, as defined in each warrant agreement, at a price less than the then current exercise price of the warrant. Warrants to acquire 436,807 shares of common stock at exercise prices ranging from \$1.29 to \$2.55 per share have weighted average anti-dilution protection if the Company sells or issues securities at less than the warrant exercise price. Warrants to acquire 9,251,994 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.

ANTARES PHARMA, INC.
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
 December 31, 2004, 2003 and 2002

6. Shareholders Equity (Continued)

Stock option and warrant activity is summarized as follows:

	Options		Warrants	
	Number of Shares	Weighted Average Price	Number of Shares	Weighted Average Price
Outstanding at December 31, 2001	712,433	\$ 3.73	899,927	\$ 7.11
Granted/Issued	143,622	4.56	160,000	2.50
Exercised				
Cancelled	(37,694)	4.09		
Outstanding at December 31, 2002	818,361	3.77	1,059,927	5.97
Granted/Issued	1,329,000	1.75	12,360,676	1.15
Exercised	(10,400)	1.56		
Cancelled	(152,073)	3.78		
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

The following table summarizes information concerning currently outstanding and exercisable options and warrants by price range at December 31, 2004:

Price Range	Outstanding			Exercisable	
	Number of Shares Outstanding	Weighted Average Remaining Life In Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
Pursuant to Option Plans:					
\$ 0.70 to 0.96	533,000	9.5	\$ 0.71	33,000	\$ 0.79
1.01 to 1.56	1,073,030	7.8	1.35	444,625	1.40
1.77 to 2.29	1,308,662	8.3	1.80	901,937	1.81
4.56	353,202	6.0	4.56	334,331	4.56
9.05 to 15.65	6,600	3.1	11.12	6,600	11.12
	3,274,494	8.1	1.79	1,720,493	2.26
Warrants:					
\$ 0.55 to 1.10	7,953,200	3.6	0.84	7,953,200	0.84
1.25	6,338,970	4.0	1.25	6,338,970	1.25
1.29 to 3.00	1,136,807	1.5	2.02	1,136,807	2.02
3.78	1,000,000	8.5	3.78	1,000,000	3.78
4.00 to 7.03	553,120	1.8	6.46	553,120	6.46

	Outstanding		Exercisable		
	16,982,097	3.9	1.43	16,982,097	1.43
Total Options & Warrants	20,256,591	4.6	1.49	18,702,590	1.51

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 year ended December 31, 2004, the Company elected to make contributions to the plan totaling \$65,571. No elective contributions were made for the years ended December 31, 2003 or 2002.

71

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

8. Supplemental Disclosures of Cash Flow Information

Cash paid for interest during the years ended December 31, 2004, 2003 and 2002 was \$25,106, \$20,321 and \$21,451, respectively.

As discussed in Note 3, the Company completed a number of noncash financing transactions in 2003 and 2002 related to its convertible debentures.

As discussed in Note 13, on September 12, 2003, the total of all Term Note agreements with the Company's largest shareholder, which included principal of \$2,300,000 and accrued interest of \$98,635, was converted into 2,398,635 shares of common stock.

On June 10, 2002, the Company's largest shareholder, Dr. Jacques Gonella, converted principal and interest of \$2,036,550, loaned to the Company under a Term Note agreement, into 509,137 shares of common stock at \$4.00 per share, the market price of the Company's stock on that date.

The Company incurred capital lease obligations of \$42,266 in the year ended December 31, 2002.

9. License Agreements

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.

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 expects the first completed registration to occur in the second quarter of 2006. The Company is recognizing the first \$1,000,000 milestone payment over a period of 109 months, the \$500,000 received in 2002 over 75 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.

