ANTARES PHARMA INC
Form 10-K
March 26, 2008
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (D) OF

THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2007

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For transition period from _____ to _____

Commission file number 1-32302

ANTARES PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	41-1350192
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification Number)

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YESo NOx

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YESo NOx

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. YESx NOo

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. x

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

Large accelerated filer o Accelerated filer o Non-accelerater filer o Smaller reporting company x

(do not check if a smaller

reporting company)

Indicate by check mark if the registrant is a shell company (as defined in Rule 12b-2 of the Act). YESo NOx

Aggregate market value of the voting and non-voting common stock held by nonaffiliates of the registrant as of June 30, 2007, was approximately $72,300,000 (based upon the last reported sale price of $1.58 per share on June 30, 2007, on The American Stock Exchange).

There were 65,529,666 shares of common stock outstanding as of March 21, 2008.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2008 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

PART I

Item 1. BUSINESS

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

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

Overview

Antares Pharma, Inc. (“Antares,” “we,” “our” or “us”) is a specialized pharma product development and pipeline company with patented drug delivery platforms including Advanced Transdermal Delivery (ATD™) gels, oral disintegrating (Easy Tec™) tablets, disposable pressure assisted auto injection systems (Vibex™), reusable needle-free injection systems (VISION® and Valeo™) and disposable pen injection systems. Two of these platforms have generated FDA approved products. These platforms and products are summarized and briefly described below:

Delivery Platforms

Transdermal Drug Delivery Systems	Advanced Transdermal Delivery (ATD™)	Systemic or Topical
Oral Disintegrating Tablets	Easy Tec™	
Parenteral Medicines	Needle-Free Reusable Injectors (MJ Platform) Medi-Jector VISION® and Valeo™	
	Pressure Assisted Auto Injectors (AJ Platform) Vibex™	
	Disposable Pen Injectors	
	Vaccine Intradermal Injectors	

2

Products

Transdermal Systems

Our transdermal systems consist of an unique formulation in semisolid dosage forms (preferably gels) that deliver medication efficiently and minimize gastrointestinal impact, as well as, the initial liver metabolism effect of some orally ingested drugs. Our gels are hydro-alcoholic and contain a combination of permeation enhancers to promote rapid drug absorption through the skin following application typically to the arms, shoulders, or abdomen. Our transdermal gel systems provide the option of delivering both systemically (penetrating into and through the subcutaneous tissues and then into the circulatory system) as well as locally (e.g. topically for skin and soft tissue injury, infection and local inflammation). Typically, the gel is administered daily, and is effective on a sustained release basis over approximately a 24-hour period of time. Our gel systems are known as our Advanced Transdermal Delivery ("ATD™") gels.

Oral Disintegrating Tablets

Our Easy Tec™ oral disintegrating tablets are designed to help patients who experience difficulty swallowing pills, tablets or capsules, while providing the same effectiveness as conventional oral dosage forms. Our tablet features a "disintegrant addition" that facilitates the disintegration of the oral drug to promote quick and easy administration in saliva without water. This could play an important role in our ability to target the pediatric, geriatric and analgesic markets. We believe that the ability of Easy Tec™ tablets to be manufactured without specialized equipment and their non-effervescent (highly moisture sensitive) qualities represents several significant processing and packaging advantages over conventional competitors. Our Easy Tec™ tablets may also be of interest to pharmaceutical firms seeking line extensions in the marketplace. There may also be further benefits if Easy Tec™ can be formulated with certain actives to provide buccal absorption.

Pressure Assisted Injection Devices

Our injection device platform features four distinct products: reusable needle-free injectors, disposable pressure assisted auto injectors, disposable pen injectors and vaccine intradermal injectors. Each 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 two years and are designed for easy use, facilitating self-injection with a disposable syringe to assure safety and efficacy. The associated sterile plastic disposables, needle-free syringes and adapters are designed for use as appropriate for the drug and indication.

We have 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 available through our partners in Europe, Japan and Asia for hGH. To date, we believe that more than 100 million such injections have been performed worldwide.

- *Disposable pressure assisted auto injectors ("Vibex™")* employ the same basic technology developed for the Medi-Jector VISION®, a controlled pressure delivery of drugs into the body utilizing a spring power source. Combining pressure with a tiny hidden needle supports the design of a disposable, single-use injection system compatible with conventional glass drug containers. The Vibex™ system is designed to economically provide highly reliable fast subcutaneous injections with minimal 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. We and our

potential partners have successfully tested the device in multiple patient preference studies. We continue to explore product extensions within this category, including the targeting of various body sites and devices with multiple dose, variable dose and user-fillable applications.

- *Disposable pen injectors* are needle-based devices designed to deliver multiple injections from multi-dose drug cartridges. The devices contain mechanisms that specify the dose to be delivered by defining the amount of movement by the stopper in the cartridge with each device actuation, similar to dose control mechanisms in the Medi-Jector VISION®. In contrast to the VISION® reusable needle-free injectors, the cartridge drug container

is integral to the pen injector and after utilizing all the drug from the cartridge, the entire device is then disposed.

- *Vaccine intradermal injectors* are a variation of the Vibex™ disposable pressure assisted auto injection technology and are being developed to deliver vaccines into the dermal and subdermal layers of the skin (a preferred site of administration in the vaccine industry). We believe that this proprietary device will offer easier and more rapid dosing compared with conventional needle-based devices.

History

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

Our Parenteral Medicines (device) division is located in Minneapolis, Minnesota, where we develop and manufacture with partners novel pressure assisted injectors, with and without needles, which allow people to self-inject drugs. We make a reusable, needle-free, spring-action injector device known as the Medi-Jector VISION®, which is legally marketed for use with insulin and human growth hormone. Using an adapter, the liquid drug is drawn from a conventional vial into the plastic needle-free syringe, through a small hole at the end of the syringe. When the syringe is held against an appropriate part of the body and the spring is released, a piston drives the fluid stream into the tissues beneath the skin, from where the drug is dispersed into systemic circulation. A person may re-arm the device and repeat the process or attach a new sterile syringe between injections. We have had success in achieving distribution of our device for use with human growth hormone through licenses to pharmaceutical partners, and it has resulted in continuing market growth and, we believe, a high degree of customer satisfaction. Distribution of growth hormone injectors occurs in Europe, Japan and other Asian countries through our pharmaceutical company relationships.

We have also developed variations of the needle-free injector by adding a very small hidden needle to a pre-filled, single-use disposable injector, called the Vibex™ pressure assisted auto injection system. This system is an alternative to the Vision® system for use with unit dose injectable drugs and is suitable for branded and branded generic injectables. Recently we also developed a disposable multi-dose pen injector for use with standard multi-dose cartridges. We have entered into multiple licenses for these devices mainly in the U.S. and Canada with Teva Pharmaceuticals.

Our Pharma division is located in Basel, Switzerland, where we develop pharmaceutical products utilizing our transdermal systems. Our first transdermal and oral disintegrating tablet products were developed under Permatec's name in the mid-1990s. Permatec's research efforts moved away from the 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 adhesives. Several licensing agreements with pharmaceutical companies of various sizes have led to successful clinical evaluation of our formulations. In 2006 the FDA approved our first transdermal gel product for the treatment of vasomotor symptoms in post-menopausal women. We are also developing our own transdermal gel-based products for the market and have initiated a pivotal safety and efficacy trial for Anturol™, our oxybutynin transdermal gel product for overactive bladder.

We believe that our transdermal gels minimize first pass liver metabolism, gastro intestinal effects and skin erythema. Other advantages include cosmetic elegance and ease of application as compared to transdermal patches and have potential applications in such therapeutic markets as

hormone replacement, overactive bladder, osteoporosis, cardiovascular, pain management and central nervous system therapies. We also believe that our proprietary ODT tablets can enable delivery of certain drugs orally in the area of opioid analgesia and nonsteroidal anti-inflammatory drugs.

We operate 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 product development to pharmaceutical manufacturers through licensing and development agreements while continuing to develop their own products for the marketplace. We also view many pharmaceutical and biotechnology companies as collaborators and primary customers. We have negotiated and executed licensing relationships in the needle-free devices segment in the U.S., Europe and Asia, the auto injector segment in the U.S. and Canada, the transdermal gels segment (several development programs in place worldwide, including the United States and Europe) and the Easy Tec™ ODT segment worldwide. In addition, we continue to market our re-usable needle-free devices for the self administration of insulin in the U.S. market through distributors and have licensed our technology in the diabetes and obesity fields.

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

Industry Trends

Based upon experience in the industry, we believe the following significant trends in healthcare have important implications for the growth of our business.

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

Major pharmaceutical companies market directly to consumers and encourage the use of innovative, user-friendly drug delivery systems, offering patients a wider choice of dosage forms. We believe the patient-friendly attributes of our transdermal gels, ODT tablets and injection technologies meet these market needs.

We believe transdermal gel formulations offer patients more choices and added convenience with no compromise of efficacy. Our ATD™ 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.

Other industry trends include the increasing difficulty in getting drugs approved by the FDA as well as the continuing need to demonstrate long term safety thus resulting in longer time lines to approval. Thus dosing and specifically minimum effective dose is becoming an ever increasing trend.

Many drugs, including selected hormones and protein biopharmaceuticals, are degraded in the gastrointestinal tract and may only be administered through the skin, the lungs or by injection. Pulmonary delivery is complex and has recently been commercialized for limited

therapeutic proteins intended for systemic delivery. Injection therefore remains the mainstay of protein delivery. The growing number of protein biopharmaceuticals requiring injection may have limited commercial potential if patient compliance with conventional injection treatment is not optimal. The failure to take all prescribed injections can lead to increased health complications for the patient, decreased drug sales for pharmaceutical companies and increased healthcare costs for society. In addition, it is becoming increasingly recognized that conventional needles and syringes are inherently unreliable and require special and often costly disposal methods. Industry expectations are that improvements in protein delivery systems will continue to be accepted by the market.

In addition to the increase in the number of drugs requiring self-injection, recommended changes in the frequency of injections may contribute to an increase in the number of self-injections. Biosimilar drug legislation

continues to gather momentum in Congress. In order to differentiate biosimilars, novel patented delivery systems are becoming more important to extend product proprietary position as well as secure patient preference.

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

Patented pharmaceutical products continue to be challenged by generic companies once substantial proprietary sales are generated. All of our proprietary delivery systems may provide pharmaceutical companies the ability to protect and extend the life of a product.

Market Opportunity

According to a February 2008 Thomson Pharma Drug Report, the worldwide market for urinary incontinence was $1.9 billion in 2006 and is estimated to be $3.1 billion by 2011. Older incontinence drugs, such as oral oxybutynin, are plagued by anticholinergic effects including moderate to severe dry mouth, constipation and somnolence. In a 2006 Cowen & Co. publication it was estimated that half of the 20 million U.S. adults suffering from overactive bladder either are too embarrassed to discuss the symptoms or are not aware that pharmacological treatment is available. It was further estimated that only 47% of U.S. incontinence patients sought treatment in 2005 and that 16% of incontinence patients were compliant with their treatment in 2005 estimated to increase to only 18% by 2010.

