ANTARES PHARMA, INC.
Form 10-K
March 25, 2009

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, 2008

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 –accelerated filer o (do not check if a smaller reporting company) Smaller reporting company x

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, 2008, was approximately $40,000,000 (based upon the last reported sale price of $0.72 per share on June 30, 2008, on The American Stock Exchange).

There were 68,049,666 shares of common stock outstanding as of March 20, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2009 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*

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 (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. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "project," "intend," "should," "plan," "believe," "hope," and other words and terms of similar meaning in connection with any discus among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and product development. In particular, these forward-looking statements include, among others, statements about:

- our expectations regarding trends in pharmaceutical drug delivery characteristics;
- our anticipated penetration into the market for traditional drug injection devices (such as needles and syringes) with our technology;
- our expectations regarding product developments with Teva Pharmaceutical Industries, Ltd.;
- our anticipated continued reliance on contract manufacturers to manufacture our products;
- our marketing and product development plans;
- our future cash flow and our ability to service or repay our existing debt;
- our projected net loss for the year ending December 31, 2009;
- the risks that our recurring losses, negative cash flows and inability to raise additional capital could threaten our ability to continue as a going concern;
- our ability to raise additional funds in light of our current and projected level of operations and general economic conditions; and
- other statements regarding matters that are not historical facts or statements of current condition.

These forward-looking statements are based on assumptions that we have made in light of our industry experience as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this annual 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 annual report speak only as of the date of this annual 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 annual report after the date of this annual report. In light of these risks and uncertainties, you should keep in mind that any forward-looking statement in this annual report or elsewhere might not occur.

Overview

Antares Pharma, Inc. (“Antares,” “we,” “our,” “us” or the “Company”) is a product development and pipeline company with patented drug delivery platforms including Advanced Transdermal Delivery (ATD™) gels, disposable pressure assisted auto injection systems (Vibex™), reusable needle-free injection systems (VISION®), disposable pen injection systems and oral disintegrating (Easy Tec™) tablets. 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
Parenteral Medicines	Needle-Free Reusable Injectors (MJ Platform) Medi-Jector VISION®	
	Pressure Assisted Auto Injectors (AJ Platform) Vibex™	
	Disposable Pen Injectors	
Oral Disintegrating Tablets	Easy Tec™	

<u>Products</u>

Transdermal Delivery Gels

Injection Devices

Oral Disintegrating Tablets (EasyTec™)

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Transdermal Systems

Our transdermal systems consist of a unique formulation in semisolid dosage forms (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, which is 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.

Pressure Assisted Injection Devices

Our injection device platform features three main products: reusable needle-free injectors, disposable pressure assisted auto injectors and disposable pen 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®, our current reusable needle-free injector product, 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 for insulin and available through our partners in Europe, Japan and Asia for hGH.

- *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 Medi-Jector 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.

Oral Disintegrating Tablets

Our Easy Tec™ oral disintegrating tablets ("ODT") 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.

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 Medi-Ject. 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 patients 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 hGH 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 Medi-Jector Vision® system for use with injectable drugs in unit dose containers and is suitable for branded and branded generic injectables. 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 Pharmaceutical Industries Ltd. (“Teva”).

Our Pharma division is located in Basel, Switzerland, where we develop pharmaceutical products utilizing our transdermal systems. Several licensing agreements with pharmaceutical companies of various sizes have led to successful clinical evaluation of our formulations. In 2006, the United States Food and Drug Administration (“FDA”) approved our first transdermal gel with a partner’s drug 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 Phase III 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 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 a non-exclusive license for our technology in the diabetes and obesity fields.

We are a Delaware corporation with principal executive offices located at Princeton Crossroads Corporate Center, 250 Phillips Boulevard, Suite 290, Ewing, New Jersey 08618. Our telephone number is (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 our experience in the healthcare 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

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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 also 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.

Additionally, 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. Dosing issues, specifically the minimum effective dose for drugs, 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. Follow-on biologic drug legislation continues to gather momentum in the United States Congress. In order to differentiate follow-on biologics, novel patented delivery systems are becoming more important to extend product proprietary position as well as secure patient preference.

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 with 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. Data from recently filed corporate annual and quarterly reports indicates the worldwide market for brand name urinary incontinence products was at least $2.3 billion in 2008. Patient acceptance of older incontinence drugs, such as oral oxybutynin, is

hindered by anticholinergic side-effects including moderate to severe dry mouth, constipation and somnolence. It is estimated that half of the U.S. adults suffering from overactive bladder either are too embarrassed to discuss the symptoms or are not aware that pharmacological treatment is available.

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. According to industry estimates, approximately six million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone therapy. According to IMS Health, the current market in the U.S. for single-entity estrogen products was approximately $1.4 billion in 2007, of which the transdermal segment, mostly patches, is reported at about

$260 million. Further growth in this sector may be achieved by the use of testosterone products in both male and female applications. According to IMS Health, the U.S. market for transdermal testosterone therapies grew approximately 22 percent in 2007 to $624 million from $510 million in 2006. We believe that a new market opportunity also exists with the use of low dose testosterone for treatment of female sexual disfunction (“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 global patient demand for transdermal hormone therapy products will continue to increase. Evidence of this belief is the 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 billion 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 in 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, comprised mainly of biological products. According to a September 2008 Deutsche Bank Global Market Research Report, U.S. sales of biological drugs in 2007 were approximately $42 billion. The same report states that $25 billion worth of these drugs are losing patent exclusivity between now and 2016, making them prime targets for follow-on biologics. Self-administered injectable biologics account for the main portion—over $22 billion—of those facing future competition from follow-on biologics. Since, by design, follow-on biologic molecules will be nearly identical to the innovator biologic, both the innovator and follow-on manufacturers will seek other ways to differentiate their products in the market. We believe that manufacturers will look to proprietary advantages in the designs of the self-administration devices, such as those offered by our injection device platforms, as a key way to compete in the market.

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

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hepatitis. We also believe that many injectable drugs currently under development will be administered by self-injection once they reach the market. Our belief 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 (and their manufacturer) introduced in recent years that 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 ATD™ gels; disposable pressure assisted auto injection systems (Vibex™); disposable pen injection systems; reusable needle-free injection systems (Medi-Jector VISION®) and oral disintegrating tablets (Easy Tec™).

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 popular as alternative drug delivery systems. Among transdermal products currently marketed are nitroglycerin for angina, diclofenac gel for pain, 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 method 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 another 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, which is 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 based ropinirole in our ATD™ system that is being developed to treat a 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, nesterone and a topically applied dermatology product. 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.

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 offer benefits in the speed and quality of injections as well as lacking the need 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 without commercial success. 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 combines proven delivery technology for molecules that require parenteral administration with a device that eliminates the part of the injection that patients dislike – the needle. 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 hGH. 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 hGH, 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 and in 2008 our partner, Teva, has supported the filing of a supplemental new drug application ("sNDA") to provide the Medi-Jector VISION® for such partners' hGH patients in the U.S.

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. We have signed two license agreements with Teva for our Vibex™ system for two undisclosed products.

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 early stage of development where devices are being used in clinical evaluations. 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.

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 to achieve product approvals 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 signed a global license agreement with an unnamed partner in the area of opioid analgesia for use with our Easy Tec™ technology.

Research and Development

We currently perform pharmaceutical product development work primarily in our Basel, Switzerland location for both our own portfolio of products and our partners. 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 three applications (i.e., three 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 toevaluate 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) versus 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 over fifty centers throughout the United States.

Device Development Projects. We are engaged in research and development activities related to our Vibex™ disposable pressure assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva Pharmaceuticals for our Vibex™ system for two undisclosed products and for our pen injector device for two undisclosed products. Our pressure assisted auto injectors are designed to deliver drugs by injection from single dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the early stage of development where devices are being evaluated in clinical studies. The development programs consist of determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly. The development timelines of the auto and pen injectors related to the Teva products are controlled by Teva. We expect development related to the Teva products to continue in 2009, but the timing and extent of near-term future development will be dependent on decisions made by Teva.

See Research and Development Programs on page 46 in Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – for amounts spent on Company sponsored research and development activities.

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 numerous patents and numerous additional patent 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 drug master file ("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 completed limited 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 Good Manufacturing Practice ("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 FDA 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 Medi-Jector 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 established pharmaceutical and medical device companies while continuing marketing of our insulin injection devices and related disposable components in the U.S. In the future and as we develop more products in niche therapeutic areas, we plan to develop commercial capabilities.

During 2008, 2007 and 2006, international revenue accounted for approximately 74%, 55% and 63% of total revenue. Europe accounted for 93%, 91% and 83% of international revenue in 2008, 2007 and 2006, with the remainder coming primarily from Asia. Ferring accounted for 60%, 39% and 39% of our worldwide revenues in 2008, 2007 and 2006. BioSante Pharmaceuticals, Inc. ("BioSante") accounted for 12%, 36% and 24% and JCR Pharmaceuticals, Co., Ltd. ("JCR") accounted for 5%, 4% and 4% of our worldwide revenues in 2008, 2007 and 2006. Revenue from Ferring and JCR resulted from sales of injection devices and related disposable components for their hGH formulations. In 2008 and 2007, 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.

See Note 12 to the Consolidated Financial Statements for revenues by geographic area.

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	Ropinirole	Central Nervous System (Worldwide)	ATD™ Gel
Population Council	Nestorone®/Estradiol	Contraception (Worldwide)	ATD™ Gel
Ferring	hGH	Growth Retardation (U.S., Europe, Asia & Pacific)	Needle Free Device
Teva Pharmaceutical Industries, Ltd.	hGH	Growth Retardation (United States)	Needle Free Device
JCR Pharmaceuticals Co., Ltd.	hGH	Growth Retardation (Japan)	Needle Free Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed Product #1	Undisclosed (U.S. and Canada)	Auto Injector Disposable Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed Product #2	Undisclosed (United States)	Auto Injector Disposable Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed Product #3	Undisclosed (North America, Europe & others)	Disposable Pen Injector Device
Teva Pharmaceutical Industries, Ltd.	Undisclosed Product #4	Undisclosed (North America, Europe & others)	Disposable Pen Injector Device
Undisclosed	Undisclosed	Opioid dependence (Worldwide)	ODT

The table above 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. (“Bradley”) 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. We also received royalties on sales of Elestrin®. Bradley was acquired by Nycomed Inc. in February 2008 and returned Elestrin to BioSante. In December 2008, Elestrin was sublicensed to Azur Pharmaceuticals (“Azur”) and subsequently relaunched in 2009. As a result of the sublicense agreement with Azur, we received payments from BioSante of $462,500 in December 2008. In addition, we will receive royalties on sales of Elestrin® as well as potential sales-based milestone payments.

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 hGH 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 “Lilly License Agreement”) with Eli Lilly and Company (“Lilly”). Under the Lilly 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 Lilly 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 November 2005, we signed an agreement with Sicor Pharmaceuticals Inc., an affiliate of Teva, 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. 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 December 2008, this agreement was amended to include development work that was outside the scope of the original agreement, resulting in additional payments to us.

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 Population 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. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from us for hGH 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 of hGH, 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 ("Jazz") for ropinirole which is 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 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, Acrux, NexMed, Inc., Auxillium, 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 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 Federal Food, Drug and Cosmetic Act (“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.