BioSante License Agreement

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 and to provide significant development assistance 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 will offset future royalties from BioSante's sale of licensed products and/or sublicense

72

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

9. License Agreements (Continued)

up front payments. This milestone payment was for the delivery of intellectual property to BioSante. BioSante is required to tender milestone payments upon commencement of manufacturing of each of the first two licensed products. In the event that the Company fails to produce or have produced the ordered clinical batches, then the Company is required to repay 25% of these two milestone payments 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. The Company is obligated to incur the first \$150,000 of production costs for each of the four products, for an aggregate of \$600,000. The Company is further obligated to provide BioSante licensed products under a twenty-year supply agreement. The supply agreement is a separately priced, independent agreement that is not tied to the license agreement.

In the agreement, the Company has granted BioSante the option for additional licensed territories and the licensed products. The Company will receive additional milestone payments if this option is exercised.

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 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 a 84-month period. The Company received a \$200,000 milestone payment in January of 2003 and is recognizing revenue over a period of 67 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.

Ferring License Agreement

The Company entered into a License Agreement, dated January 22, 2003, with Ferring BV, 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.

9. License Agreements (Continued)

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

9. License Agreements (Continued)

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.

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, as further discussed in Note 6, 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. 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 1. 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 the Company concludes that the revenues from this arrangement will not exceed the costs, part or all of the remaining prepaid license discount may be charged to earnings at that time.

10. Third Party Supply Agreement

On February 22, 2003 the Company entered into a manufacturing agreement under which all assembly work that had been performed by the Company at its Minneapolis facility was to be outsourced to a third-party supplier ("Supplier"). Under the terms of the agreement, the Supplier is responsible for procurement of raw materials and components, inspection of procured materials, production, assembly, testing, sterilization, labeling, packaging and shipping to the Company's customers. The manufacturing operations were transferred to the Supplier in April 2003. The Company will continue to have responsibility for the manufacturing of the product including the quality of all products and the release of all products produced by the Supplier. The agreement had an initial term of two years and continues with a six-month termination notice available to either party. The Company reviewed the long-lived assets related to the manufacturing operations and determined there was no impairment as a result of the transfer.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

11. 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.

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

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:

	December 31,	
	2004	2003
Switzerland	\$ 1,022,485	\$ 1,278,481
United States of America	12,155,118	4,676,372
	\$ 13,177,603	\$ 5,954,853

Revenues by customer location are summarized as follows:

	For the Years Ended December 31,		
	2004	2003	2002
United States of America	\$ 491,014	\$ 883,101	\$ 1,655,713
Europe	1,866,359	2,758,478	2,237,940
Other	388,583	145,265	102,108
	\$ 2,745,956	\$ 3,786,844	\$ 3,995,761

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

	2004	2003	2002
Ferring	\$ 1,299,469	\$ 2,370,506	\$ 1,966,082
BioSante	289,031	520,977	1,183,445
Solvay	334,276	309,326	195,299

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

	2004	2003	2002
Proskelia S.A.S	\$	\$ 113,372	\$
Solvay			48,278
Ferring	86,149	230,136	46,040
BioSante		14,164	31,642
Eli Lilly and Company	65,260		4,359
SciGen, Ltd.	85,141	23,228	11,427

75

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

12. Quarterly Financial Data (unaudited)

	First	Second	Third	Fourth
2004:				
Total revenues	\$ 725,821	\$ 691,380	\$ 613,175	\$ 715,580
Net loss applicable to common shares (2)	(1,894,427)	(1,762,015)	(2,219,185)	(2,572,905)
Net loss per common share (2)	(.07)	(.05)	(.06)	(.06)
Weighted average shares (1)	28,627,275	37,943,664	38,825,537	39,982,515

12. Quarterly Financial Data (unaudited)

	First	Second	Third	Fourth
2003:				
Total revenues	\$ 910,126	\$ 908,302	\$ 1,039,959	\$ 928,457
Net loss applicable to common shares (2)	(3,017,451)	(3,719,561)	(23,344,988)	(2,878,821)
Net loss per common share (2)	(.26)	(.31)	(1.40)	(.15)
Weighted average shares (1)	11,736,291	12,026,954	16,687,449	19,814,230

(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 preferred stock dividends of \$50,000 in each of the second and fourth quarters of 2004, and \$50,000 and \$92,857 in the

second and fourth quarters of 2003, respectively. The fourth quarters of 2004 and 2003 include patent rights impairment charges of \$233,062 and \$973,769, respectively.