According to a February 2008 Thomson Pharma Drug Report, the worldwide hormone replacement market is expected to grow from $1.9 billion in 2006 to $2.1 billion by 2011. Further growth in this sector may be achieved by the use of testosterone products in both male and female applications. According to a comprehensive study by Cowen & Co. in 2006, the female sexual dysfunction (“FSD”) market is estimated to be 78 million sufferers worldwide rising to 95 million by 2010. Additionally, the worldwide sexual dysfunction market is projected to grow to $5.6 billion by 2010. The importance of gel products containing testosterone for men has been exemplified with the success of Androgel® (Unimed-Solvay) and Testim® (Auxilium Pharmaceuticals) for treatment of male hypogonadism, where combined sales were recently estimated at approximately $500 million per year. A new market opportunity also exists with the use of low dose testosterone for treatment of FSD, a disorder according to published reports that affects an estimated 40-55% of all women and for which no drug is currently approved in the U.S. Antares Pharma, along with its U.S. partner BioSante, has a low dose testosterone product named Libi-Gel™, which has completed Phase II testing for FSD and is currently in Phase III clinical trials. We have the exclusive market rights in Europe and elsewhere outside the United States for Libi-Gel™. As evidenced in Europe we believe that patient demand for transdermal hormone therapy products will continue to increase. Evidence of this belief is the recent commercial launch, in France, Italy, Spain, U.K., Germany and others, by Proctor and Gamble of the Intrinsa® Patch, a testosterone transdermal patch for FSD. Gel products are also being formulated to address equally large opportunities in other sectors of the pharmaceutical industry, including cardiovascular, pain, infectious diseases, addiction and central nervous system therapies.

The central nervous system ("CNS") consists of the brain and spinal cord. Disorders of this system are many, varied and frequently severe, affecting a large portion of the population. These debilitating disorders include diseases such as Parkinson’s disease, restless leg syndrome, epilepsy and migraine and psychotic disorders such as anxiety, bipolar disorder, depression and schizophrenia. In addition, chronic pain is a neurological response to disease or injury; or it may have no readily apparent cause. Regardless of the cause, chronic pain can have devastating effects on those suffering from it.

Current treatments for CNS disorders vary in effectiveness, but there are many conditions for which there are few safe and effective drugs. It has been estimated that nearly $36 billion is spent annually on prescription CNS drugs. According to Wolters Kluwer Health data, the total US market for pain management pharmaceuticals, excluding over-the-counter products, totaled in excess of $20 million in 2007. Many CNS and

chronic pain drugs merely treat the symptoms and do not provide cures. According to the World Health Organization, diseases of the CNS will constitute an increasing medical need this century, attributable to an exponential increase of these diseases after the age of 65 combined with an aging population.

Our parenteral/device focus is specifically on the market for delivery of self-administered injectable drugs. The largest and most mature segments of this market consist of insulin for patients with diabetes and human growth hormone for children with growth retardation. According to a February 2008 Thomson Pharma Drug Report, the worldwide insulin market is estimated to go down from $8.9 billion in 2006 to $7.9 billion in 2011, however new non-insulin related treatments for diabetes are expected to expand the market for diabetic products. We believe that the number of injections will increase with time as the result of new diabetes management techniques, which recommend more frequent injections.

We believe that a significant portion of needles and syringes that are used for the administration of drugs could be replaced with user friendly injectors promoting better compliance and decreasing sharps concerns, but only a small percentage of people who self-administer drugs currently use needle-free/auto injector systems. We believe that this lack of market penetration is due to older technology not meeting customer needs owing to cost and performance limitations as well as the small size of the companies directly marketing to consumers not being able to gain a significant “share of voice” in the marketplace. We believe that our technology overcomes most of these limitations of the past and that our business model of working with pharmaceutical company partners has the potential for improved market penetration. Further, we anticipate developing our own pharmaceutical products using our pressure assisted auto injectors in the future.

According to a February 2008 Thomson Pharma Drug Report, the worldwide hGH market in 2006 was estimated at $2.4 billion. Our pharmaceutical partner in Europe, Ferring Pharmaceuticals BV (“Ferring”), has made significant inroads using our injectors in the hGH market, and we expect 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 our systems include therapies for the prevention of blood clots and the treatment of multiple sclerosis, migraine headaches, inflammatory diseases, impotence, infertility, AIDS and hepatitis. We also believe that many injectable drugs currently under development will be administered by self-injection once they reach the market. This is supported by the continuing development of important chronic care products that can only be given by injection, the ongoing effort to reduce hospital and institutional costs by early patient release, and the gathering momentum of new classes of drugs that require injection. A partial list of such drugs introduced in recent years that all require self injection include Enbrel® (Amgen, Wyeth) for treatment of rheumatoid arthritis, Aranesp® (Amgen) for treatment of anemia, Kineret® (Amgen) and Humira® (Abbott) for rheumatoid arthritis, Forteo™ (Lilly) for treatment of osteoporosis, Intron® A (Schering Plough) and Roferon® (Roche) for hepatitis C, Lantus® (Aventis Pharma) and Byetta® (Lilly) for diabetes, Rebif® (Serono) for multiple sclerosis, Copaxone® (Teva) for multiple sclerosis and Gonal-F® for fertility treatment.

Products and Technology

We are leveraging our experience in drug delivery systems to enhance the product performance of established drugs as well as new drugs in development. Our current technology platforms include transdermal Advanced Transdermal Delivery (ATD™) gels; oral disintegrating tablets (Easy Tec™); disposable pressure assisted auto injection systems (Vibex™); disposable pen injection systems; and reusable needle-free injection systems (Medi-Jector VISION® and Valeo™).

TRANSDERMAL DRUG DELIVERY

Transdermal drug delivery has emerged as a generally safe and patient-friendly method of drug delivery. The commercialization of transdermal products for controlled drug delivery began over two decades ago. In more recent years transdermal gels, creams and sprays have become increasingly more popular as alternative delivery systems. Among transdermal products currently marketed 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 estradiol and a norelgestimate 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. 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 can prevent certain

pharmaceuticals from entering the body as well. 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 typically minimizes first-pass metabolism by the liver as well as many of the gastrointestinal concerns of many orally ingested drugs.

Transdermal Gels

While transdermal patches remain an important aspect of the transdermal drug delivery market, transdermal gels have recently emerged as a viable means of administering an increasingly 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 typically create a subdermal reservoir of the medication. Transdermal patches, however, have recently resulted in increasingly more adverse events, specifically skin irritation events associated principally with the occlusive nature of patches and the use of adhesives that contain residual solvents and irritant monomers. Most of these factors are minimized in transdermal gels.

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.

We have developed our ATD™ gel technology that utilizes a combination of permeation enhancers to further bolster a pharmaceutical agent's ability to penetrate the skin, which leads to a sustained plasma profile of the active agent, without the skin irritation and cosmetic concerns often associated with patches.

Advanced Transdermal Delivery (ATD™) System

Our ATD™ system successfully penetrates the skin to deliver a variety of treatments. The gels consist of a hydro-alcoholic base including a combination of permeation enhancers. The gels are also designed to be absorbed quickly through the skin after application typically to the arms, shoulders, or abdomen and release the active ingredient into the blood stream predictably over approximately a 24 hour period of time. The following is a summary of the competitive advantages of our ATD™ gel system:

Competitive Advantages of ATD™ Gel System

- Discrete

- Easy application
- Cosmetically appealing compared with patches
- Reduced skin 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

Our ATD™ gels can deliver both a single active ingredient as well as a combination of active ingredients with different release profiles, and have demonstrated potential in a variety of therapeutic areas. One of our licensed gels, an estrogen gel for women to treat vasomotor symptoms associated with menopause called Elestrin®, was approved by the FDA in December 2006 and commercially launched in mid-2007. In addition, we have signed a development and license agreement for a gel product based on our ATD™ system that is being developed to treat a central nervous system ("CNS") disorder. Other current ATD™ drug gels in development encompass an oxybutynin gel for treatment of overactive bladder (Anturol™), a low dose testosterone gel to treat low libido in women (Libi-Gel™), a contraceptive gel, another CNS product (AP1126) and an alprazolam gel for anti-anxiety. We have also licensed an ibuprofen gel in 11 countries. ATD™ gels may be extended to a variety of fields, including the treatment of cardiovascular disease and chronic pain, in which potent compounds may require alternatives to oral and injectable delivery for the following reasons:

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

We have also formulated several combination gels demonstrating the ability to deliver multiple actives with different release profiles.

ORAL DRUG DELIVERY

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

Oral Disintegrating Tablets

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

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

Easy Tec™ Oral Disintegrating Tablets

Our patented Easy Tec™ technology is based on the simultaneous use of two disintegrants in an oral formulation. We believe two primary advantages of Easy Tec™ over competing technologies are that Easy Tec™

tablets can be manufactured with conventional tableting equipment and no unique packaging requirements are necessary. We also believe that Easy Tec™ possesses several other key advantages over competing technologies;

Easy Tec™ Competitive Advantages

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

In addition to being easy to take, such products are perceived as being fast acting because of rapid dispersion in the mouth. There may also be further benefits if Easy Tec™ can be formulated with certain actives to provide buccal absorption. We believe that there may be attractive opportunities to develop our own ODT products using generic active ingredients as part of our 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. We have formulated our first Easy Tec™ based product, a non-steroidal anti inflammatory (NSAID) generic currently called AP-159 for the treatment of pain. Additionally, we have signed a global license agreement with an unnamed partner in the area of opioid analgesia.

INJECTION DRUG DELIVERY

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

Pressure Assisted Auto Injection

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

Pressure assisted auto injection is a form of parenteraldrug delivery that continues to gain acceptance among the medical community. Encompassing a wide variety of sizes and designs, this technology operates by using pressure to force the drug, in solution or suspension, through the skin and deposits the drug into the subcutaneous tissue.

Needle-Free Injectors

Needle-free injection represents a combination of an accepted technology - injection, with the elimination of the part of the injection – the needle, that concerns patient's that have to self administer and health care professionals concerned about risks to themselves. Improving patient comfort through needle-free injection may increase compliance and mitigate the problem of daily injections. Needle-free delivery eliminates the risk of needlestick injuries as well, which occurs frequently in institutions in the U.S., and can result in disease transmission to healthcare workers.

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

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

Medi-Jector VISION® (MJ7)

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

The Medi-Jector VISION® administers injectables by using a spring to push the active ingredient 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 then penetrates the skin, and the dose is dispersed into the layer of fatty, subcutaneous tissue. The drug is subsequently distributed throughout the body, successfully producing the desired effect.

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

Patient Candidates for Needle-Free Injection

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

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

administration.

The Medi-Jector VISION® is primarily used in Europe, Asia, Japan and elsewhere to provide a needle-free means of administering human growth hormone to patients with growth retardation. We typically sell our injection devices to partners in these markets who manufacture and/or market human growth hormone directly. The partners then market our device with their growth hormone. We receive benefits from these agreements in the form of product sales and royalties on sales of their products. In 2006 we filed a 510(k) in the U.S. for our device for use with hGH.

MJ8 (Valeo™) Needle-Free Injection Systems

In addition to the Medi-Jector VISION®, we are also developing 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. The Medi-Jector Valeo™ aspires to provide more user-friendly capabilities.

Disposable (Vibex™) Injectors

Beyond reusable needle-free injector technologies, we have designed disposable, pressure assisted auto injector devices to address acute medical needs, such as allergic reactions, migraine headaches, acute pain, emesis and other daily therapies, as well as potentially for the delivery of vaccines. Our proprietary Vibex™ disposable 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™ system features a triggering collar that shields the needle from view. The patented retracting collar springs back and locks in place as a protective needle guard after the injection, making the device safe for general disposal. In clinical studies, this device has outperformed other delivery methods in terms of completeness of injection and user preference, while limiting pain and bleeding. A summary of the key competitive advantages of the Vibex™ system is provided below.