Drug Approval Process

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) of the FD&C Act 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 requirements 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 a new drug application ("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.

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

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complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. “Bioavailability” indicates the extent of absorption of a drug product in the blood stream. “Bioequivalence” compares the bioavailability, the peak absorption, and typically the rate of absorption of one drug product with another, and when established, indicates that the active drug substance that is the subject of the ANDA submission is equivalent to 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.

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.

Before approving a product, either through the NDA or ANDA route, 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.

Device Approval Process

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

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products. The OCP assists in determining strategies for the approval of drug/delivery combinations and assuring 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. 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. A pharmaceutical partner of ours filed an SNDA with the FDA for hGH for use with our Medi-Jector Vision in July 2008. We are currently awaiting approval of the SNDA.

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 QSR. The FDA’s interpretation and enforcement of these requirements have been increasingly strict in recent years and seem likely to be even more stringent in the future. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA and by conducting periodic FDA inspections of manufacturing facilities. If the inspector observes conditions that might violate the QSR, the manufacturer must correct those conditions or explain them satisfactorily. Failure to adhere to QSR requirements would cause the devices produced to be considered in violation of the FDA Act and subject to FDA enforcement action that might include physical removal of the devices from the marketplace.

The FDA's Medical Device Reporting Regulation requires companies to provide information to the FDA on the occurrence of any death or serious injuries alleged to have been associated with the use of their products, as well as

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

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

Foreign Approval Process

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 section 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 16, 2009, we had 24 full-time employees worldwide, of whom 15 are in the United States. Of the 24 employees, 15 are primarily involved in research, development and manufacturing activities, one is 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.

Available Information

We file with the United States Securities and Exchange Commission ("SEC") annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other documents as required by applicable law and regulations. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N. E., Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330 (1-800-732-0330). The SEC maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. We maintain an Internet site (http://www.antarespharma.com). We make available free of charge on or through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after electronically filing those documents with or furnishing them to the SEC. The information on our website is not incorporated into and is not a part of this annual report.

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 $12,690,453 and $8,578,939 in the fiscal years ended 2008 and 2007, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2008 of $120,591,845. In addition, we expect to report a net loss for the year ending December 31, 2009. 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. In addition, we received proceeds from warrant and stock option exercises of $1,319,950 and $2,292,692 in 2008 and 2007, respectively. If additional capital is needed in the near term to support operations, the current economic and market conditions will likely make it difficult to raise additional funds through debt or equity financings. Furthermore, given that our stock price is currently below the exercise prices of outstanding warrants and options, it is unlikely we will receive proceeds in the near future from warrant or option exercises.

At December 31, 2008 we had cash and cash equivalents of $13,096,298 and scheduled debt payments of $3,244,735 in 2009 and $2,324,147 beyond 2009. Although the combination of our current cash and cash equivalents balance and projected product sales, product development, license revenues, milestone payments and royalties may provide us with sufficient funds to support operations for the next 12 months, we may need to pursue alternative financing or reduce expenditures as necessary to meet our cash requirements over the next 12 months. If we do obtain such financing, we cannot assure that the amount or the terms of such financing will be as attractive as we may desire. If we are unable to obtain such financing when needed, or if the amount of such financing is not sufficient, it may be necessary for us to take significant cost saving measures or generate funding in ways that may negatively affect our business in the future. To reduce expenses, we may be forced to make further personnel reductions, eliminate departments, curtail or discontinue development programs or close certain locations and certain operations. To generate funds, it may be necessary to monetize future royalty streams, sell intellectual property, divest of technology platforms or liquidate assets. However, there is no assurance that, if required, we will be able to generate sufficient funds or reduce spending to provide the required liquidity. As such, our independent registered public accounting firm has concluded that additional revenue arrangements or financing may be needed to enable us to fund our future operations, which raises substantial doubt about our ability to continue as a going concern, and accordingly, has included this uncertainty in their report on our December 31, 2008 consolidated financial statements.

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;
- timing of our partners' development, regulatory and commercialization plans;
- 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, and 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, disposable pen 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, 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.

For the year ended December 31, 2008, we derived approximately 60% of our revenue from Ferring and 12% from BioSante. For the year ended December 31, 2007 we derived approximately 39% and 36% of our revenue from Ferring and BioSante, respectively. The revenue from Ferring was primarily product sales and royalties. The revenue from BioSante was primarily 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 operations. 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 or an affiliate of Teva. Although certain upfront and milestone payments have been received, there have been no commercial sales, timelines have been extended 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. Under the agreement an upfront payment, development milestones, and royalties on product sales are to be paid to 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 and ongoing full time equivalent (“FTE”) based revenue.

In September 2007, we entered into a worldwide product development and license agreement with an undisclosed company using our oral disintegrating tablets to develop an unnamed opioid analgesic. Under the agreement an upfront payment, development milestones, and royalties on product sales are to be paid to 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 and ongoing FTE based revenue.

If we or our third-party manufacturer are unable to supply Ferring with our devices pursuant to our current license agreement with Ferring, Ferring could 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 hGH 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 an 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 be unable to 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 be unable to 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 operate under a manufacturing agreement with Minnesota Rubber and Plastics (“MRP”), a contract manufacturing company, who manufactures and assembles our MJ7 devices and certain related disposable component parts. There can be no assurance that MRP 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. Our pharmaceutical partners retain the right to audit the quality systems of our manufacturing partner, and there can be no assurance that MRP will be successful in these audits. Any of these failures 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, an international manufacturing development company to commercialize 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, be in compliance with regulatory regulations, or pass the audits by our pharmaceutical partner 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 of our products.

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 drug delivery 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.

Various independent clinical studies have questioned the safety of hormone replacement therapy for menopausal women, and our female hormone replacement therapy business may suffer as a result.

In 2002, a long-term study being conducted on oral female hormone replacement therapy (“HRT”) using a combination of estradiol and progestin was halted because the study showed an increased risk of breast cancer, heart disease and blood clots in women taking the combination therapy. In 2003, the FDA required 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. 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. 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 product. Additionally, in 2008 BioSante reached agreement under a Special Protocol Assessment (“SPA”) for the Phase III program for LibiGel® (male testosterone) 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 not a widely understood method of drug delivery, our potential partners and consumers may 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 in June 2007. Bradley was acquired by Nycomed in February 2008. BioSante reacquired Elestrin® from Nycomed and in December 2008 relicensed all manufacturing, distribution and marketing responsibilities of Elestrin® to Azur. The multiple licenses of Elestrin has had a negative impact on the marketing efforts of Elestrin and to date, the market penetration of Elestrin® has been low.

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 and a sNDA has been filed seeking approval with human growth hormone.

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®.

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 Ferring, 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 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.

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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., Auxillium, BioChemics, Inc., Aradigm, Zogenix, Inc., Noven Pharmaceuticals, Inc., NovaDel Pharma Inc., Columbia Laboratories, Inc., Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc. and The Medical House, 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 (Gelnique®) for OAB in January 2008 and in January 2009 Gelnique was approved by the FDA. Watson's anticipated launch of their oxybutynin gel is well ahead of Anturol's potential launch 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 numerous patents and numerous patent 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.

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 (Gelnique®). We believe that we do not infringe these patents and that they should not have been granted. 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 of Anturol™ or incur significant expenses defending our patent position which may adversely affect the potential market value of Anturol™.

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 General Economic Conditions

Uncertainty in the global credit markets could adversely affect our ability to obtain financing, and we cannot assure that financing will be available to us on favorable terms or at all.

The global credit markets have recently experienced significant dislocations and liquidity disruptions, which, among other things, have caused the spreads on prospective debt financings to widen considerably. These circumstances have materially impacted liquidity in the debt markets, making financing terms for borrowers less attractive, and in certain cases resulted in the unavailability of certain types of debt financing. Continued uncertainty in the credit markets may negatively impact our ability to access additional debt financing or to refinance existing debt maturities on favorable terms or at all, which could negatively affect our ability to fund our current operations as well as our future development and our business could be adversely affected. A prolonged downturn in the credit markets may cause us to seek alternative sources of potentially less attractive financing, and may require us to adjust our business plan accordingly. The uncertainty in the credit markets could also make it more challenging for us to carry out our financing objectives, and federal legislation enacted to alleviate the current disruptions in the financial markets could have an adverse affect on our ability to raise other types of financing.

In addition, if we raise additional financing via issuance of securities, such future issuance of our securities may result in substantial dilution to existing stockholders.

We are susceptible to the current conditions of the global economy. If the conditions do not improve, our business could be adversely affected.

The current financial crisis and uncertainty in global economic conditions have resulted in a substantial slowdown in the global economy that could affect our business and financial performance by reducing the prices that our customers and third party payors may be willing or able to pay for our products. These conditions may also reduce demand for our products, which could in turn negatively impact our sales and revenue generation and result in a material adverse effect on our business, cash flow, results of operations, financial position and prospects. In addition, we may experience difficulties in scaling our operations to react to various economic pressures.

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 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 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, and Anturol™ may prove to not be efficacious and 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 our 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. Human clinical testing may be required by the FDA in order to commercialize these devices and there can be no assurance that such trials will be successful. 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 July 2008, we announced that one of our device partners filed a Prior Approval sNDA for their product human growth hormone to add needle free injection to the product label. The sNDA submission included clinical and drug-device interaction studies performed over an extended period of time. The sNDA also references a 510(k) device filing previously submitted by us in 2006. The FDA required the supplemental filing since needle-free injection is a new route of administration for this product. The submission of the sNDA does not ensure that the FDA will accept or approve the filing and without FDA approval we cannot market or sell our needle free injector for the use with hGH in the U.S. Changes to the labeling will require review by a division of the FDA concerned with medical errors, and there is no guarantee that such a review will be successfully completed.

As part of its device regulatory strategy, we have filed two device master files ("MAF") with the FDA. These master files are reviewed as part of a product application review. Amendments are made to the master files as appropriate either because of design changes, additional test data or in response to questions from the FDA. The submission of a MAF does not guarantee that the MAF contains all the information required for product approval.

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) and 505(j) (ANDA) regulatory pathway for many of our potential 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.

Drug delivery systems such as injectors are reviewed by the FDA and may be legally marketed as a medical device or may be evaluated as part of the drug approval process. 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 agreement within the FDA on review responsibilities. We may seek approval for a product including an injector and a generic pharmaceutical by filing an ANDA claiming bioequivalence and the same labeling as a comparable referenced product or as a filing under Section 505(b)(2) if there is an acceptable reference product. In reviewing the ANDA filing, the agency may decide that the unique nature of combination products allows them to dispute the claims of bioequivalence and/or same labeling resulting in our re-filing the application under Section 505(b)(2). If such combination products require filing under Section 505(b)(2) we may incur delays in product approval and may incur additional costs associated with testing including clinical trials. The result of an approval for a combination product under Section 505(b)(2) may result in additional selling expenses and a decrease in market acceptance due to the lack of substitutability by pharmacies or formularies.

If the use of our injection devices require additions to or modifications of the drug labeling regulated by the FDA, the review of this labeling may be undertaken by the FDA's Office of Surveillance and Epidemiology (OSE). With the heightened concern surrounding medical errors, the Division of Medication Errors and Technical Support (DMETS) has the responsibility of reviewing all pre-marketing labeling. Since such labeling can include device instructions for use, DMETS may be involved in evaluating device usage parameters. These reviews could increase the time needed for review completion of a successful application and may require additional studies, such as usage studies, to establish the validity of the instructions. Such reviews and requirement may extend the time necessary for the approval of drug-device combinations.