13. Related Party Transactions

In 2001 the Company entered into a consulting agreement with JG Consulting AG, a company owned by the Company's largest shareholder and Chairman of the Board, Dr. Jacques Gonella. This agreement was terminated as of December 31, 2003. The Company recognized expense of \$186,000 in each of the years 2003 and 2002 in connection with this agreement, and had liabilities to JG Consulting AG at December 31, 2003 and 2002 of \$162,595 and \$46,500, respectively.

During 2003 and 2002 the Company recognized expense of \$26,500 and \$100,612, respectively, for consulting services provided by John Gogol, one of the Company's board members until September 2003. The Company had a payable to Mr. Gogol at December 31, 2002 of \$22,211.

During 2002 the Company recognized expense of \$37,348 for legal services provided by Rinderknecht Klein and Stadelhofer, and had a payable to this firm of \$32,681 at December 31, 2002. Dr. Thomas Rinderknecht, one of the Company's board members during 2002 until his resignation on December 13, 2002, is a partner in the firm of Rinderknecht Klein and Stadelhofer.

The Company received \$1,000,000 on March 12, 2002 and \$1,000,000 on April 24, 2002 from the Company's largest shareholder, Dr. Jacques Gonella, under a Term Note agreement dated February 20, 2002. The Term Note agreement allowed for total advances to the Company of \$2,000,000 and was interest bearing at the three-month Euribor Rate as of the date of each advance, plus 5%. The principal of \$2,000,000 and accrued interest of \$36,550 was converted into 509,137 shares of common stock on June 10, 2002 at \$4.00 per share. In addition, the Company borrowed from Dr. Gonella \$300,000, \$200,000 and \$200,000 in June, September and December of 2002, respectively, to be repaid in July, September and December of 2003, respectively, with interest at the three-month Euribor Rate as of the date of the advance, plus 5%. These amounts were included in due to related parties on the consolidated balance sheet as of December 31, 2002. During 2003 the Company borrowed from Dr. Gonella an additional \$1,600,000 under various Term Note agreements. The loans were due in December 2003 with interest at the three-month Euribor Rate as of the dates of the loans, plus 5%. Dr. Gonella was also issued warrants for the purchase of 2,400,000 shares of the Company's common stock at an exercise price of \$0.55 per share in connection with the loans. The face value of the \$1,600,000 of shareholder loans was allocated between the loans and the warrants based on the relative fair values of each, with the amount allocated to the warrants being recorded as equity and as a discount on the debt, which was being amortized to interest expense over the life of the loans. The fair

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
December 31, 2004, 2003 and 2002

13. Related Party Transactions (Continued)

value of the warrants was calculated with the Black-Scholes option pricing model using risk free interest rates ranging from 2.1% to 3.9%, volatility of 136%, option life of 5 years and dividend yield of 0.0%. On September 12, 2003, the total of all Term Note agreements, which included principal of \$2,300,000 and accrued interest of \$98,635, was converted into 2,398,635 shares of common stock. In connection with this conversion the shareholder was issued warrants for the purchase of 1,798,976 shares of the Company's common stock at an exercise price of \$1.25 per share. The difference between the fair value of the common stock and warrants issued to the shareholder in excess of the carrying value of the debt on September 12, 2003, the date of the conversions, totaled \$10,266,331, and was recorded as loss on conversions of debt to equity in the statement of operations.