Competitive Advantages of Vibex™ Disposable Injectors

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

The primary goal of the Vibex™ disposable pressure assisted auto 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 Pen Injector System

Our most recently developed product, the pen injector, complements our portfolio of pressure assisted auto injector devices. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the prototype stage of development where devices are being made for engineering bench testing and clinical evaluation. Although differing from the other pressure

assisted injection strategies common to the above portfolio of injection therapy, this device includes a dosing mechanism design that is drawn from our variable dose needle-free technology. We have signed a license agreement with Teva Pharmaceuticals for our pen injector device for two undisclosed products.

Disposable Vaccine Delivery Device

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

Research and Development

We currently perform pharmaceutical product development work primarily in our Basel, Switzerland location for both partners and our own portfolio. Additionally, we perform parenteral product development work primarily at our Minneapolis, MN facility. We have various products at earlier stages of development as highlighted in our products schedule on page 3.

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

ANTUROL™. We are currently evaluating Anturol™ for the treatment of overactive bladder (OAB). Anturol™ is the anticholinergic active substance oxybutynin delivered by our proprietary ATD™ gel that is used to achieve therapeutic blood levels of the active compound that can be sustained over 24 hours after a single, daily application. It is believed that Anturol™ may offer equal or increased oxybutynin to the metabolite ratio, thus resulting in decreased reporting of adverse events when compared to patients taking comparable oral products. In addition, Anturol™ may also be more cosmetically appealing than patches and have less irritation and allergic reactions as well as comparable or decreased reporting of adverse events.

Summary of Clinical Data

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

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

In October 2007, we announced that the first patients were dosed in the pivotal trial designed to evaluate efficacy of ANTUROL™ when administered topically once daily for 12 weeks in patients predominantly with urge incontinence episodes. The randomized, double-blind, parallel, placebo controlled, multi-center trial is expected to involve 600 patients (200 per arm) using two dose strengths (selected from the Phase II clinical trial) vs. a placebo. The primary end point of the trial will be efficacy against the placebo defined as the reduction in the number of urinary incontinence episodes experienced. Secondary end points include changes from baseline in urinary urgency, average daily urinary frequency, patient perceptions as well as safety and tolerability including skin irritation. Enrollment continues in twelve centers throughout the United States.

Proprietary Rights

When appropriate, we actively seek protection for our products and proprietary information by means of U.S. and international patents and trademarks. We currently hold approximately 87 patents and have an additional 80 applications pending in the U.S. and other countries. Our

patents have expiration dates ranging from 2015 to 2022. In addition to issued patents and patent applications, we are also protected by trade secrets in all of our technology platforms.

Some of our technology is developed on our behalf by independent outside contractors. To protect the rights of our 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 us of discoveries and inventions made by such individuals while devoted to Company-sponsored activities. Companies with which we have entered into development agreements have the right to certain technology developed in connection with such agreements.

Manufacturing

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

Contract manufacturers may utilize their own technology, technology developed by us, or technology acquired or licensed from third parties. When contract manufacturers develop proprietary process technology, our reliance on such contract manufacturers is increased. Technology transfer from the original contract manufacturer may be required. Any such technology transfer may also require transfer of requisite data for regulatory purposes, including information contained in a proprietary DMF held by a contract manufacturer. FDA approval of the new manufacturer and manufacturing site would also be required.

We have contracted with a commercial supplier of pharmaceutical chemicals, to supply us with the active pharmaceutical ingredient of oxybutynin for clinical quantities of Anturol™ in a manner that meets FDA requirements via reference to their DMF for oxybutynin. We have contracted with Patheon, Inc. (Patheon), a manufacturing development company, to supply clinical quantities of Anturol™ gel in a manner that may meet FDA requirements. The FDA has not approved the manufacturing processes for Anturol™ at Patheon at this time. We have not completed any commercial scale up activities associated with Anturol™ manufacturing.

The ATD™ Gel formulations for clinical studies have, in the past, been manufactured by contract under our supervision. Early in 2005, Antares Pharma AG, our wholly owned subsidiary in Switzerland, received a GMP approval for the production and wholesaling of medicaments in small scale quantities. Further, we anticipate contracting with European GMP approved contract manufacturers for supplying ATD™ gel based products for the European Union.

We are responsible for U.S. device manufacturing in compliance with current Quality System Regulations (“QSR”) established by the Food and Drug Administration and by the centralized European regulatory authority (Medical Device Directive). Injector and disposable parts are manufactured by third-party suppliers and are assembled by a third-party supplier for our VISION® needle-free device. Packaging is performed by a third-party supplier under our direction. Product release is performed by us. We have contracted with Nypro Inc. (Nypro), an international manufacturing development company to supply commercial quantities of our Vibex™ pressure assisted auto injector device in compliance with FDA QSR regulations.

Sales and Marketing

We expect to currently market most of our products through other more substantial pharmaceutical and medical device companies while continuing marketing of our insulin injection devices and related disposable components in the U.S. In the future as we develop more products in niche therapeutic areas, we plan to develop commercial capabilities.

During 2007, 2006 and 2005, international revenue accounted for approximately 55%, 63% and 77% of total revenue, respectively. Europe accounted for 91%, 83% and 71% of international revenue in 2007, 2006 and 2005, respectively, with the remainder coming primarily from Asia. Ferring accounted for 39%, 39% and 48% of our worldwide revenues in 2007, 2006 and 2005, respectively. BioSante Pharmaceuticals, Inc. accounted for 36%, 24% and 7% and JCR Pharmaceuticals, Co., Ltd. accounted for 4%, 4% and 12% of our worldwide revenues in 2007, 2006 and 2005, respectively. Revenue from Ferring and JCR resulted from sales of injection devices and related disposable components for their

hGH formulations. In 2007 and 2006, the BioSante revenue resulted primarily from license fees and milestone payments related to Elestrin®, received under a sublicense arrangement related to an existing license agreement with BioSante.

Collaborative Arrangements and License Agreements

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

Partner	Drug	Market Segment	Platform
BioSante	Estradiol (Elestrin®)	Hormone replacement therapy (North America, other countries)	ATD™ Gel
	Testosterone (Libi-Gel™)	Female sexual dysfunction (North America, other countries)	ATD™ Gel
Jazz Pharmaceuticals	Undisclosed	Central Nervous System (Worldwide)	ATD™ Gel
Population Council	Nestorone ®/Estradiol	Contraception (Worldwide)	ATD™ Gel
Undisclosed	Undisclosed	Opioid dependence (Worldwide)	ODT
Ferring	hGH	Growth Retardation (U.S., Europe & Asia)	Needle Free Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed	Undisclosed (United States)	Needle Free Device
Eli Lilly and Company	Undisclosed	Diabetes and Obesity (Worldwide)	Needle Free Device
JCR Pharmaceuticals Co., Ltd.	hGH	Growth Retardation (Japan)	Needle Free Device
SciGen Pte Ltd.	hGH	Growth Retardation (Asia/Pacific)	Needle Free Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed	Undisclosed (U.S. and Canada)	Auto Injector Disposable Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed	Undisclosed (United States)	Auto Injector Disposable Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed	Undisclosed (North America, Europe & others)	Disposable Pen Injector Device

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

In June 2000, we granted an exclusive license to BioSante to develop and commercialize three of our 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 us in exchange for a fourth gel based product. BioSante paid us $1 million upon execution of the agreement and is also required to make 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 us upon the occurrence of certain events related to regulatory filings and approvals. In November 2006 BioSante entered into a sublicense and marketing agreement with Bradley Pharmaceuticals, Inc. for Elestrin® (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a payment to us of $875,000. In December 2006 the FDA approved for marketing Elestrin® in the United States triggering payments to us totaling $2.6 million, which were received in 2007. In addition, we will receive royalties on sales of Elestrin® as well as potential sales-based milestone payments. Bradley was acquired by Nycomed Inc. in February 2008 and presently the commercial interest of Elestrin® with Nycomed is unknown.

In June 1999, we granted an exclusive license to Solvay for our 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 we and Solvay collaborate to bring the product to market. Solvay must pay us 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, we have received $1.75 million of this fee. Development work performed by Solvay has been limited due to concerns about certain forms of hormone replacement therapy that have been debated in scientific literature. When and if commercial sale of the product begins, Solvay is required to, on a quarterly basis, pay us a royalty based on a percentage of sales. The royalty payments will be required for a period of 15 years or when the last patent for the product expires, whichever is later.

In August 2001, Solvay entered into an exclusive agreement with BioSante in which Solvay has sublicensed from BioSante the U.S. and Canadian rights to our estrogen/progestin combination transdermal hormone replacement gel product, one of the drug-delivery products we previously licensed to BioSante. Under the terms of this license agreement between us and BioSante, we received a portion of the upfront payment made by Solvay to BioSante. We are also entitled to a portion of any milestone payments or royalties BioSante receives from Solvay under the sublicense agreement. To date, development work performed by Solvay has been limited and further development and commercialization is uncertain.

In January 2003, we entered into a revised License Agreement with Ferring, under which we licensed certain of our intellectual property and extended the territories available to Ferring for use of certain of our reusable needle-free injection devices to include all countries and territories in the world except Asia/Pacific. Specifically, we granted to Ferring an exclusive, royalty-bearing license, within a prescribed manufacturing territory, to utilize certain of our 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. We granted to Ferring similar non-exclusive rights outside of the prescribed manufacturing territory. In addition, we granted to Ferring a non-exclusive right to make and have made the equipment required to manufacture the licensed products, and an exclusive, royalty-free license in a prescribed territory to use and sell the licensed products under certain circumstances. In 2007 we amended this agreement providing for non-exclusive rights in Asia along with other changes to financial terms of the agreement.

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

In March of 2008 we entered into a second amendment to the original development and license agreement with Lilly dated September 12, 2003. The amendment narrows the scope of the license grant to Lilly under the agreement whereby (a) certain devices (as defined in the agreement) owned by us are no longer licensed to Lilly, including our MJ7 device, (b) the scope of the license for the remaining devices licensed to Lilly are converted to nonexclusive from exclusive and (c) the scope of such remaining nonexclusive license is limited to use with a smaller subset of compounds in a narrower field of use. We are now able to exclusively license and supply certain devices that were previously licensed to Lilly under the agreement. In connection with the return of rights with respect to the devices, no device development plan is required going forward.

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

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

In July 2006, we entered into an exclusive License Development and Supply Agreement with Sicor Pharmaceuticals Inc., an affiliate of Teva Pharmaceutical Industries Ltd. Pursuant to the agreement; the affiliate is obligated to purchase all of its delivery device requirements from us for an undisclosed product to be marketed in the United States and Canada. We received an upfront cash payment, and will receive milestone fees, a

negotiated purchase price for each device sold, as well as royalties on sales of their product.

In July 2006, we entered into a joint development agreement with the Population Council, an international, non-profit research organization, to develop contraceptive formulation products containing Nestorone®, by using the

Council's patented and other proprietary information covering the compound, and our transdermal delivery gel technology. Under the terms of the joint development agreement, we are responsible for research and development activities as they relate to ATD formulation and manufacturing. The Population Council will be responsible for clinical trial design development and management. Together, we expect to identify a worldwide or regional commercial development partner as clinical data becomes available.

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

In July 2007, we entered into a worldwide product development and license agreement with Jazz Pharmaceuticals for a product being developed to treat a CNS disorder that will utilize our transdermal gel delivery technology ATD™. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by us under certain circumstances.

In September 2007, we entered into a worldwide product development and license agreement with an undisclosed company for a product in the field of opioid analgesia that will utilize our oral disintegrating tablet delivery technology. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by us under certain circumstances.

In December 2007, we entered into a license, development and supply agreement with Teva Pharmaceutical Industries Ltd. under which we will develop and supply a disposable pen injector for use with two undisclosed patient-administered pharmaceutical products. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by us under certain circumstances.