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

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

As of March 16, 2009, we have warrants outstanding that are exercisable, at prices ranging from $1.00 per share to $5.00 per share, for an aggregate of approximately 13,100,000 shares of our common stock. We also have options outstanding that are exercisable, at exercise prices ranging from $0.37 to $4.56 per share, for an aggregate of approximately 7,900,000 shares of our common stock. Purchasers of our common stock could therefore experience substantial dilution of their investment upon exercise of the above warrants or options. The majority of the shares of our 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 16, 2009, our officers and directors beneficially owned an aggregate of approximately 14,700,000 shares (or approximately 21%) 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 certificate 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. PROPERTIES.

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.

Market Information

Our Common Stock trades on the NYSE Amex, formerly known as 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 NYSE Amex, for each quarterly period during the two most recent fiscal years.

	High	Low
2008:		
First Quarter	$ 1.08	$ 0.88
Second Quarter	$ 1.02	$ 0.50
Third Quarter	$ 0.88	$ 0.65
Fourth Quarter	$ 0.69	$ 0.32
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

Common Shareholders

As of March 16, 2009, we had 118 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 our 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.

Performance Graph

The graph below provides an indication of cumulative total stockholder returns ("Total Return") for the Company as compared with the Amex Composite Index and the Amex Biotechnology Stock Index weighted by market value at each measurement point. The graph covers the period beginning December 31, 2003, through December 31, 2008. The graph assumes $100 was invested in each of our Common Stock, the Amex Composite Index and the Amex Biotechnology Stock Index on December 31, 2003 (based upon the closing price of each). Total Return assumes reinvestment of dividends.

	December 31, 2003	**December 31, 2004**	**December 31, 2005**	**December 31, 2006**	**December 31, 2007**	**December 31, 2008**
Antares Pharma, Inc.	$ 100.00	$ 131.07	$ 150.49	$ 116.50	$ 95.15	$ 35.92
Amex Composite Index	100.00	122.22	149.89	175.23	205.33	119.09
Amex Biotechnology Stock Index	100.00	111.05	138.93	153.90	160.48	132.05

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 consolidated financial statements accompanying this annual report (amounts expressed in thousands, except per share amounts).

	At December 31,				
	2008	2007	2006	2005	2004
Balance Sheet Data:					
Cash and cash equivalents	$ 13,096	$ 9,759	$ 2,706	$ 2,718	$ 1,652
Short-term investments	-	16,301	4,953	-	7,972
Working capital	7,537	21,891	5,979	965	8,489
Total assets	19,911	30,217	11,534	6,166	13,178
Long-term liabilities, less current maturities	5,297	7,295	3,556	3,062	3,339
Accumulated deficit	(120,592)	(107,901)	(99,322)	(91,123)	(82,575)
Total stockholders' equity	7,243	17,499	5,080	757	8,189

	Year Ended December 31,				
	2008	2007	2006	2005	2004
Statement of Operations Data:					
Product sales	$ 3,350	$ 3,211	$ 2,195	$ 1,512	$ 1,834
Development revenue	541	956	594	184	197
Licensing fees	1,238	3,231	1,254	374	635
Royalties	532	459	225	155	80
Revenues	5,661	7,857	4,268	2,225	2,746
Cost of revenues (1)	2,020	3,442	1,556	1,137	1,372
Research and development	7,866	5,362	3,778	3,677	2,870
Sales, marketing and business development	1,625	1,641	1,350	1,161	676
General and administrative (2)	6,348	6,058	5,861	4,839	6,203
Operating expenses	15,839	13,061	10,989	9,677	9,749
Operating loss	(12,198)	(8,646)	(8,277)	(8,589)	(8,375)
Net other income (expense)	(492)	67	177	91	26
Net loss	(12,690)	(8,579)	(8,100)	(8,498)	(8,349)
Deemed dividend to warrant holder	-	-	(99)	-	-
Preferred stock dividends	-	-	-	(50)	(100)
Net loss applicable to common shares	$ (12,690)	$ (8,579)	$ (8,199)	$ (8,548)	$ (8,449)
Net loss per common share (3) (4)	$ (0.19)	$ (0.14)	$ (0.16)	$ (0.21)	$ (0.23)
Weighted average number of common shares	67,233	59,605	51,582	41,460	36,348

(1) In 2007 we recorded non-cash impairment of prepaid license discount and related charges of $1,439.
(2) In 2007, 2006, and 2004 we recorded non-cash patent impairment charges of $296, $139, and $233, 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 consolidated financial statements included elsewhere in this annual 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 product development/drug delivery 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 the U.S., 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 support our customers of our 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 auto and pen injection devices to Teva for use in undisclosed fields and territories.

We have reported net losses of $12,690,453, $8,578,939 and $8,099,846 in the fiscal years ended 2008, 2007 and 2006. We have accumulated aggregate net losses from the inception of business through December 31, 2008 of $120,591,845. In addition, we expect to report a net loss for the year ending December 31, 2009. We have not historically generated sufficient revenue to provide the cash needed to support our operations, and have continued to operate primarily by raising capital and incurring debt. Given the current economic and market conditions, it will likely be difficult to raise additional funds through debt or equity financings. If our operations do not provide sufficient cash in 2009, we intend to pursue alternative financing arrangements or reduce expenditures as necessary to meet our cash requirements over the next 12 months. To reduce expenses, we may be forced to make further personnel reductions, eliminate departments, curtail or discontinue development programs or close certain locations and certain operations. To generate funds, it may be necessary to monetize future royalty streams, sell intellectual property, divest of technology platforms or liquidate assets. However, there is no assurance that, if required, we will be able to obtain alternative financing or reduce spending to provide the required liquidity.

Critical Accounting Policies and Use of Estimates

In preparing the consolidated 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 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. Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"), 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 ($4,237,721 at December 31, 2008) 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.

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.

	2008	**2007**	**2006**
Product sales	$ 3,349,532	$ 3,211,397	$ 2,195,218
Development fees	1,481,254	912,172	785,720
Licensing fees and milestone payments	762,500	3,478,642	2,082,742
Royalties	314,189	218,042	140,110
Billings received and/or accrued per contract terms	5,907,475	7,820,253	5,203,790

Deferred billings received and/or accrued	(1,387,380)	(1,068,804)	(1,409,268)
Deferred revenue recognized	1,140,616	1,195,880	670,126
Amortization of prepaid license discount	-	(90,333)	(196,249)
Total revenue as reported	$ 5,660,711	$ 7,856,996	$ 4,268,399

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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 or asset group 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 2008. The 2007 impairment charge relates to the Eli Lilly amendment discussed further in Note 11 to the consolidated financial statements. The gross carrying amount and accumulated amortization of patents, which are our only intangible assets subject to amortization, were $1,471,536 and $826,680 at December 31, 2008 and were $1,308,327 and $736,153 at December 31, 2007. The estimated aggregate patent amortization expense for the next five years is $82,000, $96,000, $48,000, $45,000 and $45,000 in 2009, 2010, 2011, 2012 and 2013.

We have $1,095,355 of goodwill recorded as of December 31, 2008 that relates to our Minnesota operations. We evaluate the carrying amount 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 2008, 2007 and 2006 resulted in no impairment losses.

Results of Operations

Years Ended December 31, 2008, 2007 and 2006

Revenues

Total revenue was $5,660,711, $7,856,996 and $4,268,399 for the years ended December 31, 2008, 2007 and 2006. The decrease in 2008 compared to 2007 and the increase in 2007 compared to 2006 was primarily due to $2,625,000 received in 2007 under a sublicense arrangement related to an existing license agreement with BioSante.

Product sales were $3,349,532, $3,211,397 and $2,195,218 for the years ended December 31, 2008, 2007 and 2006. Product sales include sales of reusable needle-free injector devices, related parts, disposable components, and repairs. In 2008, 2007 and 2006, revenue from sales of

needle-free injector devices totaled $1,045,296, $1,027,986 and $804,481. Sales of disposable components in 2008, 2007 and 2006 totaled $2,201,076, $2,100,253 and $1,326,758. The increases in device and disposable revenue in 2008 and 2007 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

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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 $540,557, $955,402 and $593,797 for the years ended December 31, 2008, 2007 and 2006. The revenue in 2008 was attributable primarily to projects related to our proprietary ATD™ gel technology. 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.

Licensing revenue was $1,238,211, $3,231,305 and $1,254,250 for the years ended December 31, 2008, 2007 and 2006. The licensing revenue in 2008, 2007 and 2006 included $462,500, $2,625,000 and $875,000 received under sublicense arrangements related to an existing license agreement with BioSante. In November 2006, BioSante entered into a marketing agreement with Bradley for Elestrin® (formerly Bio-E-Gel) and 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 of $2,625,000 which we received in 2007. In 2008, BioSante reacquired the rights to Elestrin® and entered into new marketing agreements in December, triggering payments to us of $462,500. The remaining licensing revenue in each year is primarily due to recognizing portions of previously deferred amounts related to upfront license fees or milestone payments received under various agreements.

Royalty revenue was $532,411, $458,892 and $225,134 for the years ended December 31, 2008, 2007 and 2006. Nearly all royalty revenue has been related to the Medi-Jector 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 11 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 increases in 2008 and 2007 were primarily related to the increase in the number of injector devices sold to Ferring, as well as a renegotiated increased royalty rate with Ferring.

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 56%, 55% and 59% for the years ended December 31, 2008, 2007 and 2006. The decrease in 2007 compared to 2006 was mainly the result of an increase in selling prices to Ferring.

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 was 24%, 25% and 44% for the years ended December 31, 2008, 2007 and 2006. The higher percentage in 2006 was primarily due to a lower average hourly billing rate in 2006 compared to 2007 and 2008, along with a higher percentage of total costs that were attributable to direct external costs passed through to the customer at 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 11 to the consolidated financial statements, we determined it was unlikely that future cash flows from the Lilly License 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 amount of related capitalized patent

costs of $296,338 was impaired, and was recorded in general and administrative expenses in the 2007 consolidated 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 $7,866,499, $5,362,291 and $3,778,469 for the years ended December 31, 2008, 2007 and 2006. The increase in 2008 compared to 2007 was mainly due to an increase of approximately $1,900,000 in expenses related to a Phase III study of Anturol™ and an increase of approximately $450,000 in connection with establishing an internal clinical and regulatory department in early 2008. The increase in 2007 compared to 2006 was primarily due to an increase of approximately $1,200,000 related to the Phase III study of Anturol™ and to a lesser extent was due to an increase in expenses related to device development projects.

Sales, Marketing and Business Development

Sales, marketing and business development expenses were $1,624,599, $1,640,875 and $1,349,678 for the years ended December 31, 2008, 2007 and 2006. In 2008, increases in expenses related to marketing research were offset by decreases in legal expenses. 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.