14. Litigation

On September 25, 2003, Josephberg Grosz & Company (JGC) notified the Company that it intends to commence an arbitration action against the Company in New York State. The Company and JGC entered into a letter agreement on April 8, 2002. JGC claims that, pursuant to the letter agreement the Company owes it seven percent of the proceeds received by the Company, as well as ten percent of various shares and securities issued by the Company, in connection with up to \$6 million in financing received by the Company since April 5, 2002. The Company disputes that it owes any amounts to JGC. The Company intends to vigorously defend this claim.

77

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, as of the end of such period, the Company's disclosure controls and procedures are effective.

Internal Control over Financial Reporting.

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

The Company's management, including the CEO and CFO, does not expect that its disclosure controls and procedures will prevent all error and all fraud. 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

78

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information provided under the captions "Election of Directors" on pages 2-6 and "Section 16(a) Beneficial Ownership Reporting Compliance" on page 36 in the Proxy Statement is incorporated herein by reference.

On February 5, 2004, the Board of Directors adopted a Code of Business Conduct and Ethics that is applicable to all employees and directors. A copy of the Code of Business Conduct and Ethics is filed as an exhibit to this report.

Item 11. EXECUTIVE COMPENSATION

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

The information provided under the caption "Executive Compensation" on pages 12-14 in the Proxy Statement is incorporated herein by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information provided under the captions "Security Ownership of Certain Beneficial Owners and Management" on page 9 and "Equity Compensation Plan Information" on pages 15 and 16 in the Proxy Statement is incorporated herein by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information provided under the caption "Certain Relationships and Related Transactions" on pages 9-12 in the Proxy Statement is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information provided under the captions "Audit Fees," "Audit Related Fees," "Tax Fees," "All Other Fees" and "Pre-Approval Policies and Procedures" on pages 33-34 in the Proxy Statement is incorporated herein by reference.

79

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 - see page 87
Schedule II - Valuation and Qualifying Accounts - see page 88

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 filed as an exhibit to Part I of this Form 10-K:

Exhibits	Description
3.1	Second Amended and Restated Articles of Incorporation as amended to date (a)
3.2	Articles of Amendment Restating Articles of Incorporation (g)
3.3	Second Amended and Restated Bylaws (a)
3.4	Third Amended and Restated Articles of Incorporation (l)
3.5	Certificate of Designations for Series A Convertible Preferred Stock (d)
3.6	Certificate of Designations for Series B Convertible Preferred Stock (h)

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

Exhibits	Description
3.7	Certificate of Designations for Series C Convertible Preferred Stock (g)
3.8	Articles of Amendment to Third Amended and Restated Articles of Incorporation (o)
3.9	Certificate of Designations for Series D Convertible Preferred Stock (s)
4.1	Form of Certificate for Common Stock (a)
4.2	Stock Warrant, dated January 25, 1996, issued to Becton Dickinson and Company (a)
4.3	Stock Option, dated January 25, 1996, issued to Becton Dickinson and Company (a)
4.6	Preferred Stock, Option and Warrant Purchase Agreement, dated January 25, 1996, with Becton Dickinson and Company (a)
4.7	Warrant issued to Elan International Services, Ltd. on November 10, 1998 (d) 80
4.8	Warrant issued to Plexus Ventures, Ltd. on September 12, 2000 (g)
4.9	Form of warrant issued to: Aventic Partners AG on February 5, 2001 for 85,324 shares Basellandschaftliche Kantonalbank on February 5, 2001 for 85,324 shares HCI Healthcare Investments Limited on February 5, 2001 for 127,986 shares Lombard Odier & Cie on March 5, 2001 for 127,986 shares (g)
10.0	Stock Purchase Agreement with Permatec Holding AG, Permatec Pharma AG, Permatec Technologie AG and Permatec NV with First and Second Amendments dated July 14, 2000 (f)
10.1	Third Amendment to Stock Purchase Agreement, dated January 31, 2001 (g)
10.2	Registration Rights Agreement with Permatec Holding AG dated January 31, 2001 (g)
10.3	Registration Rights Agreement with Aventic Partners AG, Basellandschaftliche Kantonalbank and HCI Healthcare Investments Limited dated February 5, 2001, and Lombard Odier & Cie dated March 5, 2001 (g)
10.4	Office/Warehouse/Showroom Lease, dated January 2, 1995, including amendments thereto (a)
10.5	Exclusive License & Supply Agreement with Bio-Technology General Corporation, dated December 22, 1999 (e)
10.6	Preferred Stock Purchase Agreement with Bio-Technology General Corporation, dated December 22, 1999 (e)
10.7	Preferred Stock, Option and Warrant Purchase Agreement, dated January 25, 1996, with Becton Dickinson and Company (a)
10.8*	Employment Agreement, dated January 31, 2001, with Franklin Pass, M.D. (g)
10.9*	Employment Agreement, dated March 12, 2001, with Roger Harrison, Ph.D. (g)
10.10*	Employment Agreement and Term and Compensation Addendum for 2000, dated May 1, 2000, with Lawrence Christian (g)
10.11*	Employment Agreement and Term and Compensation Addendum for 2000, dated May 1, 2000, with Peter Sadowski (g)
10.12*	Employment Agreement, dated May 31, 2000 with Dr. Dario Carrara (h)
10.13*	1993 Stock Option Plan (a)
10.14*	Form of incentive stock option agreement for use with 1993 Stock Option Plan (a)
10.15*	Form of non-qualified stock option agreement for use with 1993 Stock Option Plan (a)