Distribution/supply agreements are arrangements under which our products are supplied to end-users through the distributor or supplier. We provide the distributor/supplier with injection devices and related disposable components, and the distributor/supplier often receives a margin on sales. We currently have a number of distribution/supply arrangements under which the distributors/suppliers sell our needle-free injection devices and related disposable components for use with insulin.

Competition

Competition in the specialty pharmaceutical sector is significant, mature and dominated by companies like ALZA Corporation, Elan Corporation plc, SkyePharma plc and Alkermes, Inc. Competition in the transdermal delivery market includes companies like Watson Pharmaceuticals, Solvay, NexMed, Inc., Auxillium, Inc., Bentley Pharmaceuticals, Inc., Novavax, Inc. and many others. Competition in the oral disintegrating tablet market includes Eurand, Cardinal Health, Yamanouchi Pharmaceutical Co., Ltd. and many others. Competition in the disposable, single-use injector market includes, but is not limited to, Ypsomed AG, SHL Group AB, OwenMumford Ltd. and The Medical House PLC, while competition in the reusable needle-free injector market includes Bioject Medical Technologies Inc. and The Medical House PLC.

Competition in the injectable drug delivery market is intensifying. We clearly face competition from traditional needles and syringes as well as newer pen-like and sheathed needle syringes and other injection systems as well as alternative drug delivery methods including oral, transdermal and pulmonary delivery systems. Nevertheless, the majority of injections are still currently administered using needles. Because injections are typically only used when other drug delivery methods are not feasible, the auto injector 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 we have currently targeted. In addition, because we intend to, at least in part, enter into collaborative arrangements with pharmaceutical companies, our competitive position

will depend upon the competitive position of the pharmaceutical company with which we collaborate for each drug application.

Government Regulation

We and our collaborative partners are subject to, and any potential products discovered, developed and manufactured by us or our collaborative partners must comply with, comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, and local entities regulate, among other things, the pre-clinical and clinical testing, safety, effectiveness, approval, manufacturing operations, quality, labeling, distribution, marketing, export, storage, record keeping, event reporting, advertising and promotion of pharmaceutical products and medical devices. Facilities and certain company records are also subject to inspections by the FDA and comparable authorities or their representatives. The FDA has broad discretion in enforcing the FD&C Act and the regulations thereunder, and noncompliance can result in a variety of regulatory steps ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal actions or penalties.

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

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

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

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

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

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

- § evaluate preliminarily the efficacy of the product for specific, targeted indications;
- § determine dosage tolerance and optimal dosage; and
- § identify possible adverse effects and safety risks.

Pivotal or Phase III adequate and well-controlled trials are undertaken in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for the purpose of registering the new drug. The FDA may suspend or terminate clinical trials at any point in this process if it concludes that patients are being exposed to an unacceptable health risk or if they decide it is unethical to continue the study. Results of pre-clinical and clinical trials must be summarized in comprehensive reports for the FDA. In addition, the results of Phase III studies are often subject to rigorous statistical analyses. This data may be presented in accordance with the guidelines for the International Committee of Harmonization that can facilitate registration in the United States, the EU and Japan.

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

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

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

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

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

20

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.

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

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

Products regulated as medical devices can be commercially distributed in the United States following approval by the FDA, through a finding of substantial equivalence to a marketed product, or by having been exempted from the FD&C Act and regulations thereunder. In cases of substantial equivalence, under Section 510(k) of the FD&C Act, 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 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 PMN, 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. A PMA 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.

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 such as a 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 ("OCP") to address the challenges associated with the review and regulation of combination products. The OCP assists in determining strategies for the approval of drug/delivery combinations and assuring

21

agreement within the FDA on review responsibilities. To the extent permitted under the FD&C Act and current FDA policy, we intend to seek regulatory review for drug delivery systems for use in specific drug applications under the medical device provisions, rather than under the new drug provisions, of the FD&C Act. We intend to use the OCP to further this goal. Device regulatory filings could take the form of a PMN, PMA, or the filing of a device master file ("MAF"). In some cases, the device specific information may need to be filed as part of the drug approval submission, and in those cases we will seek agreement from the Agency for review of the device portion of the submission by the Center for Devices and Radiological Health ("CDRH") under the medical device provisions of the law.

A MAF filing typically supports a regulatory filing in the approval pathway. Where common data elements may be part of several submissions for regulatory approval, as in the case of information supporting an injection platform; a MAF filing with the FDA may be the preferred route. A delivery device that is considered a product only when combined with a drug, and where such a device is applicable to a variety of drugs, represents another opportunity for such a filing. We intend to pursue such strategies as permitted by the law and as directed by the FDA either through guidance documents or discussions.

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 for insulin. In the future we or our partners may submit additional 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 our 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. Our 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, our 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 our modified injectors are packaged with the drug, as part of a drug delivery system, the entire package may be subject to the requirements for drug/device combination products. These include drug manufacturing requirements, drug adverse reaction reporting requirements, and all of the restrictions that apply to drug labeling and advertising. In general, the drug requirements under the FD&C Act are more onerous than medical device requirements. These requirements could have a substantial adverse impact on our ability to commercialize our products and our operations.

The FD&C Act also regulates quality control and manufacturing procedures by requiring that we and our contract manufacturers 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

22

any product malfunction that would likely cause or contribute to a death or serious injury if the malfunction were to recur. In addition, FDA regulations prohibit a device from being marketed for unapproved or uncleared indications. If the FDA believes that a company is not in compliance with these regulations, it could institute proceedings to detain or seize company products, issue a recall, seek injunctive relief or assess civil and criminal penalties against the company or its executive officers, directors or employees.

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

In addition to regulations in the United States, we are subject to various foreign regulations governing clinical trials and the commercial sales and distribution of our products. We must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement and the regulatory approval process all vary greatly from country to country. Additionally, the time it takes to complete the approval process in foreign countries may be longer or shorter than that required for FDA approval. Foreign regulatory approvals of our products are necessary whether or not we obtain FDA approval for such products. Finally, before a new drug may be exported from the United States, it must either be approved for marketing in the United States or meet the requirements of exportation of an unapproved drug under Section 802 of the Export Reform and Enhancement Act or comply with FDA regulations pertaining to INDs.

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

Sales of medical devices outside of the U.S. are subject to foreign legal and regulatory requirements. Certain of our 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. We rely upon the companies marketing our injectors in foreign countries to obtain the necessary regulatory approvals for sales of our products in those countries. Generally, products having an effective 510(k) clearance or PMA may be exported without further FDA authorization.

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

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

Employees

We believe that our success is largely dependent upon our ability to attract and retain qualified personnel in the research, development, manufacturing, business development and commercialization fields. As of March 15, 2008, we had 30 full-time and 3 part-time employees worldwide, of whom 18 are in the United States. Of the 33 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.

Item 1A. RISK FACTORS

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

Risks Related to Our Operations

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

We incurred net losses of ($8,578,939) and ($8,099,846) in the fiscal years ended 2007 and 2006, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2007 of ($107,901,392). The costs for research and product development of our drug delivery technologies along with marketing and selling expenses and general and administrative expenses have been the principal causes of our losses. We may not ever become profitable and if we do not become profitable your investment would be harmed.

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

In July of 2007, we completed a private placement of our common stock and warrants in which we received aggregate gross proceeds of $16,000,000. In February of 2007, we received gross proceeds of $5,000,000 upon closing of the first tranche of a $10,000,000 credit facility, to help fund working capital needs. In December of 2007 we received gross proceeds of $2,500,000, after amending the credit facility agreement to reduce the amount available to draw down in the second tranche from $5,000,000 to $2,500,000. We believe that the combination of the debt and equity financings and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations beyond 2008. However, if we need additional financing and are unable to obtain such financing when needed, or obtain it on favorable terms, we may be required to curtail development of new drug technologies, limit expansion of operations, accept financing terms that are not as attractive as we may desire or be forced to liquidate and close operations.

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

- the demand for our technologies from current and future biotechnology and pharmaceutical partners;
- our ability to manufacture products efficiently, at the appropriate commercial scale, and with the required quality;
- our ability to increase and continue to outsource manufacturing capacity to allow for new product introductions;
- the level of product competition and of price competition;
- our ability to develop, maintain or acquire patent positions;
- patient acceptance of our current and future products;
- our ability to develop additional commercial applications for our products;
- our limited regulatory and commercialization experience;
- our reliance on outside consultants;
- our ability to obtain regulatory approvals;

- our ability to attract the right personnel to execute our plans;
- our ability to control costs; and
- general economic conditions.

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

We must make choices as to the drugs that we will combine with our transdermal gel, oral disintegrating tablet and disposable pressure assisted auto injector and reusable needle free technologies to move into the marketplace. We may not make the correct choice of drug or technologies when combined with a drug, which may not be accepted by the marketplace as we expected or at all. FDA approval processes for the drugs and drugs with devices may be longer in time and/or more costly and/or require more extended clinical evaluation than anticipated. Funds required to bring our own products to market may be more than anticipated or may not be available at all. We have limited experience in development of compounds and in regulatory matters and bringing such products to market; therefore, we may experience difficulties in execution of development of internal product candidates.

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 2007, we derived approximately 39% and 36% of our revenue from Ferring and BioSante Pharmaceuticals, respectively, and in 2006 we derived approximately 39% and 24% of our revenue from Ferring and BioSante Pharmaceuticals, respectively. The revenue from Ferring was primarily product sales and royalties. The revenue from BioSante was milestone based and will likely not be recurring in the near future.

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

We have entered into four License, Development and/or Supply agreements for five potential products since November of 2005 with Teva Pharmaceutical Industries Ltd. or an affiliate of Teva. Although certain upfront payments have been received, there have been no commercial sales and there can be no assurance that there ever will be commercial sales or future milestone payments under these agreements.

In July 2007, we entered into a worldwide product development and license agreement with Jazz Pharmaceuticals. Under the agreement an upfront payment, development milestones, and royalties on product sales are due us under certain circumstances. If the development program conducted by Jazz is not a success we may never receive any compensation other than the upfront payment earned at agreement execution.

In September 2007, we entered into a worldwide product development and license agreement with an undisclosed company. Under the agreement an upfront payment, development milestones, and royalties on product sales are due us under certain circumstances. If the development program conducted by this company is not a success we may never receive any compensation other than the upfront payment earned at agreement execution.

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

Pursuant to our license agreement with Ferring, we licensed certain of our intellectual property related to our needle-free injection devices, including a license that allows Ferring to manufacture our devices on its own under certain circumstances for use with its human growth hormone product. In accordance with the license agreement, we entered into a manufacturing agreement with a third party to manufacture our devices for Ferring. If we or this third party are unable to meet our obligations to supply Ferring with our devices, Ferring would own a fully paid up license to manufacture our devices and to use and exploit our intellectual property in connection with Ferring's

human growth hormone product. In such event, we would no longer receive product sales and manufacturing margins from Ferring, however we would still receive royalties.

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

We do not possess the capabilities or facilities to manufacture commercial quantities of Anturol™, which is currently in development for overactive bladder, or any other of our future drug candidates. We must contract with manufacturers to produce Anturol™ according to government regulations. Our future development and delivery of our product candidates depends on the timely, profitable and competitive performance of these manufacturers. A limited number of manufacturers exist which are capable of manufacturing our product candidates. We may fail to contract with the necessary manufacturers or we may contract with manufactures on terms that may not be favorable to us. Our manufacturers must obtain FDA approval for their manufacturing processes, and we have no control over this approval process. Additionally, use of contract manufacturers exposes us to risks in the manufacturer's business such as their potential inability to perform from a technical, operational or financial standpoint.