General and Administrative

General and administrative expenses were $6,347,997, $6,057,396 and $5,861,111 for the years ended December 31, 2008, 2007 and 2006. The increase in 2008 compared to 2007 was mainly due to the expense associated with a separation agreement with our former Chief Executive Officer and the hiring of a Chief Operating Officer in July of 2008. 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. In 2006, patent impairment charges totaled $138,632. The patent impairment charges were recognized after we determined it was unlikely that future cash flows would exceed the net carrying amount 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 ($492,484), $66,647 and $176,983 for the years ended December 31, 2008, 2007 and 2006. The change to expense in 2008 from income in 2007 was due to a decrease in interest income and an increase in interest expense. In 2008, interest income decreased to $553,061 from $872,095 in 2007 due primarily to a reduction in market interest rates received on invested funds. Interest expense increased in 2008 to $1,021,675 from $772,417 in 2007 in connection with notes payable that originated in the first and fourth quarters of 2007 that were outstanding for the full year of 2008. 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 in 2007 compared to 2006, which offset the increase in interest income and resulted in an overall decrease in other income.

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 2008 and 2007, we also received proceeds of $1,319,950 and $2,292,692, respectively, in connection with warrant and stock option exercises which resulted in the issuance of 2,400,000 and 2,187,317 shares of common stock, respectively.

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 have reported net losses of $12,690,453, $8,578,939 and $8,099,846 in the fiscal years ended 2008, 2007 and 2006. We have accumulated aggregate net losses from the inception of business through December 31, 2008 of $120,591,845. In addition, we expect to report a net loss for the year ending December 31, 2009. We have not historically generated sufficient revenue to provide the cash needed to support our operations, and have continued to operate primarily by raising capital and incurring debt. Given the current economic and market conditions, it will likely be difficult to raise additional funds through debt or equity financings.

At December 31, 2008, we had cash and cash equivalents of $13,096,298 and scheduled debt payments of $3,244,735 in 2009 and $2,324,147 beyond 2009. Although the combination of our current cash and cash equivalents balance and projected product sales, product development, license revenues, milestone payments and royalties may provide us with sufficient funds to support operations for the next 12 months, we may need to pursue alternative financing or reduce expenditures as necessary to meet our cash requirements over the next 12 months. If we do obtain such financing, we cannot assure that the amount or the terms of such financing will be as attractive as we may desire. If we are unable to obtain such financing when needed, or if the amount of such financing is not sufficient, it may be necessary for us to take significant cost saving measures or generate funding in ways that may negatively affect our business in the future. To reduce expenses, we may be forced to make further personnel reductions, eliminate departments, curtail or discontinue development programs or close certain locations and certain operations. To generate funds, it may be necessary to monetize future royalty streams, sell intellectual property, divest of technology platforms or liquidate assets. However, there is no assurance that, if required, we will be able to generate sufficient funds or reduce spending to provide the required liquidity. The consolidated financial statements accompanying this annual report have been prepared assuming that we will continue as a going concern.

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 $10,324,412, $5,394,276 and $6,118,050 for the years ended December 31, 2008, 2007 and 2006. Net operating cash outflows were primarily the result of net losses of $12,690,453, $8,578,939 and $8,099,846 in 2008, 2007 and 2006, adjusted by noncash expenses and changes in operating assets and liabilities.

In 2008, the net loss increased by $4,111,514 to $12,690,453 from $8,578,939 in 2007. This increase was due to a number of factors which consisted primarily of the following:

- an increase in research and development expenses of approximately $2,500,000 related mainly to the Anturol™ Phase III trial;
- a decrease in gross profit of approximately $800,000 due mainly to a reduction in licensing revenue from BioSante of approximately $2,200,000 which was partially offset by a reduction in cost of revenue of approximately $1,400,000 related to impairment charges recognized in 2007 in connection with the Eli Lilly agreement;
- an increase in general and administrative expenses of approximately $300,000;
- a decrease in interest income of approximately $300,000; and
- an increase in interest expense of approximately $250,000.

Noncash expenses totaled $1,713,321, $4,276,731 and $1,798,524 in 2008, 2007 and 2006. The decrease in 2008 compared to 2007 and the increase in 2007 compared to 2006 was mainly due to the impairment charges in 2007 related to the Lilly License Agreement, including the prepaid license discount impairment and amortization charge of $2,305,929 and the patent rights impairment charge of $296,338. The increase in 2007 compared to 2006 was also 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.

In 2008, the change in operating assets and liabilities generated cash of $652,720. Changes resulting in the generation of cash included increases in accounts payable and deferred revenue and a decrease in prepaid expenses and other current assets. Accounts payable increased by $1,195,006 primarily due to costs incurred in connection with the Phase III study of Anturol™. Deferred revenue increased by $554,717 due primarily to payments received and deferred in connection with injector device development projects. The decrease in prepaid expenses and other current assets was due to a reduction in prepaid expenses related to the Phase III study of Anturol™. Changes resulting in the use of cash included increases in accounts receivable and other assets. Accounts receivable increased by $853,964 primarily due to invoices generated in December related to injector device projects. Deferred costs increased by $740,276 due to costs incurred and deferred related to injector device projects.

In 2007, the change in operating assets and liabilities resulted in a use of cash of $1,092,068. This was primarily due 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 deferred costs of $340,004, 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 deferred costs 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.

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 2008, as short term investments matured, the proceeds of $16,015,057 were either used to fund operations or were invested in a money market account with an interest rate that equaled or exceeded interest rates available on most short-term investments as market interest rates were decreasing during the year. In 2007 and 2006 the use of cash to purchase securities exceeded cash generated from maturities by $11,163,507 and $4,851,551, 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. Investing activities in 2008, 2007 and 2006 also included additions to patent rights of $177,425, $145,590 and $142,751 and purchases of equipment, molds, furniture and fixtures of $1,379,344, $96,575, and $35,703. The 2008 purchases of equipment, molds, furniture and fixtures were primarily for tooling and production equipment related to commercial injector device deals with Teva. As of December 31, 2008, approximately $1,200,000 of molds and tooling related to production of commercial devices for Teva has been capitalized. In the event Teva does not continue to develop these products or purchase the molds and tooling from us, and we have no alternative uses for the molds and tooling, the assets may be considered impaired and we would be required to write off all or a part of the capitalized amount.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by (used in) financing activities totaled $(808,641), $23,851,897 and $11,117,141 for the years ended December 31, 2008, 2007 and 2006. In 2008, principal payments on long term debt totaled $2,128,591 and proceeds received from the exercise of warrants totaled $1,319,950. 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.

Our contractual cash obligations at December 31, 2008 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	$5,568,882	$3,244,735	$2,324,147	$-	$ -
Capital leases, including interest	147,734	73,854	73,880	-	-
Operating leases	1,674,858	416,369	1,069,922	188,567	-
Total contractual cash obligations	$7,391,474	$3,734,958	$3,467,949	$188,567	$ -

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.

Research and Development Programs

During 2008, our research and development activities were primarily related to Anturol™ and device development projects.

Anturol™. We are currently evaluating Anturol™ for the treatment of overactive bladder (OAB). In the fourth quarter of 2007 we initiated a Phase III pivotal trial designed to evaluate the 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. Enrollment expanded to approximately sixty centers throughout the United States in 2009. In addition to the Phase III trial, we have incurred significant costs related to Anturol™ manufacturing development. We have contracted with Patheon, Inc. (Patheon), a manufacturing development company, to supply clinical quantities of Anturol™ and to develop a commercial manufacturing process for Anturol™. With Patheon, we have completed limited commercial scale up activities associated with Anturol™ manufacturing. As of December 31, 2008, we have incurred total external costs of approximately $7,700,000 in connection with our Anturol™ research and development, of which $3,750,000 was incurred in 2008. We intend to seek a marketing partner to further the development of Anturol™ and to complete the Phase III trial. If we cannot find a marketing partner, we may not have the resources to complete the trial and may have to delay or stop the trial. Our 2009 operating plan encompasses two scenarios for development of Anturol™ under which expenses could range from $3,500,000 without a marketing partner to $8,500,000 with a marketing partner. The level of expenditures will determine the progress of the Phase III program for Anturol™.

Device Development Projects. We are engaged in research and development activities related to our Vibex™ disposable pressure assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva Pharmaceuticals for our Vibex™ system for two undisclosed products and for our pen injector device for two undisclosed products. Our pressure assisted auto injectors are designed to deliver drugs by injection from single dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the early stage of development where devices are being evaluated in clinical studies. The development programs consist of determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly. As of December 31, 2008, we have incurred total external costs of approximately $2,300,000 in connection with research and development activities associated with the auto and pen injectors, of which approximately $838,000 was incurred in 2008. As of December 31, 2008, $1,292,000 of the total costs have been deferred and will be recognized as expense over the same period as the related deferred revenue will be recognized. The development timelines of the auto and pen injectors related to the Teva products are controlled by Teva. We expect development related to the Teva products to continue in 2009, but the timing and extent of near-term future development will be dependent on decisions made by Teva. Although certain upfront and milestone payments have been received from Teva, there have been no commercial sales, timelines have been extended and there can be no assurance that there ever will be commercial sales or future milestone payments under these agreements.

Other research and development costs. In addition to the Anturol™ project and Teva related device development projects, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include salaries, administrative and other overhead costs of managing our research and development projects. Total other research and development costs were approximately $4,020,000 for the year ended December 31, 2008.

New Accounting Pronouncements

Effective January 1, 2008, we adopted Emerging Issues Task Force ("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"). 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. Adoption of EITF 07-3 had no impact on our consolidated financial statements.

Effective January 1, 2008, we adopted FASB 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"), which permits an entity to measure certain financial assets and financial liabilities at fair value. The objective of SFAS 159 is to improve financial reporting by allowing entities to mitigate volatility in reported earnings caused by the measurement of related assets and liabilities using different attributes, without having to apply complex hedge accounting provisions. Under SFAS 159, entities that elect the fair value option (by instrument) will report unrealized gains and losses in earnings at each subsequent reporting date. The fair value

option election is irrevocable, unless a new election date occurs. SFAS 159 establishes presentation and disclosure requirements to help financial statement users understand the effect of the entity's election on its earnings, but does not eliminate disclosure requirements of other accounting standards. Assets and liabilities that are measured at fair value must be displayed on the face of the balance sheet. We chose not to elect the fair value option for financial assets and liabilities existing at January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the year ended December 31, 2008. Therefore, the adoption of SFAS 159 had no impact on our consolidated financial statements.

Effective January 1, 2008, we adopted FASB Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157") for financial assets and liabilities and any other assets and liabilities carried at fair value. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. On February 12, 2008, the FASB delayed the effective date for non-financial assets and liabilities to fiscal years beginning after November 15, 2008; however, the effective date for financial assets and liabilities remained applicable to fiscal years beginning after November 15, 2007. Adoption of SFAS 157 had no impact on our consolidated financial statements, other than the disclosures related to short-term investments, and we do not expect it to have a material impact on our consolidated financial statements in the future.

In October 2008, the FASB issued FSP No. FAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active," or FSP FAS 157-3. The FSP clarifies the application of FASB Statement No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The FSP was effective upon issuance, including prior periods for which financial statements have not been issued and did not have an impact on our consolidated financial statements.

In November 2008, the FASB ratified EITF Issue No. 08-7, "Accounting for Defensive Intangible Assets," or EITF 08-7, which clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over the period the asset diminishes in value. EITF 08-7 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. It is effective prospectively for intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. EITF 08-7 is not expected to have a material impact on our consolidated financial statements.