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

- 10.16* 1996 Stock Option Plan, with form of stock option agreement (a)
- 10.18 Office - Warehouse lease with Carlson Real Estate Company, dated February 11, 1997 (b)

81

-
- 10.19* 1998 Stock Option Plan for Non-Employee Directors (c)
 - 10.20* Letter consulting agreement dated February 20, 1998 with Geoffrey W. Guy (c)
 - 10.21# Agreement with Becton Dickinson dated January 1, 1999 (d)
 - 10.22 Securities Purchase Agreement with Elan International Services, Ltd. dated November 10, 1998 (d)
 - 10.23# License & Development Agreement with Elan Corporation, plc, dated November 10, 1998 (d)
 - 10.24 Amended and Restated 2001 Stock Option Plan for Non-Employee Directors and Consultants (p)
 - 10.25 Amended and Restated 2001 Incentive Stock Option Plan for Employees (p)
 - 10.26* Consulting Agreement with JG Consulting AG dated February 1, 2001 (h)
 - 10.27 Office lease agreement with 707 Eagleview Boulevard Associates, a Pennsylvania Partnership dated June 18, 2001 (h)
 - 10.28 \$2,000,000 Term Note with Dr. Jacques Gonella dated February 20, 2002 (i)
 - 10.29 Securities Purchase Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership (j)
 - 10.30 Registration Rights Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund L.P.; XMark Fund, Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership (j)
 - 10.31 Security Agreement, dated July 12, 2002, between Antares Pharma, Inc. and AJW Partners, LLC; AJW/New Millennium Offshore, Ltd.; Pegasus Capital Partners, LLC; XMark Fund, L.P.; XMark Fund Ltd.; SDS Merchant Fund, LP; and OTATO Limited Partnership (j)
 - 10.32 Form of Secured Convertible Debenture, dated July 12, 2002 (j)
 - 10.33** License Agreement with Solvay Pharmaceuticals BV, dated June 9, 1999 (k)
 - 10.34** License Agreement with BioSante Pharmaceuticals, Inc., dated June 13, 2000 (k)
 - 10.35** Amendment No. 1 to License Agreement with BioSante Pharmaceuticals, Inc., dated May 20, 2001 (k)
 - 10.36** Amendment No. 2 to License Agreement with BioSante Pharmaceuticals, Inc., dated July 5, 2001 (k)
 - 10.37** Amendment No. 3 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 28, 2001 (k)