We have contracted with a commercial supplier of pharmaceutical chemicals to supply us with the active pharmaceutical ingredient of oxybutynin for clinical quantities of Anturol™ in a manner that meets FDA requirements via reference of their DMF for oxybutynin. Additionally, we have contracted with Patheon, a manufacturing development company, to supply clinical quantities of Anturol™ in a manner that meets FDA requirements. The FDA has not approved the manufacturing processes of Patheon for Anturol™. Any failure by Patheon or our supplier of the active ingredient oxybutynin to achieve or maintain compliance with FDA standards could significantly harm our business since we do not currently have approved secondary manufacturers for Anturol™ gel or oxybutynin

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

Our device manufacturing for our needle-free device has involved the assembly of products from machined stainless steel and composite components in limited quantities. Our planned future device business necessitates significant changes and additions to our contract manufacturing and assembly process due to the anticipated larger scale of manufacturing in our business plan. Our devices must be manufactured in compliance with regulatory requirements, in a timely manner and in sufficient quantities while maintaining quality and acceptable manufacturing costs. In the course of these changes and additions to our manufacturing and production methods, we may encounter difficulties, including problems involving scale-up, yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment and component supplies, any of which could result in significant delays in production.

We entered into a manufacturing agreement under which a third party manufactures and assembles our MJ7 devices and certain related disposable component parts. There can be no assurance that this third-party manufacturer will be able to continue 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 continue to outsource manufacturing of our future disposable injection products to third parties. Such products will be price sensitive and may be required to be manufactured in large quantities, and we have no assurance that this can be done. Additionally, use of contract manufacturers exposes us to risks in the manufacturers' business such as their potential inability to perform from a technical, operational or financial standpoint.

We have contracted with Nypro Inc (Nypro), an international manufacturing development company to supply commercial quantities of our Vibex™ pressure assisted auto injector device in compliance with FDA QSR regulations. Any failure by Nypro to successfully manufacture the

pressure assisted auto injector device in commercial quantities, and be in compliance with regulatory regulations, would have a negative impact on our future revenue expectations.

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

Certain of our technologies contain a number of customized components manufactured by various third parties. Regulatory requirements applicable to manufacturing can make substitution of suppliers costly and time-consuming. In the event that we could not obtain adequate quantities of these customized components from our suppliers, there can be no assurance that we would be able to access alternative sources of such components within a reasonable period of time, on acceptable terms or at all. The unavailability of adequate quantities, the inability to develop alternative sources, a reduction or interruption in supply or a significant increase in the price of components could have a material adverse effect on our ability to manufacture and market our products.

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

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

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

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

In July 2002, the NIH halted a long-term study, known as the Women's Health Initiative, being conducted on oral female hormone replacement therapy ("HRT") using a combination of estradiol and 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 predict whether our alternative route of transdermal administration of HRT products will carry the same risk as the oral products used in the study.

In 2006 the FDA approved Elestrin®, an estrogen gel developed by our partner BioSante for the treatment of vasomotor symptoms associated with menopause. The determination by the FDA of Elestrin's efficacy and safety may not impact the acceptance by physicians and patients of this newly approved product. In 2008 our partner BioSante reached agreement under a Special Protocol Assessment (SPA) for the Phase III program for LibiGel® for the treatment of female sexual dysfunction. The receipt of the SPA does not ensure the FDA will find LibiGel® safe or effective nor does it impact future acceptance by physicians and patients.

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

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

Elestrin®, our transdermal estradiol gel, was launched by BioSante's marketing partner Bradley Pharmaceuticals in June 2007. To date, the market penetration of Elestrin® has been low. Additionally, Bradley was acquired by Nycomed in February 2008 and presently the commercial interest of Elestrin® with Nycomed is unknown.

We are developing Anturol, our oxybutynin gel for overactive bladder. We may seek a pharmaceutical partner to assist in the development and marketing of this potential product. However, we may be unsuccessful in partnering Anturol™ which may delay or affect the timing of the clinical program due to availability of resources.

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

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

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

We have not yet completed research and development work or obtained regulatory approval for any technologies for use with any drugs other than insulin, human growth hormone and estradiol (Elestrin®). There can be no assurance that any newly developed technologies will ultimately be successful or that unforeseen difficulties will not occur in research and development, clinical testing, regulatory submissions and approval,

product manufacturing and commercial scale-up, marketing, or product distribution related to any such improved technologies or new uses. Any such occurrence could materially delay the commercialization of such improved technologies or new uses or prevent their market introduction entirely.

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

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

Although it is impossible for us to identify the amount of sales of our products that our customers will submit for payment to third-party insurers, at least some of these sales may be dependent in part on the availability of adequate reimbursement from these third-party healthcare payors. Currently, insurance companies and other third-party payors reimburse the cost of certain technologies on a case-by-case basis and may refuse reimbursement if they do not perceive benefits to a technology's use in a particular case. Third-party payors are increasingly challenging the pricing of medical products and devices, 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 products or technologies or maintain price levels sufficient to realize profitable operations. There is also a possibility of increased government control or influence over a broad range of healthcare expenditures in the future. Any such trend could negatively impact the market for our drug delivery products and technologies.

Elestrin®, for which we receive royalties from our partner based on any commercial sales, was launched in June 2007. We have no way of knowing at this time if health insurance companies reimbursement has negatively impacted patient use of Elestrin® as this typically becomes known after the first year of launch.

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

One of our primary business pathways requires us to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use and marketing of drug delivery technologies with specific drug therapies. Under these arrangements, the partner companies typically assist us in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. Our licensees may also be responsible for distribution and marketing of the technologies for these drug therapies either worldwide or in specific territories. We are currently a party to a number of such agreements, all of which are currently in varying stages of development. We may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product) and thus, would not receive the fees expected from such arrangements, related future royalties or product sales. Moreover, there can be no assurance that we will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of our drug delivery technologies. In such event, our business, results of operations and financial condition could be adversely affected, and our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability. As a result of our collaborative agreements, we are dependent upon the development, data collection and marketing efforts of our licensees. The amount and timing of resources such licensees devote to these efforts are not within our control, and such licensees could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug or drug device covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales of our drug delivery technology. We are relying on partners such as Teva, Jazz, BioSante and an undisclosed partner in our device, gel and ODT platforms for future milestone, sales and royalty revenue. Any or all of these partners may never commercialize a product with our technologies or significant delays in anticipated launches of these products may occur. Any potential loss of anticipated future revenue could have an adverse affect on our business and the value of your investment.

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

29

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.

Additionally, there is no assurance that regulatory filings by our partners in the U.S. will be deemed sufficient by agencies equivalent to the FDA outside the U.S., potentially delaying non U.S. product launches.

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

Competitors in the overactive bladder, transdermal gel drug delivery, injector and other markets, some with greater resources and experience than us, may enter these markets, as there is an increasing recognition of a need for less invasive methods of delivering drugs. Additionally, there is an ever increasing list of competitors in the oral disintegrating tablet business. Our success depends, in part, upon maintaining a competitive position in the development of products and technologies in rapidly evolving fields. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical company partners may choose to adopt the drug delivery technologies of our competitors. Companies that compete with our technologies include Watson Pharmaceuticals, Bioject Medical Technologies, Inc., Bentley Pharmaceuticals, Inc., Auxillium, BioChemics, Inc., Aradigm, Cellegy Pharmaceuticals, Inc., Cardinal Health, CIMA Laboratories, Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc., The Medical House and Novavax, Inc., along with other companies. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do, and, therefore, represent significant competition.

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

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

One of our competitors, Watson Pharmaceuticals, completed a Phase III study of its own oxybutynin gel for OAB in January 2008. While there is no guarantee their drug will ultimately be approved or launched in the U.S., at this point Watson's development of their oxybutynin gel is ahead of Anturol™ which may limit the success of Anturol™ in the market, if approved. Additionally, Watson has greater resources than we do, which may impact our ability to be competitive in the OAB market.

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

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

We currently hold approximately 87 patents and have an additional 80 applications pending in the U.S. and other countries. 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. Additionally, our technologies are complex and one patent may not be sufficient to protect our products where a series of patents may be needed. Further, we may not have the necessary financial resources to enforce or defend our patents or patent applications. In addition, 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.

We have received a notice of rejection from the U.S. patent and trademark office (USPTO) for a key patent in the Anturol™ patent portfolio which was posted on the USPTO website (USPTO.gov) in January 2008. As part of the patent process, after a meeting held with the patent examiner, we filed a response that amended the claims. While we believe that the claims are patentable, there is no assurance that the USPTO will issue the patent, and, if the patent is not issued, the market value of Anturol™ may be adversely affected.

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 the patent office or the courts. If we cannot avoid infringement or obtain required licenses on acceptable terms, we may not be able to continue to develop and commercialize our product candidates. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property. If we are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by patents of others. Even if we were able to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. We may not have identified, or be able to identify in the future, United States or foreign patents that pose a risk of potential infringement claims. Furthermore, in the event a patent infringement suit is brought against us, the development, manufacture or potential sale of product candidates claimed to infringe on a third party's intellectual property may have to stop or be delayed. Ultimately, we may be unable to commercialize some of our product candidates as a result of patent infringement claims, which could harm our business.

We are aware of two related U.S. Patents issued to Watson Pharmaceuticals relating to a gel formulation of oxybutynin. We believe that we do not infringe these patents and that they should not have been issued. We may seek to invalidate these patents but there can be no assurance that we will prevail. If the patents are determined to be valid and if Anturol™ is approved, we may be delayed in our marketing and the potential market value of Anturol™ may be adversely affected.

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

The drugs to which our drug delivery technologies are applied are generally the property of the pharmaceutical companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical companies or third parties. If those patents or other forms of protection expire, become ineffective or are subject to the control of third parties, sales of the drugs by the

collaborating pharmaceutical company may be restricted or may cease. Our expected revenues, in that event, may not materialize or may decline.

Our business may suffer if we lose certain key officers or employees or if we are not able to add additional key officers or employees necessary to reach our goals.

The success of our business is materially dependent upon the continued services of certain of our key officers and employees. The loss of such key personnel could have a material adverse effect on our business, operating results or financial condition. There can be no assurance that we will be successful in retaining key personnel. We consider our employee relations to be good; however, competition for personnel is intense and we cannot assume that we will continue to be able to attract and retain personnel of high caliber.

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

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

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

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

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

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

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

Our business entails the risk of product liability and clinical trial claims. Although we have not experienced any material claims to date, any such claims could have a material adverse impact on our business. Insurance coverage is expensive and may be difficult to obtain, and may not be available in the future on acceptable terms, or at all. We maintain product and clinical trial liability insurance with coverage of $5 million per occurrence and an annual aggregate maximum of $5 million and evaluate our insurance requirements on an ongoing basis. If the coverage limits of the product liability insurance are not adequate, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Risks Related to Regulatory Matters

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

The design, development, testing, manufacturing and marketing of pharmaceutical compounds, medical nutrition and diagnostic products and medical devices are subject to regulation by governmental authorities, including the FDA and comparable regulatory authorities in other countries. The approval process is generally lengthy, expensive and subject to unanticipated delays. Currently, we, along with our partners, are actively pursuing marketing approval for a number of products from regulatory authorities in other countries and anticipate seeking regulatory approval from the FDA for products developed internally and pursuant to our license agreements. In the future we, or our partners, may need to seek approval for newly developed products. Our revenue and profit will depend, in part, on the successful introduction and marketing of some or all of such products by our partners or us.

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

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

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

The FDA however, may not concur with our analysis of the data.