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. Adoption of SFAS 141R will apply prospectively to business combinations completed on or after January 1, 2009.

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, 2008, 2007

and 2006 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.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

ANTARES PHARMA, INC.

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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, 2008. 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, 2008.

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/ Paul K. Wotton
Dr. Paul K. Wotton
President and Chief Executive Officer
(Principal Executive Officer)

March 24, 2009

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

March 24, 2009

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Antares Pharma, Inc.:

We have audited the accompanying consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the "Company") as of December 31, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations since inception. Additional revenue arrangements or financing may be needed to enable the Company to fund the Company's future operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Minneapolis, Minnesota

March 24, 2009

ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,096,298	$ 9,758,924
Short-term investments	-	16,300,844
Accounts receivable, less allowance for doubtful accounts of $10,000	1,334,648	486,887
Inventories	182,038	125,409
Prepaid expenses and other current assets	294,818	641,114
Total current assets	14,907,802	27,313,178
Equipment, molds, furniture and fixtures, net	1,788,163	467,676
Patent rights, net	644,856	572,174
Goodwill	1,095,355	1,095,355
Deferred costs	1,292,090	551,814
Other assets	183,139	216,519
Total Assets	$ 19,911,405	$ 30,216,716
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,103,493	$ 804,848
Accrued expenses and other liabilities	1,382,306	1,543,401
Notes payable and capital lease – current, net of discount of $121,762 and $199,060, respectively	2,705,070	2,109,385
Deferred revenue	1,179,820	964 ,673
Total current liabilities	7,370,689	5,422,307
Notes payable and capital lease – long term, net of discount of $32,427 and $154,189, respectively	2,239,550	4,665,467
Deferred revenue – long term	3,057,901	2,629,651
Total liabilities	12,668,140	12,717,425
Stockholders' Equity:		
Preferred Stock: $0.01 par; authorized 3,000,000 shares, none outstanding	-	-
Common Stock: $0.01 par; authorized 150,000,000 shares;		
68,049,666 and 65,529,666 issued and outstanding at		
December 31, 2008 and 2007, respectively	680,496	655,296
Additional paid-in capital	127,926,205	125,430,653
Accumulated deficit	(120,591,845)	(107,901,392)
Accumulated other comprehensive loss	(771,591)	(685,266)
	7,243,265	17,499,291
Total Liabilities and Stockholders' Equity	$ 19,911,405	$ 30,216,716

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2008	**2007**	**2006**
Revenue:			
Product sales	$ 3,349,532	$ 3,211,397	$ 2,195,218
Development revenue	540,557	955,402	593,797
Licensing revenue	1,238,211	3,231,305	1,254,250
Royalties	532,411	458,892	225,134
Total revenue	5,660,711	7,856,996	4,268,399
Cost of revenue:			
Cost of product sales	1,889,317	1,768,799	1,293,192
Cost of development revenue	130,268	234,583	262,778
Impairment of prepaid license discount and related charges	-	1,438,638	-
Total cost of revenue	2,019,585	3,442,020	1,555,970
Gross profit	3,641,126	4,414,976	2,712,429
Operating expenses:			
Research and development	7,866,499	5,362,291	3,778,469
Sales, marketing and business development	1,624,599	1,640,875	1,349,678
General and administrative	6,347,997	6,057,396	5,861,111
	15,839,095	13,060,562	10,989,258
Operating loss	(12,197,969)	(8,645,586)	(8,276,829)
Other income (expense):			
Interest income	553,061	872,095	353,236
Interest expense	(1,021,675)	(772,417)	(3,132)
Foreign exchange gains (losses)	17,001	(46,268)	(128,268)
Other, net	(40,871)	13,237	(44,853)
	(492,484)	66,647	176,983
Net loss	(12,690,453)	(8,578,939)	(8,099,846)
Deemed dividend to warrant holders	-	-	(99,500)
Net loss applicable to common shares	$ (12,690,453)	$ (8,578,939)	$ (8,199,346)
Basic and diluted net loss per common share	$ (0.19)	$ (0.14)	$ (0.16)
Basic and diluted weighted average common shares outstanding	67,232,889	59,604,646	51,582,111

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS
Years Ended December 31, 2006, 2007 and 2008

	Common Stock					Accumulated	
	Number of Shares	Amount	Additional Paid-In Capital	Prepaid License Discount	Accumulated Deficit	Other Comprehensive Loss	Total Stockholders' Equity
December 31, 2005	**43,019,486**	**$430,195**	**$94,547,105**	**$(2,502,178)**	**$ (91,123,107)**	**$(595,366)**	**$756,649**
Issuance of common stock in private placement	8,770,000	87,700	9,694,355	-	-	-	9,782,055
Exercise of warrants and options	1,443,470	14,435	1,320,651	-	-	-	1,335,086
Stock-based compensation	86,666	866	1,131,363	-	-	-	1,132,229
Amortization of prepaid license discount	-	-	-	196,249	-	-	196,249
Deemed dividend to warrant holder	-	-	99,500	-	(99,500)	-	-
Net loss	-	-	-	-	(8,099,846)	-	(8,099,846)
Translation adjustments	-	-	-	-	-	(21,977)	(21,977)
Comprehensive loss	-	-	-	-	-	-	(8,121,823)
December 31, 2006	**53,319,622**	**533,196**	**106,792,974**	**(2,305,929)**	**(99,322,453)**	**(617,343)**	**5,080,445**
Issuance of common stock in private placement	10,000,000	100,000	14,642,671	-	-	-	14,742,671
Issuance of warrants in debt financing	-	-	505,379	-	-	-	505,379
Exercise of warrants and options	2,187,317	21,873	2,270,819	-	-	-	2,292,692
Stock-based compensation	22,727	227	1,218,810	-	-	-	1,219,037
Impairment and amortization of prepaid license discount	-	-	-	2,305,929	-	-	2,305,929
Net loss	-	-	-	-	(8,578,939)	-	(8,578,939)
Translation adjustments	-	-	-	-	-	(67,923)	(67,923)
Comprehensive loss	-	-	-	-	-	-	(8,646,862)
December 31, 2007	**65,529,666**	**655,296**	**125,430,653**	**-**	**(107,901,392)**	**(685,266)**	**17,499,291**
Exercise of warrants	2,400,000	24,000	1,295,950	-	-	-	1,319,950
Stock-based compensation	120,000	1,200	1,199,602	-	-	-	1,200,802
Net loss	-	-	-	-	(12,690,453)	-	(12,690,453)
Translation adjustments	-	-	-	-	-	(86,325)	(86,325)
Comprehensive loss	-	-	-	-	-	-	(12,776,778)
December 31, 2008	**68,049,666**	**$680,496**	**$127,926,205**	**$-**	**$ (120,591,845)**	**$(771,591)**	**$7,243,265**

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2008	**2007**	**2006**
Cash flows from operating activities:			
Net loss	$ (12,690,453)	$ (8,578,939)	$ (8,099,846)
Adjustments to reconcile net loss to net cash used in operating activities:			
Patent rights impairment charge	-	296,338	138,632
Depreciation and amortization	283,320	251,827	297,375
Stock-based compensation expense	1,160,454	1,202,603	1,166,268
Amortization of debt discount and issuance costs	269,547	220,034	-
Impairment and amortization of prepaid license discount	-	2,305,929	196,249
Changes in operating assets and liabilities:			
Accounts receivable	(853,964)	379,129	(616,327)
Inventories	(56,629)	(40,630)	(48,757)
Prepaid expenses and other current assets	659,726	(452,224)	12,762
Deferred costs	(740,276)	(340,004)	(97)
Other assets	(562)	(435)	(12,941)
Accounts payable	1,195,006	(17,686)	(155,391)
Accrued expenses and other current liabilities	(105,298)	441,698	185,789
Deferred revenue	554,717	(1,061,916)	818,234
Net cash used in operating activities	(10,324,412)	(5,394,276)	(6,118,050)
Cash flows from investing activities:			
Purchase of short-term investments	-	(24,326,544)	(10,694,799)
Proceeds from maturity of short-term investments	16,015,057	13,163,037	5,843,248
Additions to patent rights	(177,425)	(145,590)	(142,751)
Purchases of equipment, molds, furniture and fixtures	(1,379,344)	(96,575)	(35,703)
Net cash provided by (used in) investing activities	14,458,288	(11,405,672)	(5,030,005)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	-	14,742,671	9,782,055
Proceeds from exercise of warrants and stock options	1,319,950	2,292,692	1,335,086
Proceeds from notes payable, net of debt issuance costs	-	7,309,279	-
Principal payments on long term debt	(2,128,591)	(492,745)	-
Net cash provided by (used in) financing activities	(808,641)	23,851,897	11,117,141
Effect of exchange rate changes on cash and cash equivalents	12,139	928	18,489
Net increase (decrease) in cash and cash equivalents	3,337,374	7,052,877	(12,425)
Cash and cash equivalents:			
Beginning of year	9,758,924	2,706,047	2,718,472
End of year	$ 13,096,298	$ 9,758,924	$ 2,706,047

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

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

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Foreign Currency Translation

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

Cash Equivalents

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

Short-Term Investments

All short-term investments are commercial paper or U.S. government agency discount notes that mature within one year of purchase and are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. The Company held no short-term investments at December 31, 2008. At December 31, 2007, the securities had a fair value of $16,332,927 and a carrying amount of $16,300,844. Securities with fair values totaling $8,902,400 and $7,430,527 were determined using Level 1 and Level 2 inputs, respectively, at December 31, 2007. As defined in Statement of Financial Accounting Standards No. 157, "Fair Value Measurements," Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities and Level 2 inputs include (i) quoted prices for similar assets or liabilities in active markets, (ii) quoted prices for identical or similar assets or liabilities in markets that are not active, (iii) inputs other than quoted prices that are observable for the asset or liability such as interest rates and yield curves observable at commonly quoted intervals, volatilities, prepayment speeds, loss severities, credit risks, and default rates, and (iv) inputs that are derived principally from or corroborated by observable market data by correlation or other means (market-corroborated inputs).

Allowance for Doubtful Accounts

Trade accounts receivable are stated at the amount the Company expects to collect. The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. The Company considers the following factors when determining the collectibility of specific customer accounts: customer credit-worthiness, past transaction history with the customer, current economic industry trends, and changes in customer payment terms. If the financial condition of the Company's customers were to deteriorate, adversely affecting their ability to make payments, additional allowances would be required. The Company provides for estimated uncollectible amounts through a charge to earnings and a credit to a valuation allowance. Balances that remain outstanding after the Company has used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. The Company recorded no bad debt expense in each of the last three years, and had deductions in the allowance for doubtful accounts of $10,800 in 2006. The allowance for doubtful accounts balance was $10,000 at December 31, 2008, 2007 and 2006.

Inventories

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

Equipment, Molds, Furniture, and Fixtures

Equipment, molds, furniture, and fixtures are stated at cost and are depreciated using the straight-line method over their estimated useful lives ranging from three to ten years. Certain equipment and furniture held under capital leases is classified in equipment, molds, furniture and fixtures and is amortized using the straight-line method over the lease term or estimated useful life, and the related obligations are recorded as liabilities. Lease amortization is included in depreciation expense. Depreciation expense was $158,864, $137,085 and $144,225 for the years ended December 31, 2008, 2007 and 2006, respectively.