82

-
- 10.38** Amendment No. 4 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 8, 2002 (k)
 - 10.39 Debenture and Warrant Purchase Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP (m)
 - 10.40 Debenture and Warrant Purchase Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P. and XMark Fund, Ltd. (m)
 - 10.41 Registration Rights Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP (m)

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

- 10.42 Amended and Restated Security Agreement, dated January 31, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P., XMark Fund, Ltd. and SDS Merchant Fund, LP (m)
- 10.43 Form of Warrant, dated January 31, 2003 (m)
- 10.44 Form of 8% Senior Secured Convertible Debenture, dated January 31, 2003 (m)
- 10.45 Form of Amended and Restated 8% Senior Secured Convertible Debenture, dated January 31, 2003 (m)
- 10.46 Form of Promissory Note (m)
- 10.47** License Agreement between Antares Pharma, Inc. and Ferring BV, dated January 21, 2003 (n)
- 10.48 Securities Purchase Agreement dated July 7, 2003 (q)
- 10.49 Form of Registration Rights Agreement dated July 7, 2003 (q)
- 10.50 Voting Agreement, dated July 7, 2003, by and among Antares Pharma, Inc., XMark Fund, L.P. and XMark Fund, Ltd. (q)
- 10.51 Form of Warrant, dated July 7, 2003 (q)
- 10.52 Form of Securities Purchase Agreement dated July 17, 2003 (r)
- 10.53 Form of Registration Rights Agreement dated July 17, 2003 (r)
- 10.54 Form of Warrant, dated July 17, 2003 (r)
- 10.55 Form of Lock-Up Agreement dated July 17, 2003 (r)
- 10.56 Investment Letter and Conversion Notice, dated September 12, 2003 (s)
- 10.57 Securities and Exchange Agreement, dated September 12, 2002 (s)
- 10.58 Form of Lien Release Letter, dated July 7, 2003 (s)
- 10.59** Development and License Agreement, dated September 12, 2003, with Eli Lilly and Company (t)

83

-
- 10.60 Warrant Agreement with Eli Lilly and Company dated September 12, 2003 (t)
 - 10.61 Registration Rights Agreement with Eli Lilly and Company dated September 12, 2003 (t)
 - 10.62 Form of Securities Purchase Agreement dated February 10, 2004 (u)
 - 10.63 Form of Registration Rights Agreement, dated February 10, 2004 (u)
 - 10.64 Form of Warrant Agreement, dated February 10, 2004 (u)
 - 10.65 Office lease with The Trustees Under the Will and of the Estate of James Campbell, Deceased, dated February 19, 2004 (v)
 - 10.66 Form of Indemnification Agreement, dated January 2, 2004, between Antares Pharma, Inc. and each of its directors and executive officers (v)
 - 10.67 Employment Agreement, dated July 22, 2004, with Jack E. Stover (w)
 - 10.68 Employment Agreement, dated February 14, 2005, with James Hattersley (x)
 - 14.1 Code of Business Conduct and Ethics (v)
 - 21.1 Subsidiaries of the Registrant

Edgar Filing: ANTARES PHARMA INC - Form 10-K/A

23.1 Consent of Independent Registered Public Accounting Firm (KPMG LLP)

31.1 Section 302 CEO Certification

31.2 Section 302 CFO Certification

32.0 Section 906 CEO and CFO Certification

* Indicates management contract or compensatory plan or arrangement.

** Confidential portions of this document have been redacted and have been separately filed with the Securities and Exchange Commission.

Pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, confidential portions of Exhibits 10.21 and 10.23 were deleted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

(a) Incorporated by reference to the Registration Statement on Form S-1 (File No. 333-6661), filed with the Securities and Exchange Commission on October 1, 1996.

(b) Incorporated by reference to Form 10-K for the year ended December 31, 1996.

(c) Incorporated by reference to Form 10-K for the year ended December 31, 1997.

(d) Incorporated by reference to Form 10-K for the year ended December 31, 1998.

(e) Incorporated by reference to Form 10-K for the year ended December 31, 1999.