In July 2007, we completed a Special Protocol Assessment (SPA) with the FDA for a pivotal trial of Anturol. A SPA documents the FDA's agreement that the design and planned analysis of the trial adequately addresses objectives, in support of a regulatory submission such as a New Drug Application (NDA). The completion of the SPA does not ensure success of the trial or that the FDA will ultimately accept the results of the trial and we may never receive FDA approval for Anturol™ and without FDA approval, we cannot market or sell Anturol™.

In October 2007, we announced the first patient dosing in a pivotal safety and efficacy trial of Anturol™ for OAB. The three arm study will enroll approximately 600 patients for a 12-week clinical trial. The randomized, double-blind, placebo controlled, multi-center trial will principally evaluate the efficacy of Anturol™ when administered topically once daily for 12 weeks. The primary end point of the trial will be efficacy against the placebo defined as the reduction in the number of urinary incontinence episodes experienced. Secondary end points include changes from baseline in urinary urgency, average daily urinary frequency, patient perceptions as well as safety and tolerability. The initiation of the trial does not ensure success of the trial. We may not have the resources to complete the trial, Anturol™ may prove to not be efficacious, may not beat placebo or may have undesired side effects not previously experienced. We may have to modify the trial which may delay the trial or cause the costs of the trial to increase significantly. Additionally, the FDA may require further studies for approval. Any of these potential outcomes could have a negative impact on the value of our stock price.

We are also developing, with partners, injection devices for use with our partner’s drugs. The regulatory path for approval of such combination products maybe subject to review by several centers within the FDA and although precedent and guidance exists for the requirements for such combination products, there is no assurance that the FDA will not change what it requires or how it reviews such submissions. Additionally,

there is no assurance that the FDA will not require human clinical testing in order to commercialize these devices. Such changes in review processes or the requirement for clinical studies could delay anticipated launch dates or be at a cost which makes launching the device cost prohibitive for our partners. Such delay or failure to launch these devices could adversely affect our revenues and future profitability.

In other jurisdictions, we, and the pharmaceutical companies with whom we are developing technologies (both drugs and devices), 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. Additionally, clinical data that we generate or obtain from partners from FDA regulatory filings may not be sufficient for regulatory filings in other jurisdictions and we may be required to incur significant costs in obtaining those regulatory approvals.

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

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

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

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

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

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

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

- warning letters;
- fines;
- product seizures or recalls;
- injunctions;
- refusals to permit products to be imported into or exported out of the applicable regulatory jurisdiction;
- total or partial suspension of production;

- withdrawals of previously approved marketing applications; or
- criminal prosecutions.

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

Once a drug product is approved by the FDA, the Division of Drug Marketing, Advertising and Communication, the FDA's marketing surveillance department within the Center for Drugs, must approve marketing claims asserted by our pharmaceutical company partners. If we or a pharmaceutical company partner fails to obtain

from the Division of Drug Marketing acceptable marketing claims for a product incorporating our drug technologies, our revenues from that product may be limited. Marketing claims are the basis for a product's labeling, advertising and promotion. The claims the pharmaceutical company partners are asserting about our drug delivery technologies, or the drug product itself, may not be approved by the Division of Drug Marketing.

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

The testing, manufacturing and marketing of products utilizing our drug delivery technologies may expose us to potential product liability and other claims resulting from their use in practice or in clinical development. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical companies with whom we are developing drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses that may have been suffered. A successful product liability claim against us, if not covered by, or if in excess of our product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations. Adverse claim experience for our products or licensed technologies or medical device, pharmaceutical or insurance industry trends may make it difficult for us to obtain product liability insurance or we may be forced to pay very high premiums, and there can be no assurance that insurance coverage will continue to be available on commercially reasonable terms or at all.

Risks Related to our Common Stock

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

As a result of our reverse business combination with Permatec in January 2001 and subsequent additional debt and equity financings, Permatec Holding AG and its controlling stockholder, Dr. Jacques Gonella, own a substantial portion (as of March 14, 2008, approximately 14%) 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 144,500 shares of common stock. Additionally, three investors (Perceptive Life Sciences Fund, SCO Capital Group and SDS Funds) own warrants that are, as of March 14, 2008, exercisable into an aggregate of 5,286,588 shares of our common stock. Some of these investors also directly own shares of our common stock. If Dr. Gonella and all of the above investors exercised all of the warrants and options owned by them, Dr. Gonella would own approximately 18%, and the four investors as a group would own, at a minimum, over 7%, of our common stock.

Because the parties described above either currently own or could potentially own a large portion of our stock, they may be able to generally determine or they may be able to significantly influence the outcome of corporate actions requiring stockholder approval. As a result, these parties may be in a position to control matters affecting our company, including decisions as to our corporate direction and policies; future issuances of certain securities; our incurrence of debt; amendments to our certificate of incorporation and bylaws; payment of dividends on our common stock; and acquisitions, sales of our assets, mergers or similar transactions, including transactions involving a change of control. As a result, some investors may be unwilling to purchase our common stock. In addition, if the demand for our common stock is reduced because of these stockholders' control of the Company, the price of our common stock could be adversely affected. Additionally, future sales of large blocks of our common stock by any of the above investors could substantially adversely affect our stock price.

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

As of March 14, 2008, we have warrants outstanding that are exercisable, at prices ranging from $0.55 per share to $5.00per share, for an aggregate of approximately 23,141,000 shares of our common stock. We also have options outstanding that are exercisable, at exercise prices ranging from $0.70 to $9.40 per share, for an aggregate of

approximately 5,582,000 shares of our common stock. Purchasers of common stock could therefore experience substantial dilution of their investment upon exercise of the above warrants or options. The majority of the shares of common stock issuable upon exercise of the warrants or options held by these investors are currently registered.

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

As of March 14, 2008, our officers and directors beneficially owned an aggregate of approximately 16,700,000 shares (or approximately 23%) of our common stock, including stock options exercisable within 60 days. If our officers and directors, or other stockholders, sell a substantial amount of our common stock, it could cause the market price of our common stock to decrease and could hamper our ability to raise capital through the sale of our equity securities.

We do not expect to pay dividends in the foreseeable future.

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. DESCRIPTION OF PROPERTY

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

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

We also lease approximately 650 square meters of facilities in Basel, Switzerland, for office space and formulation and analytical laboratories. The lease will terminate in September 2013. We believe the facilities will be sufficient to meet our requirements through the lease period at this location.

Item 3. LEGAL PROCEEDINGS

None.

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

None.

PART II

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

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

	High	Low
2007:		
First Quarter	$ 1.34	$ 1.09
Second Quarter	$ 2.15	$ 1.25
Third Quarter	$ 1.83	$ 1.25
Fourth Quarter	$ 1.44	$ 0.92
2006:		
First Quarter	$ 1.89	$ 1.10
Second Quarter	$ 1.75	$ 1.09
Third Quarter	$ 1.35	$ 0.86
Fourth Quarter	$ 1.38	$ 1.00

Common Shareholders

As of March 14, 2008, we had 130 shareholders of record of our common stock.

Dividends

We have not paid or declared any cash dividends on our common stock during the past ten years. We have no intention of paying cash dividends in the foreseeable future on common stock. We paid semi-annual dividends on Series A Convertible Preferred Stock ("Series A") at an annual rate of 10%, payable on May 10 and November 10 each year until June 2005, when all of the Series A was converted into common stock. The covenants of our current credit facility, in certain circumstances, restrict our ability to declare or pay any dividends on any shares of our capital stock.

Item 6. SELECTED FINANCIAL DATA

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

	At December 31,				
	2007	2006	2005	2004	2003
Balance Sheet Data:					
Cash and cash equivalents	$ 9,759	$ 2,706	$ 2,718	$ 1,652	$ 1,929
Short-term investments	16,301	4,953	-	7,972	-
Working capital	21,891	5,979	965	8,489	615
Total assets	30,217	11,534	6,166	13,178	5,955
Long-term liabilities, less current maturities	7,295	3,556	3,062	3,339	3,558
Accumulated deficit	(107,901)	(99,322)	(91,123)	(82,575)	(74,127)
Total stockholders' equity	17,499	5,080	757	8,189	307

	Year Ended December 31,				
	2007	2006	2005	2004	2003
Statement of Operations Data:					
Product sales	$ 3,211	$ 2,195	$ 1,512	$ 1,834	$ 2,647
Development revenue	956	594	184	197	310
Licensing fees	3,231	1,254	374	635	695
Royalties	459	225	155	80	135
Revenues	7,857	4,268	2,225	2,746	3,787
Cost of revenues (1)	3,442	1,556	1,137	1,372	2,008
Research and development	5,362	3,778	3,677	2,870	2,389
Sales, marketing and business development	1,641	1,350	1,161	676	462
General and administrative (2)	6,058	5,861	4,839	6,203	7,562
Operating expenses	13,061	10,989	9,677	9,749	10,413
Operating loss	(8,646)	(8,277)	(8,589)	(8,375)	(8,634)
Net other income (expense)	67	177	91	26	(24,184)
Net loss	(8,579)	(8,100)	(8,498)	(8,349)	(32,818)
Deemed dividend to warrant holder	-	(99)	-	-	-
Preferred stock dividends	-	-	(50)	(100)	(143)
Net loss applicable to common shares	$ (8,579)	$ (8,199)	$ (8,548)	$ (8,449)	$ (32,961)
Net loss per common share (3) (4)	$ (0.14)	$ (0.16)	$ (0.21)	$ (0.23)	$ (2.18)
Weighted average number of common shares	59,605	51,582	41,460	36,348	15,093

(1) In 2007 we recorded non-cash impairment of prepaid license discount and related charges of $1,439.
(2) In 2007, 2006, 2004 and 2003 we recorded non-cash patent impairment charges of $296, $139, $233 and $974, respectively.
(3) Basic and diluted loss per share amounts are identical as the effect of potential common shares is anti-dilutive.
(4) We have not paid any dividends on our Common Stock since inception.

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

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

Overview

We develop, produce and market pharmaceutical delivery products, including transdermal gels, oral disintegrating tablets and reusable needle-free and disposable pressure assisted auto injector and pen injector systems. In addition, we have several products and compound formulations under development. We have operating facilities in the U.S. and Switzerland. Our U.S. operation manufactures and markets reusable needle-free injection devices and related disposables, and develops disposable pressure assisted auto injector and pen injector systems. These operations, including all development and some U.S. administrative activities, are located in Minneapolis, Minnesota. We also have operations located in Basel, Switzerland, which consist of administration and facilities for the development of transdermal gels and oral disintegrating tablet products. Our Swiss operations focus principally on research, development and commercialization of pharmaceutical products and include a number of license agreements with pharmaceutical companies for the application of its drug delivery systems. Our corporate offices are located in Ewing, New Jersey.

We operate as a specialty pharmaceutical company in the broader pharmaceutical industry. Companies in this sector generally bring technology and know-how in the area of drug formulation and/or delivery to pharmaceutical product marketers through licensing and development agreements while actively pursuing development of their own products. We currently view pharmaceutical and biotechnology companies as our primary customers. We have negotiated and executed licensing relationships in the growth hormone segment (reusable needle-free devices in Europe and Asia), the transdermal gels segment (several development programs in place worldwide, including the United States and Europe) and the oral disintegrating tablet segment. In addition, we continue to market reusable needle-free devices for the home or alternate site administration of insulin in the U.S. market through distributors and have licensed both disposable and reusable injection devices to Teva Pharmaceuticals for use in undisclosed fields and territories.