Goodwill

The Company has $1,095,355 of goodwill recorded as of December 31, 2008 that relates to the Minnesota operations. The Company evaluates the carrying amount of goodwill during the fourth quarter of each year and between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the Minnesota reporting unit below its carrying amount. Such circumstances could include, but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, (3) an adverse action or assessment by a regulator, or (4) a sustained significant drop in the Company's stock price. When evaluating whether goodwill is impaired, the Company compares the fair value of the Minnesota operations to the carrying amount, including goodwill. If the carrying amount of the Minnesota operations exceeds its fair value, then the amount of the impairment loss must be measured. The impairment loss would be calculated by comparing the implied fair value of goodwill to its carrying amount. In calculating the implied fair value of goodwill, the fair value of the Minnesota operations would be allocated to all of its other assets and liabilities based on their fair values. The excess of the fair value of the Minnesota operations over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. An impairment loss would be recognized when the carrying amount of goodwill exceeds its implied fair value. The Company's evaluation of goodwill completed during 2008, 2007 and 2006 resulted in no impairment losses.

Patent Rights

The Company capitalizes the cost of obtaining patent rights. These capitalized costs are being amortized on a straight-line basis over periods ranging from six to fifteen years beginning on the earlier of the date the patent is issued or the first commercial sale of product utilizing such patent rights. Amortization expense for the years ended December 31, 2008, 2007 and 2006 was $124,455, $112,383 and $153,150, respectively.

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

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

In the fourth quarter of each year the Company updates its long-range business plan. The Company then reviews patent costs for impairment and identifies patents related to products for which there are no signed distribution or license agreements or for which no revenues or cash flows are included in the business plan. In 2007 and 2006 the Company 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 2008. The 2007 impairment charge relates to the Eli Lilly amendment discussed further in Note 11. The gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, were $1,471,536 and $826,680, respectively, at December 31, 2008 and were $1,308,327 and $736,153, respectively, at December 31, 2007. The Company’s estimated aggregate patent amortization expense for the next five years is $82,000, $96,000, $48,000, $45,000 and $45,000 in 2009, 2010, 2011, 2012 and 2013, respectively.

Fair Value of Financial Instruments

Cash and cash equivalents are stated at cost, which approximates fair value. The fair value of notes payable was approximately $4,923,000 at December 31, 2008, estimated using rates that may be available to the Company for debt with similar remaining maturities.

Revenue Recognition

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

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

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

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

accounting. If it does not meet the separation criteria, then an up-front payment is deferred and would be recognized consistent with the remaining deliverables.

If the Company earns development fees for time and material costs incurred in connection with a development agreement, the development fees will be recognized as revenue when earned if that portion of the agreement meets the separation criteria of EITF 00-21. If the separation criteria are not met, the development fees received would be recognized consistent with the remaining deliverables. Likewise, costs directly related to the development fees are recognized as a cost of sales when incurred if the separation criteria are met, and are capitalized as deferred costs and are amortized on a straight-line basis over the same period as the development fees if the criteria are not met. Costs capitalized and deferred are reviewed for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Deferred costs are limited to the amount of directly related deferred revenue.

Stock-Based Compensation

The Company records compensation expense associated with share based awards granted to employees in accordance with SFAS No. 123R, which requires the Company to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award.

Under SFAS No. 123R, the Company uses the Black-Scholes option valuation model to determine the fair value of stock options. The fair value model includes various assumptions, including the expected volatility and expected life of the awards. These assumptions reflect the Company’s best estimates, but they involve inherent uncertainties based on market conditions generally outside of the Company’s control. As a result, if other assumptions had been used, stock-based compensation expense, as calculated and recorded under SFAS No. 123R, could have been materially impacted. Furthermore, if the Company uses different assumptions in future periods, stock-based compensation expense could be materially impacted in future periods.

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

Product Warranty

The Company provides a warranty on its reusable needle-free injector devices. Warranty terms for devices sold to end-users by dealers and distributors are included in the device instruction manual included with each device sold. Warranty terms for devices sold to corporate customers who provide their own warranty terms to end-users are included in the contracts with the corporate customers. The Company is obligated to repair or replace, at the Company’s option, a device found to be defective due to use of defective materials or faulty workmanship. The warranty does not apply to any product that has been used in violation of instructions as to the use of the product or to any product that has been neglected, altered, abused or used for a purpose other than the one for which it was manufactured. The warranty also does not apply to any

damage or defect caused by unauthorized repair or the use of unauthorized parts. The warranty period on a device is typically 24 months from either the date of retail sale of the device by a dealer or distributor or the date of shipment to a customer if specified by contract. The Company recognizes the estimated cost of warranty obligations at the time the products are shipped based on historical claims incurred by the Company. Actual warranty claim costs could differ from these estimates. Warranty liability activity is as follows:

	Balance at Beginning of Year	**Provisions**	**Claims**	**Balance at End of Year**
2008	$ 20,000	$ 8,496	$ (8,496)	$ 20,000
2007	$ 20,000	$ 6,075	$ (6,075)	$ 20,000

Research and Development

Research and development costs are expensed as incurred.

Use of Estimates

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

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the

years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to historical net losses of the Company, a valuation allowance is established to offset the deferred tax asset.

Net Loss Per Share

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

Potentially dilutive securities at December 31, 2008, 2007 and 2006, excluded from dilutive loss per share as their effect is anti-dilutive, are as follows:

	2008	**2007**	**2006**
Stock options and warrants	26,268,701	28,723,412	25,699,542

New Accounting Pronouncements

Effective January 1, 2008, the Company adopted Emerging Issues Task Force ("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"). 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. The Company's adoption of EITF 07-3 had no impact on the Company's consolidated financial statements.

Effective January 1, 2008, the Company adopted FASB 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"), which permits an entity to measure certain financial assets and financial liabilities at fair value. The objective of SFAS 159 is to improve financial reporting by allowing entities to mitigate volatility in reported earnings caused by the measurement of related assets and liabilities using different attributes, without

having to apply complex hedge accounting provisions. Under SFAS 159, entities that elect the fair value option (by instrument) will report unrealized gains and losses in earnings at each subsequent reporting date. The fair value option election is irrevocable, unless a new election date occurs. SFAS 159 establishes presentation and disclosure requirements to help financial statement users understand the effect of the entity's election on its earnings, but does not eliminate disclosure requirements of other accounting standards. Assets and liabilities that are measured at fair value must be displayed on the face of the balance sheet. The Company chose not to elect the fair value option for its financial assets and liabilities existing at January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the year ended December 31, 2008. Therefore, the adoption of SFAS 159 had no impact on the Company's consolidated financial statements.

Effective January 1, 2008, the Company adopted FASB Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157") for financial assets and liabilities and any other assets and liabilities carried at fair value. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. On February 12, 2008, the FASB delayed the effective date for non-financial assets and liabilities to fiscal years beginning after November 15, 2008; however, the effective date for financial assets and liabilities remained applicable to fiscal years beginning after November 15, 2007. The Company's adoption of SFAS 157 had no impact on the Company's consolidated financial statements, other than the disclosures related to short-term investments, and in the future is not expected to have a material impact on the Company's consolidated financial statements.

In October 2008, the FASB issued FSP No. FAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active," or FSP FAS 157-3. The FSP clarifies the application of FASB Statement No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The FSP was effective upon issuance, including prior periods for which financial statements have not been issued and did not have an impact on the Company's consolidated financial statements.

In November 2008, the FASB ratified EITF Issue No. 08-7, "Accounting for Defensive Intangible Assets," or EITF 08-7, which clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over the period the asset diminishes in value. EITF 08-7 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. It is effective prospectively for intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. EITF 08-7 is effective for the Company beginning January 1, 2009 and is not expected to have a material impact on the Company's consolidated financial statements.

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. The Company's adoption of SFAS 141R will apply prospectively to business combinations completed on or after January 1, 2009.

3. Liquidity

The Company incurred net losses of $12,690,453, $8,578,939 and $8,099,846 in the fiscal years ended 2008, 2007 and 2006, respectively, and the Company has accumulated aggregate net losses from the inception of business through December 31, 2008 of $120,591,845. In addition, the Company expects to report a net loss for the year ending December 31, 2009. The Company has not historically generated sufficient revenue to provide the cash needed to support operations, and has continued to operate primarily by raising capital and incurring debt. Given the current

economic and market conditions, it will likely be difficult to raise additional funds through debt or equity financings.

At December 31, 2008 the Company had cash and cash equivalents of $13,096,298 and scheduled debt payments of $3,244,735 in 2009 and $2,324,147 beyond 2009. Although the combination of the current cash and cash equivalents balance and projected product sales, product development, license revenues, milestone payments and royalties may provide the Company with sufficient funds to support operations for the next 12 months, the Company may need to pursue alternative financing or reduce expenditures as necessary to meet its cash requirements over the next 12 months. If the Company does obtain such financing, there can be no assurance that the amount or the terms of such financing will be as attractive as desired. If the Company is unable to obtain such financing when needed, or if the amount of such financing is not sufficient, it may be necessary to take significant cost saving measures or generate funding in ways that may negatively affect the business in the future. To reduce expenses, the Company may be forced to make further personnel reductions, eliminate departments, curtail or discontinue development programs or close certain locations and certain operations. To generate funds, it may be necessary to monetize future royalty streams, sell intellectual property, divest of technology platforms or liquidate assets. However, there is no assurance that, if required, the Company will be able to obtain alternative financing or reduce spending to provide the required liquidity.

The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

4. Composition of Certain Financial Statement Captions

	December 31, 2008	**December 31, 2007**
Inventories:		
Raw material	$ 103,456	$ 65,985
Finished goods	78,582	59,424
	$ 182,038	$ 125,409
Equipment, molds, furniture and fixtures:		
Furniture, fixtures and office equipment	$ 1,395,209	$ 1,297,635
Production molds and equipment	2,458,692	2,210,369
Molds and tooling in process	1,395,325	168,820
Less accumulated depreciation	(3,461,063)	(3,209,148)
	$ 1,788,163	$ 467,676
Patent rights:		
Patent rights	$ 1,471,536	$ 1,308,327
Less accumulated amortization	(826,680)	(736,153)
	$ 644,856	$ 572,174
Accrued expenses and other liabilities:		
Accrued employee compensation and benefits	$ 994,810	$ 877,844
Other liabilities	387,496	665,557
	$ 1,382,306	$ 1,543,401

In connection with certain Teva agreements, the Company has capitalized production molds and tooling in process of approximately $1,200,000 as of December 31, 2008. In the event Teva does not continue to develop these products or purchase the molds and tooling from the Company, and the Company has no alternative uses for the molds and tooling, the assets may be considered impaired and the Company would be required to write off all or a part of the capitalized amount.

5. Notes Payable

In February of 2007, the Company received gross proceeds of $5,000,000 upon closing of the first tranche of a $10,000,000 credit facility. In December of 2007 the Company 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. 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 the Company's ability to create or incur indebtedness (subject to enumerated exceptions);
- restrict the Company's ability to create or incur certain liens on its property (subject to enumerated exceptions);
- in certain circumstances, require the Company to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least $2,500,000;
- in certain circumstances, restrict the Company's ability to declare or pay any dividends on any shares of its capital stock, purchase or redeem any shares of its capital stock, return any capital to any holder of its equity securities or payment of certain bonuses; and
- restrict the Company's ability to make certain investments.