(f) Incorporated by reference to the Proxy Statement filed December 28, 2000.

(g) Incorporated by reference to Form 10-K for the year ended December 31, 2000.

(h) Incorporated by reference to Form 10-K for the year ended December 31, 2001.

(i) Incorporated by reference to Form 10-Q for the quarter ended March 31, 2002.

(j) Incorporated by reference to Form 8-K filed with the SEC on July 17, 2002.

(k) Incorporated by reference to Form 10-K/A for the year ended December 31, 2001, filed on September 19, 2002.

(l) Incorporated by reference to Form 10-Q for the quarter ended September 30, 2002.

(m) Incorporated by reference to Form 8-K filed with the SEC on February 12, 2003.

(n) Incorporated by reference to Form 8-K filed with the SEC on February 20, 2003.

84

(o) Incorporated by reference to Form 10-Q for the quarter ended March 31, 2003.

(p) Incorporated by reference to the Registration Statement on Form S-8 (File No. 333-111177), filed with the Securities and Exchange Commission on December 15, 2003.

(q) Incorporated by reference to Form 8-K filed with the SEC on July 9, 2003.

(r) Incorporated by reference to Form 8-K filed with the SEC on July 22, 2003.

(s) Incorporated by reference to Form 8-K filed with the SEC on September 15, 2003.

(t) Incorporated by reference to Form 8-K filed with the SEC on September 18, 2003.

(u) Incorporated by reference to Form 8-K filed with the SEC on February 10, 2004.

(v) Previously filed as an exhibit to our Form 10-K for the year ended December 31, 2003, filed with the SEC on March 30, 2004, and incorporated herein by reference.

(w) Previously filed as an exhibit to our Form 10-Q for the quarter ended September 30, 2004, filed with the SEC on November 15, 2004, and incorporated herein by reference.

(x) Previously filed as an exhibit to our Form 8-K filed with the SEC on February 15, 2005, and incorporated herein by reference.

85

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 Exton, State of Pennsylvania, on August 24, 2005.

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 August 24, 2005.

Signature

Title

/s/Jack E. Stover	President, Chief Executive Officer and Director (principal executive officer)
Jack E. Stover	
/s/Lawrence M. Christian	Vice President of Finance, Secretary and Chief Financial Officer (principal financial and accounting officer)
Lawrence M. Christian	
/s/Dr. Jacques Gonella	Director, Chairman of the Board
Dr. Jacques Gonella	
/s/Thomas J. Garrity	Director
Thomas J. Garrity	
/s/Anton Gueth	Director
Anton Gueth	
/s/Dr. Rajesh Shrotriya	Director
Dr. Rajesh Shrotriya	
/s/Dr. Paul Wotton	Director
Dr. Paul Wotton	

86

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 16, 2005, we reported on the consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2004, as included in Antares Pharma, Inc.'s Annual Report on Form 10-K/A for the fiscal year ended December 31, 2004. 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 financial statement schedule is the responsibility of Antares Pharma, Inc.'s management. Our responsibility is to express an opinion on this 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.

/s/ KPMG LLP

Minneapolis, Minnesota
March 16, 2005

87

Antares Pharma, Inc.

Schedule II

Valuation and Qualifying Accounts
For the Years Ended December 31, 2004, 2003 and 2002

Description	Balance at Beginning of Year	Charged to Costs and Expenses	Deductions	Balance at End of Year
Year Ended December 31, 2004				
Allowance for doubtful accounts (Deducted from accounts receivable)	\$ 21,500	\$ 1,000	\$ 0	\$ 22,500
Year Ended December 31, 2003				
Allowance for doubtful accounts (Deducted from accounts receivable)	\$ 12,000	\$ 33,705	\$ 24,205	\$ 21,500
Year Ended December 31, 2002				
Allowance for doubtful accounts (Deducted from accounts receivable)	\$ 18,000	\$ 34,829	\$ 40,829	\$ 12,000