We are reporting a net loss of $8,578,939 for the year ended December 31, 2007 and expect to report a net loss for the year ending December 31, 2008, as marketing and development costs related to bringing future generations of products to market continue. Long-term capital requirements will depend on numerous factors, including the status of collaborative arrangements and payments received under such arrangements, the progress of research and development programs, the receipt of revenues from sales of products and royalties and the ability to control costs.

Included in the current year net loss is a net charge to earnings of $1,629,060 recorded in the fourth quarter after we determined Eli Lilly was no longer committed to development of our product on the previously agreed upon timeline under a development and license agreement, resulting in our conclusion that the carrying value of the prepaid license discount associated with the agreement was impaired.

During 2007 we raised net proceeds of $14,742,671 in a private placement of our common stock and received proceeds of $7,500,000 from debt financings. We believe that the combination of the recent equity and debt financings and projected product sales, product development, license revenues, milestone payments and royalties will provide sufficient funds to support operations beyond 2008. Additionally, we believe we have the funds required for capital expenditures that may exceed $2.5 million in 2008 in connection with tooling and production equipment related to commercial device deals, and have the funds necessary for the pivotal safety and efficacy trial of Anturol™ for overactive bladder which began in 2007.

39

Critical Accounting Policies and Use of Estimates

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

Revenue Recognition

A significant portion of our 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. We also enter 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, our 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. Our 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 we 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. For major licensing contracts, this results in the deferral of significant revenue amounts ($3,594,324 at December 31, 2007) 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.

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 certain deferred development costs over an extended period of time, revenue recognized and cost of revenue may be materially different from cash flows.

In connection with a license agreement entered into with Eli Lilly and Company in 2003, we issued to Lilly a ten-year warrant to purchase 1,000,000 shares of our common stock at an exercise price of $3.776 per share. At the time of issue, we 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 was being reduced on a straight-line basis over the term of the agreement, offsetting revenue generated under the agreement.

As discussed further in Note 10 to the consolidated financial statements, the agreement with Lilly was amended in March of 2008. Considering the renegotiations with Lilly and drafts of the then pending amendment, we evaluated the prepaid license discount related to the original agreement (recorded as contra equity in the stockholders' equity section of the balance sheet) for potential impairment in connection with our preparation and review of the 2007 financial statements. Given that Lilly was no longer committed to development of our product on the previously agreed upon timeline under the agreement, we determined it was unlikely that future cash flows would be received by us that would

exceed the unamortized carrying value, indicating that the recorded prepaid

license discount was impaired. In addition, we determined that capitalized patent costs associated with the agreement had been impaired. We also recognized related deferred revenue and deferred costs related to the agreement. Accordingly, we recorded a net non-cash charge to earnings in the fourth quarter totaling $1,629,060, consisting principally of the patent impairment charge of $296,338 and the impairment of prepaid license discount and related charges of $1,438,638. The patent impairment charge was recorded in general and administrative expense, while the impairment of prepaid license discount and recognition of deferred revenue and deferred costs was recorded in cost of revenue. The net impact to stockholders' equity was an increase of approximately $480,000 as a result of the recognition of deferred revenue in excess of deferred costs and patent impairment charges.

On an overall basis, our 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.

	2007	2006	2005
Product sales	$ 3,211,397	$ 2,195,218	$ 1,511,929
Development fees	912,172	785,720	214,210
Licensing fees and milestone payments	3,478,642	2,082,742	275,524
Royalties	218,042	140,110	105,276
Billings received and/or accrued per contract terms	7,820,253	5,203,790	2,106,939
Deferred billings received and/or accrued	(1,068,804)	(1,409,268)	(360,949)
Deferred revenue recognized	1,195,880	670,126	675,005
Amortization of prepaid license discount	(90,333)	(196,249)	(196,249)
Total revenue as reported	$ 7,856,996	$ 4,268,399	$ 2,224,746

Valuation of Long-Lived and Intangible Assets and Goodwill

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

In the fourth quarter of each year we update our long-range business plan. We then review patent costs for impairment and identify patents related to products for which there are no signed distribution or license agreements or for which no revenues or cash flows were included in the business plan. In 2007 and 2006 we recognized impairment charges of $296,338 and $138,632, respectively, in general and administrative expenses, which represented the gross carrying amount, net of accumulated amortization, for the identified patents. No impairment charges were recognized in 2005. The 2007 impairment charge relates to the Eli Lilly amendment discussed further in Note 10 to the consolidated financial statements. After the impairment charge, the gross carrying amount and accumulated amortization of patents, which are our only intangible assets subject to amortization, were $1,308,327 and $736,153, respectively, at December 31, 2007 and were $1,526,714 and $713,122, respectively, at December 31, 2006. The Company's estimated aggregate patent amortization expense for the next five years is $78,000 in each of 2008, 2009 and 2010, $31,000 in 2011 and $25,000 in 2012.

We evaluate 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 our stock price. When evaluating whether goodwill is impaired, we compare 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. Our evaluation of goodwill completed during 2007, 2006 and 2005 resulted in no impairment losses.

Results of Operations

Years Ended December 31, 2007, 2006 and 2005

Revenues

Total revenue was $7,856,996, $4,268,399 and $2,224,746 for the years ended December 31, 2007, 2006 and 2005, respectively. The increases in 2007 and 2006 were primarily due to increases in licensing revenue and product sales. The licensing revenue increase was mainly due to $2,625,000 and $875,000 received in 2007 and 2006, respectively, under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc. The increase in product sales in each year was mainly due to an increase in sales to our major customer, Ferring.

Product sales include sales of reusable needle-free injector devices, related parts, disposable components, and repairs. In 2007, 2006 and 2005, revenue from sales of needle-free injector devices totaled $1,027,986, $804,481 and $549,070, respectively. Sales of disposable components in 2007, 2006 and 2005 totaled $2,100,253, $1,326,758 and $896,764, respectively. The increases in device and disposable revenue in 2007 and 2006 were due mainly to increases in sales to Ferring. The increases were primarily due to increases in product quantities sold to Ferring in each year. However, in 2007, a portion of the increase was attributable to a renegotiated contract with Ferring in which selling prices were increased. In addition, as the selling prices of certain products sold to Ferring are denominated in Euros, the decreasing value of the U.S. dollar against the Euro in 2007 resulted in an increase in revenue compared to 2006. The increases in product sales to Ferring in 2007 and 2006 followed two years of decreasing sales that occurred while Ferring was working down high inventory levels they had accumulated in prior years.

Development revenue was $955,402, $593,797 and $183,760 for the years ended December 31, 2007, 2006 and 2005, respectively. The revenue in 2007 was attributable primarily to an agreement related to our oral disintegrating tablet technology, along with recognized revenue in connection with our proprietary ATD™ gel technology. The revenue in 2006 was attributable to projects related to injector systems and transdermal gel technologies, but resulted primarily from one agreement related to use of our proprietary ATD™ gel technology. In 2006 we also generated development fees of approximately $217,000 in connection with an agreement related to our oral disintegrating tablet technology, all of which was deferred and was recognized as revenue in 2007. In 2005 approximately half of the development revenue was generated from projects related to injector devices, with most of this coming from one-time projects. The remainder of the recognized development revenue in 2005 was generated under licensing and development agreements related to use of our transdermal gel technology.

Licensing revenue was $3,231,305, $1,254,250 and $374,021 for the years ended December 31, 2007, 2006 and 2005, respectively. The licensing revenue in 2007 and 2006 was primarily due to $2,625,000 and $875,000, respectively, received under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc. In November 2006 BioSante entered into a marketing agreement with Bradley Pharmaceuticals, Inc. for Elestrin® (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a payment to us of $875,000. In December 2006 the FDA approved for marketing Elestrin® in the United States triggering the payments of $2,625,000 received in 2007. In addition, we have begun to receive royalties on sales of Elestrin® and may receive potential sales-based milestone payments in the future.

Royalty revenue was $458,892, $225,134 and $155,036 for the years ended December 31, 2007, 2006 and 2005, respectively. Nearly all royalty revenue has been related to the Vision® reusable needle-free injection device, and has been generated primarily under the license agreement with Ferring dated January 22, 2003, described in

more detail in Note 10 to the consolidated financial statements. Royalties from Ferring are earned on device sales and under a provision in the Ferring agreement in which royalties are triggered by the achievement of certain quality standards. The increase in 2007 was primarily related to the increase in the number of injector devices sold to Ferring, as well as a renegotiated increased royalty rate with Ferring. The increase in 2006 was due to increases both in royalties earned from device sales and in the royalty earned under the quality standards provision.

Cost of Revenues

The costs of product sales are primarily related to reusable injection devices and disposable components. Cost of sales as a percentage of product sales were 55%, 59% and 69% for the years ended December 31, 2007, 2006 and 2005, respectively. The decrease in 2007 was mainly the result of an increase in selling prices to Ferring. The decrease in 2006 was due to a combination of factors including a change in the mix of products sold and a higher sales volume absorbing a slightly decreased level of fixed overhead costs.

The cost of development revenue consists of labor costs, direct external costs and an allocation of certain overhead expenses based on actual costs and time spent in these revenue-generating activities. Cost of development revenue as a percentage of development revenue can fluctuate considerably between periods depending on the development projects in process. In some cases development projects are substantially labor based, resulting in relatively high margins, while in other cases development projects include a significant amount of external cost passed through to the customer at little or no markup, resulting in lower margins. Cost of development revenue as a percentage of development revenue was 25%, 44% and 51% for the years ended December 31, 2007, 2006 and 2005, respectively. The 2007 decrease was primarily due to an increased average hourly billing rate, due primarily to one project which was the source of the majority of the development revenue for the year. The percentage decrease in 2006 was primarily due to projects having fewer external costs that were billed to customers with little or no markup.

Impairment of prepaid license discount of $2,215,596, partially offset by recognizing deferred revenue net of deferred costs, resulted in a net non-cash impairment charge of $1,438,638 in 2007. As discussed in Note 10 to the consolidated financial statements, we determined it was unlikely that future cash flows from the Lilly agreement would exceed the unamortized prepaid license discount (recorded as contra equity in the stockholders' equity section of the balance sheet). In addition, we determined that the carrying value of related capitalized patent costs of $296,338 was impaired, and is recorded in general and administrative expenses in the 2007 statement of operations.

Research and Development

The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development. While we are typically engaged in research and development activities involving each of our drug delivery platforms, over 75% of the total research and development expenses in each year were generated in connection with projects related to transdermal gels and oral disintegrating tablet products. Research and development expenses were $5,362,291, $3,778,469 and $3,677,015 for the years ended December 31, 2007, 2006 and 2005, respectively. The increase in 2007 compared to 2006 was primarily due to the initiation of a Phase III study of Anturol™ (oxybutynin gel) for the treatment of overactive bladder. The overall increase in 2006 compared to 2005 was primarily due to an increase in stock based compensation expense of approximately $128,000.

Sales, Marketing and Business Development

Sales, marketing and business development expenses were $1,640,875, $1,349,678 and $1,160,752 for the years ended December 31, 2007, 2006 and 2005, respectively. The increase in 2007 was primarily due to increases in payroll and legal fees. The payroll increases were partially

due to the addition of personnel and the legal fees increases were due to increased activity as a result of new license, development and/or supply agreements that were completed or in process at year end. The increase in 2006 compared to 2005 was due mainly to an increase in professional services in connection with business development projects related to transdermal gels and oral disintegrating tablets, along with an increase in stock based compensation expense of approximately $80,000.