Total interest expense related to the credit facility was $996,832 and $756,262 in 2008 and 2007, respectively, of which $269,546 and $221,775 in 2008 and 2007, respectively, was noncash interest consisting of amortization of debt discount and debt issuance costs. In connection with the credit facility, the Company issued warrants to purchase a total of 640,000 shares of common stock at an exercise price of $1.25. The fair value of the warrants was approximately $505,000, calculated using the Black-Scholes valuation model, and was recorded as debt discount and is being amortized and recorded as interest expense using the interest method over the term of the credit agreement. The Company capitalized debt issuance costs totaling $190,721, which are being amortized and recorded as interest expense using the interest method over the term of the agreement.

Principal payments of $2,758,779 and $2,206,325 are due in each of the twelve month periods ended December 31, 2009 and 2010, respectively.

6. Leases

The Company has non-cancelable operating leases for its corporate headquarters facility in Ewing, New Jersey, its office, research and development facility in Minneapolis, MN and for its office and research facility in Basel, Switzerland. The leases require payment of all executory costs such as maintenance and property taxes. The Company also leases certain equipment and furniture under various operating and capital leases. The cost of equipment and furniture under capital leases was $213,386 and $116,923 and accumulated amortization was $54,673 and $15,507 at December 31, 2008 and 2007, respectively.

Rent expense, net, incurred for the years ended December 31, 2008, 2007 and 2006 was $395,031, $353,966 and $352,473, respectively.

Future minimum lease payments are as follows as of December 31, 2008:

	Capital Leases	Operating Leases
2009	$ 73,854	$ 401,505
2010	40,570	426,619
2011	27,711	384,193
2012	5,599	259,109
2013	-	188,568
Thereafter	-	-
Total future minimum lease payments	147,734	$ 1,659,994
Amount representing interest	(14,029)	
Obligations under capital leases	133,705	
Obligations due within one year	(68,053)	
Long-term obligations under capital leases	$ 65,652	

7. Income Taxes

The Company incurred losses for both book and tax purposes in each of the years in the three-year period ended December 31, 2008, and, accordingly, no income taxes were provided. The Company was subject to taxes in both the U.S. and Switzerland in each of the years in the three-year period ended December 31, 2008. Effective tax rates differ from statutory income tax rates in the years ended December 31, 2008, 2007 and 2006 as follows:

	2008	2007	2006
Statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(0.4)	(0.6)	(0.7)
Valuation allowance increase	17.2	11.5	21.9
Effect of foreign operations	16.4	11.9	13.1
Expiration of unused NOL and credit carryforwards	1.7	2.8	0.5
Nondeductible items	1.7	5.6	0.1
Other	(2.6)	2.8	(0.9)
	0.0 %	0.0 %	0.0 %

Deferred tax assets as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Net operating loss carryforward – U.S.	$ 16,415,000	$ 15,326,000
Net operating loss carryforward – Switzerland	6,547,000	4,701,000
Research and development tax credit carryforward	919,000	973,000
Deferred revenue	636,000	687,000
Depreciation and amortization	208,000	325,000
Stock-based compensation	1,114,000	975,000

Other	641,000	971,000
	26,480,000	23,958,000
Less valuation allowance	(26,480,000)	(23,958,000)
	$—	$—

The valuation allowance for deferred tax assets as of December 31, 2008 and 2007 was $26,480,000 and $23,958,000, respectively. The net change in the total valuation allowance for the years ended December 31, 2008 and 2007 was an increase of $2,522,000 and $1,370,000, respectively. In assessing the realizability of deferred tax

assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Due to the uncertainty of realizing the deferred tax asset, management has recorded a valuation allowance against the entire deferred tax asset.

The Company has a U.S. federal net operating loss carryforward at December 31, 2008, of approximately $44,600,000, which, subject to limitations of Internal Revenue Code Section 382, is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2009 through 2028, with approximately $5,061,000 expiring over the next three years. Additionally, the Company has a research credit carryforward of approximately $919,000. These credits expire in years 2009 through 2028.

The Company also has a Swiss net operating loss carryforward at December 31, 2008, of approximately $48,493,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2009 through 2015, with approximately $17,074,000 expiring over the next three years.

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

The Company adopted the provisions of FASB Interpretation No. 48 (FIN 48),*Accounting for Uncertainty in Income Taxes*, on January 1, 2007. Implementation of FIN 48 had no impact on the consolidated financial statements. As of both the date of adoption, and as of December 31, 2008, the unrecognized tax benefit accrual was zero. Accordingly, a tabular reconciliation from beginning to ending periods is not provided. In accordance with FIN 48, paragraph 19, the Company has decided to classify any future interest and penalties as a component of income tax expense if incurred. To date, there have been no interest or penalties charged or accrued in relation to unrecognized tax benefits.

8. Stockholders' Equity

Common Stock

In July of 2007, the Company received proceeds of $14,742,671, net of offering costs of $1,257,329, in a private placement of its 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, the Company 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 March of 2006, the Company received proceeds of $9,782,055, which was net of offering costs of $1,180,445, in a private placement of its common stock in which a total of 8,770,000 shares of common stock were sold at a price of $1.25 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 7,454,500 shares of common stock with an exercise price of $1.50 per share.

Warrant and stock option exercises during 2008, 2007 and 2006 resulted in proceeds of $1,319,950, $2,292,692 and $1,335,086, respectively, and in the issuance of 2,400,000, 2,187,317 and 1,443,470 shares of common stock, respectively.

Stock Options and Warrants

The Company's 2008 Equity Compensation Plan (the "Plan"), which became effective on May 14, 2008, merged all active prior stock option and equity incentive plans and this new plan into one plan. The Plan allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock

appreciation rights, dividend equivalents and other stock-based awards. All of the Company's officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. Under the Plan, the maximum number of shares of stock that may be granted to any one participant during a calendar year is 1,000,000 shares. Options to purchase shares of Common Stock are granted at exercise prices not less than 100% of fair market value on the dates of grant. The term of the options range from three to eleven years and they vest in varying periods. As of December 31, 2008, the Plan had 1,608,050 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the Plan as of December 31, 2008 and the changes during the year then ended is as follows:

	Number of Shares	**Weighted Average Exercise Price ($)**	**Weighted Average Remaining Contractual Term (Years)**	**Aggregate Intrinsic Value ($)**
Outstanding at December 31, 2007	5,582,391	1.58		
Granted/Issued	3,477,023	0.66		
Exercised	-	-		
Cancelled	(1,002,758)	1.55		
Outstanding at December 31, 2008	8,056,656	1.19	6.7	-
Exercisable at December 31, 2008	4,897,977	1.49	4.8	-

As of December 31, 2008, there was approximately $1,300,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.0 years.

Stock option expense recognized in 2008, 2007 and 2006 was approximately $1,076,000, $1,146,000 and $997,000, respectively. In 2008, expense included approximately $65,000 recognized due to modifications of option terms in connection with separation agreements for two employees whose employment with the Company ended in 2008. The per share weighted average fair value of options granted during 2008, 2007 and 2006 was estimated as $0.40, $1.14 and $1.35, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock. The weighted average expected life is based on both historical and anticipated employee behavior.

	December 31,		
	2008	**2007**	**2006**
Risk-free interest rate	2.9 %	4.7 %	4.5 %
Annualized volatility	70.0 %	109.0 %	126.0 %
Weighted average expected life, in years	5.0	5.0	7.0
Expected dividend yield	0.0 %	0.0 %	0.0 %

As compensation to non-employees for professional services, in 2006 the Company issued options and warrants to purchase a total of 277,500 shares of the Company's common stock. The Company recorded these options and warrants at their fair values of $116,909, using the Black-Scholes option pricing model. The options and warrants have exercise prices ranging from $1.25 to $1.55 per share and expire three years after issuance.

Certain warrants to acquire 5,167,545 shares of common stock at exercise prices ranging from $1.00 to $1.25 have full antidilution protection which reduces the exercise price of the warrants to the effective price paid or payable under new stock or stock equivalent issuances. These warrants expire by March of 2009.

Stock option and warrant activity is summarized as follows:

	Options		Warrants	
	Number of Shares	Weighted Average Price	Number of Shares	Weighted Average Price
Outstanding at December 31, 2005	3,255,901	1.76	16,584,397	1.44
Granted/Issued	1,535,000	1.48	7,659,500	1.49
Exercised	(3,333)	1.32	(1,513,687)	0.97
Cancelled	(360,809)	2.00	(1,457,427)	3.48
Outstanding at December 31, 2006	4,426,759	1.65	21,272,783	1.35
Granted/Issued	1,307,632	1.42	4,440,000	1.89
Exercised	(35,000)	1.54	(2,430,095)	1.09
Cancelled	(117,000)	2.31	(141,667)	1.10
Outstanding at December 31, 2007	5,582,391	1.58	23,141,021	1.49
Granted/Issued	3,477,023	0.66	-	-
Exercised	-	-	(2,400,000)	0.55
Cancelled	(1,002,758)	1.55	(2,528,976)	1.19
Outstanding at December 31, 2008	8,056,656	1.19	18,212,045	1.65

The following table summarizes information concerning currently outstanding and exercisable options and warrants by price range at December 31, 2008:

	Outstanding			Exercisable	
	Number of Shares Outstanding	Weighted Average Remaining Life In Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
Price Range Pursuant to Option Plans:					
$ 0.37 to 0.50	1,709,000	9.9	$ 0.48	33,333	$ 0.50
0.70 to 0.96	1,939,023	7.3	0.80	847,512	0.76
1.01 to 1.50	1,887,441	5.6	1.31	1,623,065	1.31
1.51 to 1.77	2,311,458	4.9	1.64	2,184,333	1.64
4.56	209,734	2.7	4.56	209,734	4.56
	8,056,656	6.7	1.19	4,897,977	1.49
Warrants:					
$ 1.00	1,382,550	0.2	1.00	1,382,550	1.00
1.25 to 1.50	11,879,495	1.6	1.40	11,879,495	1.38
2.00	3,800,000	3.5	2.00	3,800,000	2.00
3.00 to 5.00	1,150,000	4.0	3.81	1,150,000	3.81

	18,212,045	2.0	1.65	18,212,045	1.65
Total Options & Warrants					
	26,268,701	3.4	1.51	23,110,022	1.62

Stock Awards

The employment agreements with the Chief Executive Officer, Chief Financial Officer and other members of executive management include stock-based incentives under which the executives could be awarded up to approximately 1,380,000 shares of common stock upon the occurrence of various triggering events. Of these shares, 22,727 were awarded in each of 2008 and 2007. In 2006, 86,666 shares were awarded. A total of approximately $11,000, $91,000 and $23,000 in compensation expense was recorded in 2008, 2007 and 2006, respectively, in connection with the shares awarded and others considered probable of achievement.

In 2008, four executive officers received stock awards totaling 180,000 shares of common stock. The stock awards vest in equal annual installments over a three year period. Expense is recognized on a straight line basis over the vesting period and is based on the fair value of the stock on the grant date. The fair value of the stock awards is determined based on the number of shares granted and the market price of the Company’s common stock on the date

of grant. Expense recognized in connection with these awards was approximately $28,000 in 2008. The weighted average fair value of the shares granted in 2008 was $0.82 per share.