General and Administrative

General and administrative expenses were $6,057,396, $5,861,111 and $4,839,408 for the years ended December 31, 2007, 2006 and 2005, respectively. The increase in 2007 compared to 2006 was due mainly to the patent impairment charge of $296,338 related to the Lilly agreement, along with increases in other patent related expenses. The increase in 2006 compared to 2005 was due primarily to an increase in stock based compensation expense of approximately $826,000, along with an increase in patent impairment charges of $138,632. The patent impairment charges were recognized after we determined it was unlikely that future cash flows would exceed the net carrying value of the capitalized patent costs. The impairment charges represented the gross carrying amount net of accumulated amortization for the identified patent costs.

Other Income (Expense)

Other income (expense), net, was $66,647, $176,983 and $91,218 for the years ended December 31, 2007, 2006 and 2005, respectively. In 2007, interest income increased to $872,095 from $353,236 in 2006 due mainly to investment of the net proceeds from issuance of common stock of $14,742,671, the exercise of warrants and options of $2,292,692, and the debt financing of $7,500,000. The debt financing resulted in an increase in interest expense and was the primary reason interest expense increased by $769,285, which offset the increase in interest income and resulted in an overall decrease in other income. The increase in 2006 compared to 2005 was primarily due to an increase in interest income resulting from investment of the proceeds from the private placement of common stock in the first quarter of 2006, partially offset by an increase in foreign exchange losses related mainly to the impact of exchange rate fluctuations on liabilities due in foreign currencies.

Liquidity and Capital Resources

We have not historically generated, and do not currently generate, enough revenue to provide the cash needed to support our operations, and have continued to operate primarily by raising capital and incurring debt. In order to better position ourselves to take advantage of potential growth opportunities and to fund future operations, during 2007 we raised additional capital and received proceeds from debt financings.

In July of 2007 we received net proceeds of $14,742,671 in a private placement of our common stock in which a total of 10,000,000 shares of common stock were sold at a price of $1.60 per share. In connection with the private placement, we issued five-year warrants to purchase an aggregate of 3,800,000 shares of common stock with an exercise price of $2.00 per share. In 2007 we also received proceeds of $2,292,692 in connection with warrant and stock option exercises which resulted in the issuance of 2,187,317 shares of common stock.

In February of 2007, we received gross proceeds of $5,000,000 upon closing of the first tranche of a $10,000,000 credit facility, to help fund working capital needs. In December of 2007 we received gross proceeds of $2,500,000, after we amended the credit facility agreement to reduce the amount available to draw down in the second tranche from $5,000,000 to $2,500,000. The per annum interest rate is 12.7% in the case of the first tranche and 11% in the case of the second tranche. The maturity date (i) with respect to the first tranche is forty-two months from the first funding date and (ii) with respect to the second tranche is thirty-six months from the second funding date. The credit agreement is secured by all personal property of the Company, including all intellectual property. The credit agreement contains certain covenants and provisions, including, without limitation, covenants and provisions that:

- restrict our ability to create or incur indebtedness (subject to enumerated exceptions);
- restrict our ability to create or incur certain liens on our property (subject to enumerated exceptions);
- in certain circumstances, require us to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least $2,500,000;

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

In connection with the credit facility, we issued warrants to purchase a total of 640,000 shares of common stock at an exercise price of $1.25.

We believe that the combination of the recent debt and equity financings and projected product sales, product development, license revenues, milestone payments and royalties will provide sufficient funds to support operations beyond 2008. We anticipate that capital expenditures may increase to over $2.5 million in 2008, primarily in connection with tooling and production equipment related to commercial device deals. We do not currently have any bank credit lines. If we do 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 or accept financing terms that are not as attractive as we may desire.

Net Cash Used in Operating Activities

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, general and administrative costs, research and development projects and sales, marketing and business development activities. Net cash used in operating activities was $5,394,276, $6,118,050 and $7,218,529 for the years ended December 31, 2007, 2006 and 2005, respectively. This was primarily the result of net losses of $8,578,939, $8,099,846 and $8,497,956 in 2007, 2006 and 2005, respectively, adjusted by noncash expenses and changes in operating assets and liabilities.

Noncash expenses totaled $4,276,731, $1,798,524 and $695,967 in 2007, 2006 and 2005, respectively. The increase in 2007 compared to 2006 was mainly due to the impairment charges related to the Lilly agreement, including the prepaid license discount impairment and amortization charge of $2,305,929 and the patent rights impairment charge of $296,338. In addition, noncash expenses increased in 2007 due to amortization of debt discount and issuance costs of $220,034, which began in 2007 as a result of the debt financing during the year. The increase in 2006 compared to 2005 was primarily the result of an increase in noncash stock-based compensation expense of nearly $1.0 million, which was principally due to the adoption of SFAS No. 123R in 2006.

In 2007, the change in operating assets and liabilities resulted in a use of cash of $1,092,068. This was due primarily to a decrease in deferred revenue of $1,061,916, which was mainly the result of eliminating the deferred revenue related to the Lilly agreement. Other changes included increases in prepaid expenses of $312,075 and other assets of $340,439, which were partially offset by a decrease in accounts receivable of $379,129 and an increase in accrued expenses and other current liabilities of $441,698. The increases in prepaid expenses and other assets were the result of costs incurred in connection with development projects related mainly to injector devices and Anturol™. The increase in accrued expenses was primarily due to compensation related accruals such as vacation and bonuses, along with accruals for project costs and certain professional fees.

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

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

45

Net Cash Provided by (Used in) Investing Activities

Investing activities are comprised primarily of short-term investment purchases and maturities. All short-term investments are commercial paper or U.S. government agency discount notes that mature within six to twelve months of purchase and are classified as held-to-maturity because we have the positive intent and ability to hold the securities to maturity. In 2007 and 2006 the use of cash to purchase securities exceeded cash generated from maturities by $11,163,507 and $4,851,551, respectively, due primarily to the investment of excess funds from the private placements in each of those years and in 2007 the debt financing provided additional funds for investment. In 2005, maturities exceeded purchases by $7,941,688, as cash was required to fund operations and was not available for reinvestment. Investing activities in 2007, 2006 and 2005 also included additions to patent rights of $145,590, $142,751 and $154,193, respectively, and purchases of equipment, furniture and fixtures of $96,575, $35,703, and $89,651, respectively.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled $23,851,897, $11,117,141 and $619,700 for the years ended December 31, 2007, 2006 and 2005, respectively. In 2007 we received net proceeds of $14,742,671 from the private placement of common stock in which a total of 10,000,000 shares of common stock were sold at a price of $1.60 per share. In addition, in 2007 we received proceeds of $2,292,692 from the exercise of warrants and stock options and received proceeds of $7,500,000 from debt financings. In 2007 cash was used for debt principal payments and debt issuance costs, which totaled $492,745 and $190,721, respectively. In 2006, we received $1,335,086 from the exercise of warrants and stock options and received net proceeds of $9,782,055 from the private placement of common stock in which a total of 8,770,000 shares of common stock were sold at a price of $1.25 per share. In 2005, we received $476,000 from the sale of common stock and $193,700 from the exercise of warrants, which was partially offset by the payment of preferred stock dividends of $50,000.

Our contractual cash obligations at December 31, 2007 are associated with long-term debt, capital and operating leases and are summarized in the following table:

	Payment Due by Period				
	Total	**Less than 1 year**	**1-3 years**	**4-5 years**	**After 5 years**
Long-term debt, including interest	$ 8,314,427	$ 2,995,140	$ 5,319,287	$ -	$ -
Capital leases, including interest	99,056	43,471	55,585	-	-
Operating leases	2,047,245	390,550	874,778	607,415	174,502
Total contractual cash obligations	$ 10,460,728	$ 3,429,161	$ 6,249,650	$ 607,415	$ 174,502

Off Balance Sheet Arrangements

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

New Accounting Pronouncements

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141R (revised 2007), “Business Combinations” (“SFAS 141R”). SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired in the business combination. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. The provisions of SFAS 141R are effective beginning January 1, 2009. We are currently evaluating the impact of adopting this pronouncement on our consolidated financial statements and related disclosures.

In June 2007, EITF Issue No. 07-3, “Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities” (“EITF 07-3”) was issued. EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research

and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 will be effective beginning on January 1, 2008. We are currently evaluating the effect of EITF 07-3 on our consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 will be effective beginning on January 1, 2008. We are currently evaluating the impact of adopting this pronouncement on our consolidated financial statements and related disclosures.

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

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

Our 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 our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with the licensing agreement entered into in January 2003 with Ferring, which established pricing in Euros for products sold under the supply agreement and for all royalties. In March 2007 we amended the 2003 agreement with Ferring, establishing prices in U.S. dollars rather than Euros for certain products, reducing the exchange rate risk. Most of our sales and licensing fees are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. We do not currently use derivative financial instruments to hedge against exchange rate risk. Because exposure increases as intercompany balances grow, we will continue to evaluate the need to initiate hedging programs to mitigate the impact of foreign exchange rate fluctuations on intercompany balances. The effect of foreign exchange rate fluctuations on our financial results for the years ended December 31, 2007, 2006 and 2005 was not material.

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

47

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

ANTARES PHARMA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Index

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Antares Pharma, Inc. (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States and include those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States;
- Provide reasonable assurance that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Company management assessed the effectiveness of its internal control over financial reporting as of December 31, 2007. In making this assessment, management used the criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2007.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

/s/ Jack E. Stover
Jack E. Stover
President and Chief Executive Officer
(Principal Executive Officer)

March 25, 2008

/s/ Robert F. Apple
Robert F. Apple
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

March 25, 2008

Index

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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Antares Pharma, Inc. and subsidiaries as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

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

/s/ KPMG LLP

Minneapolis, Minnesota

March 25, 2008

Index

ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2007	December 31, 2006
Assets		
Current Assets:		
Cash and cash equivalents	$ 9,758,924	$ 2,706,047
Short-term investments	16,300,844	4,953,421
Accounts receivable, less allowance for doubtful accounts of $10,000	486,887	855,866
Other receivables	20,181	55,794
Inventories	125,409	84,779
Prepaid expenses and other current assets	620,933	221,669
Total current assets	27,313,178	8,877,576
Equipment, furniture and fixtures, net	467,676	382,096
Patent rights, net	572,174	813,592
Goodwill	1,095,355	1,095,355
Other assets	768,333	365,864
Total Assets	$ 30,216,716	$ 11,534,483
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 804,848	$ 813,014
Accrued expenses and other liabilities	1,543,401	1,071,086
Notes payable and capital lease – current, net of discount of $199,060	2,109,385	-
Deferred revenue	964,673	1,014,337
Total current liabilities	5,422,307	2,898,437
Notes payable and capital lease – long term, net of discount of $154,189	4,665,467	-
Deferred revenue – long term	2,629,651	3,555,601
Total liabilities	12,717,425	6,454,038
Stockholders' Equity:		
Common Stock: $0.01 par; authorized 100,000,000 shares;		
65,529,666 and 53,319,622 issued and outstanding at		
December 31, 2007 and 2006, respectively	655,296	533,196
Additional paid-in capital	125,430,653	106,792,974

Prepaid license discount	-	(2,305,929)
Accumulated deficit	(107,901,392)	(99,322,453)
Accumulated other comprehensive loss	(685,266)	(617,343)
	17,499,291	5,080,445
Total Liabilities and Stockholders' Equity	$ 30,216,716	$ 11,534,483

See accompanying notes to consolidated financial statements.

Index

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2007	**2006**	**2005**
Revenue:			
Product sales	$ 3,211,397	$ 2,195,218	$ 1,511,929
Development revenue	955,402	593,797	183,760
Licensing revenue	3,231,305	1,254,250	374,021
Royalties	458,892	225,134	155,036
Total revenue	7,856,996		