In 2008, the Company's former Chief Executive Officer was granted 70,000 shares of common stock in connection with his separation agreement. The Company recognized $35,000 of expense based on the market price of $0.50 per share of the Company's common stock on the date of grant.

9.   Employee 401(k) Savings Plan

The Company sponsors a 401(k) defined contribution retirement savings plan that covers all U.S. employees who have met minimum age and service requirements. Under the plan, eligible employees may contribute up to 50% of their annual compensation into the plan up to the IRS annual limits. At the discretion of the Board of Directors, the Company may contribute elective amounts to the plan, allocated in proportion to employee contributions to the plan, employee's salary, or both. For the years ended December 31, 2008, 2007 and 2006, the Company elected to make contributions to the plan totaling $61,180, $75,553 and $68,369, respectively.

10. Supplemental Disclosures of Cash Flow Information

Cash paid for interest during the years ended December 31, 2008, 2007 and 2006 was $677,456, $550,642 and $3,132, respectively.

11.   License Agreements

Teva License Development and Supply Agreements

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 Teva's product sales, as well as a purchase price for each device sold are to be received by us under certain circumstances. Based on an analysis under EITF 00-21, the entire arrangement is considered a single unit of

accounting. Therefore, payments received and development costs incurred will be deferred and will be recognized from the start of manufacturing through the end of the initial contract period.

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

In July 2006, the Company entered into an exclusive License Development and Supply Agreement with an affiliate of Teva, Sicor Pharmaceuticals Inc. Pursuant to the agreement, the affiliate is obligated to purchase all of its delivery device requirements from Antares for an undisclosed product to be marketed in the United States and Canada. Antares received an upfront cash payment, and will receive milestone fees, a negotiated purchase price for each device sold, as well as royalties on sales of their product. Based on an analysis under EITF 00-21, the entire arrangement is considered a single unit of accounting. Therefore, payments received and development costs incurred will be deferred and will be recognized from the start of manufacturing through the end of the initial contract period. In December 2008, this agreement was amended to include additional development work. Payments received as a result of this amendment are expected to be recognized as revenue over the development period.

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

Agreement, Sicor purchased 400,000 shares of Antares common stock at a per share price of $1.25. Antares granted Sicor certain registration rights with respect to the purchased shares of common stock. Based on an analysis under EITF 00-21, the entire arrangement is considered a single unit of accounting. Therefore, payments received and development costs incurred will be deferred and will be recognized from the start of manufacturing through the end of the initial contract period.

Eli Lilly Development and License Agreement

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

The Company analyzed this contract to determine the proper accounting treatment under EITF 00-21, discussed in Note 2. The Company reached the conclusion that although there are multiple deliverables in the contract, the entire contract must be accounted for as one unit of accounting. Therefore, all revenue was being deferred when billed under the contract terms and was being recognized into revenue on a straight-line basis over the remaining life of the contract. All related costs were also being deferred and recognized as expense over the remaining life of the contract on a straight-line basis. The prepaid license discount was being amortized against revenue on a straight-line basis over the life of the contract.

In March of 2008 the Company entered into a second amendment to the original development and license agreement with Lilly dated September 12, 2003. The amendment narrowed the scope of the license grant to Lilly under the agreement whereby (a) certain devices (as defined in the agreement) owned by the Company are no longer licensed to Lilly, including the Company’s 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. The Company is 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.

Considering the renegotiations with Lilly and drafts of the then pending amendment, the Company 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 the preparation and review of the 2007 consolidated financial statements. Given that Lilly was no longer committed to development of the Company’s product on the previously agreed upon timeline under the agreement, the Company determined it was unlikely that future cash flows would be received that would exceed the unamortized carrying amount, indicating that the recorded prepaid license discount was impaired. In addition, the Company determined that capitalized patent costs associated with the agreement had been impaired. The Company also recognized related deferred revenue and deferred costs related to the agreement. Accordingly, the Company 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.

Ferring License Agreement

The Company entered into a License Agreement, dated January 22, 2003, with Ferring, under which the Company licensed certain of its intellectual property and extended the territories available to Ferring for use of

certain of the Company's reusable needle-free injector devices. Specifically, the Company granted to Ferring an exclusive, perpetual, irrevocable, royalty-bearing license, within a prescribed manufacturing territory, to manufacture certain of the Company's reusable needle-free injector devices for the field of human growth hormone. The Company granted to Ferring similar non-exclusive rights outside of the prescribed manufacturing territory. In addition, the Company granted to Ferring a non-exclusive right to make and have made the equipment required to manufacture the licensed products, and an exclusive, perpetual, royalty-free license in a prescribed territory to use and sell the licensed products.

As consideration for the license grants, Ferring paid the Company an upfront payment upon execution of the License Agreement, and paid an additional milestone in 2003. Ferring will also pay the Company royalties for each device manufactured by or on behalf of Ferring, including devices manufactured by the Company. Beginning in 2004, a portion of the license fee received in 2003 was credited against future royalties owed by Ferring, until such amount is exhausted. These royalty obligations expire, on a country-by-country basis, when the respective patents for the products expire, despite the fact that the License Agreement does not itself expire until the last of such patents expires. The license fees have been deferred and are being recognized in income over the period from 2003 through expiration of the patents in 2016.

In March 2007 the Company amended the agreement increasing the royalty rate and device pricing, included a next generation device and provided for payment principally in U.S. dollars rather than Euros.

BioSante License Agreement

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

received by BioSante under a sublicense agreement. The initial upfront payment received by the Company was for the delivery of intellectual property to BioSante.

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

Under the cumulative deferral method, the Company ratably recognizes revenue related to milestone payments from the date of achievement of the milestone through the estimated date of receipt of final regulatory approval in the BioSante Territory. The Company is recognizing the initial milestone payment in revenue over a 129-month period. All other milestone payments will be recognized ratably on a product-by-product basis from the date the milestone payment is earned and all repayment obligations have been satisfied until the receipt of final regulatory approval in the BioSante Territory for each respective product. It is expected that these milestones will be earned at various dates from January 2009 to December 2011 and will be recognized as revenue over periods of up to 36 months.

In November 2006 BioSante entered into a sublicense and marketing agreement with Bradley Pharmaceuticals, Inc. for Elestrin® (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a payment to the Company of $875,000. In December 2006 the FDA approved for marketing Elestrin® in the United States triggering payments to the Company totaling $2,625,000, which was received in 2007. In 2008, BioSante reacquired the rights to Elestrin® and entered into new marketing agreements in December, triggering payments to the Company of $462,500. Because final regulatory approval for this product was obtained by BioSante and Antares had no further obligations in connection with this product, the sublicense payments of $462,500, $2,625,000 and $875,000 received in 2008, 2007 and 2006, respectively, were recognized as revenue in those years. In addition, the Company has received royalties on sales of Elestrin®, which have been recognized as revenue when received.

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

Jazz License Agreement

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. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by us under certain circumstances. The upfront payment is being recognized as revenue over the development period. The milestone fees and royalties will be recognized as revenue when earned.

Solvay License Agreement

In June 1999, the Company entered into an exclusive agreement to license one application of its gel based drug-delivery technology to Solvay Pharmaceuticals in all countries except the United States, Canada, Japan and Korea (collectively, ‘‘the Solvay Territories’’). The Company is required to transfer technology know-how and to provide developmental assistance to Solvay until each country’s applicable regulatory authorities approve the licensed product. Solvay will reimburse the Company for all technical assistance provided during Solvay’s development. Solvay will use the licensed technology for the development of a hormone replacement therapy gel. The license agreement required Solvay to pay the Company a milestone payment upon signing of the license, milestones upon the start of Phase IIb/III clinical trials, additional milestones upon the first submission by Solvay to regulatory authorities in the Solvay Territories and upon the first completed registration in Germany, France or the United Kingdom. The Company will receive from Solvay a royalty from the sale of licensed products. In 2002 the agreement was amended to change the terms associated with certain milestone payments. 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.

Under the cumulative deferral method, the Company ratably recognizes revenue related to milestone payments from the date of achievement of the milestone through the estimated date of completion.

Other License Agreements

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. The upfront payment is being recognized as revenue over the development period. The milestone fees and royalties will be recognized as revenue when earned.

12. Segment Information and Significant Customers

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

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

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

	December 31,	
	2008	2007
Switzerland	$1,154,987	$1,784,230
United States of America	18,756,418	28,432,486
	$19,911,405	$30,216,716

Revenues by customer location are summarized as follows:

	For the Years Ended December 31,		
	2008	2007	2006
United States of America	$ 1,451,092	$ 3,576,310	$ 1,939,802
Europe	3,899,115	3,915,031	1,856,847
Other	310,504	365,655	471,750
	$ 5,660,711	$ 7,856,996	$ 4,268,399

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

	2008	2007	2006
Ferring	$ 3,383,071	$ 3,080,545	$ 1,660,016
BioSante	668,853	2,836,016	1,038,339

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

	2008	2007
Ferring	$ 360,035	$ 274,582
Teva	918,948	137,500

13. Quarterly Financial Data (unaudited)

	First	Second	Third	Fourth
2008:				
Total revenues	$ 1,114,378	$ 1,390,115	$ 1,388,582	$ 1,767,636
Gross profit	662,330	855,406	792,604	1,330,786
Net loss applicable to common shares	(3,497,698)	(3,260,770)	(3,188,834)	(2,743,151)

Net loss per common share (1)	(0.05)	(0.05)	(0.05)	(0.04)
Weighted average shares	65,628,567	67,320,325	67,979,666	67,986,514
2007:				
Total revenues	$ 2,843,738	$ 1,806,275	$ 1,230,674	$ 1,976,309
Gross profit	2,376,186	1,238,544	679,034	121,212
Net loss applicable to common shares	(429,581)	(2,297,038)	(2,610,732)	(3,241,588)
Net loss per common share (1)	(0.01)	(0.04)	(0.04)	(0.05)
Weighted average shares	53,413,326	54,626,788	64,660,101	65,529,666

(1) Net loss per common share is computed based upon the weighted average number of shares outstanding during each period. Basic and diluted loss per share amounts are identical as the effect of potential Common Shares is anti-dilutive.

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

None.

Item 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures.

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

Internal Control Over Financial Reporting.

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

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

Management's report on internal control over financial reporting is included in Item 8,*Financial Statements and Supplementary Data*, of this annual report on Form 10-K.

Item 9B. OTHER INFORMATION.

None.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item concerning our directors will be set forth under the caption “Election of Directors” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

Information required by this item concerning our executive officers will be set forth under the caption “Executive Officers of the Company” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the United States Securities Exchange Act of 1934, as amended, will be set forth under the caption “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

Information required by this item concerning the audit committee of the Company, the audit committee financial expert of the Company and any material changes to the way in which security holders may recommend nominees to the Company’s Board of Directors will be set forth under the caption “Corporate Governance” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

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

Item 11. EXECUTIVE COMPENSATION.

Information required by this item will be set forth under the caption “Executive Compensation” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

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

Information required by this item concerning ownership will be set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

The following table provides information for our equity compensation plans as of December 31, 2008:

Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding shares reflected in the first column)**
Equity compensation plans approved by security holders	8,056,656	$ 1.19	1,608,050
Equity compensation plans not approved by security holders (1)	350,000	2.36	—
Total	8,406,656	$ 1.24	1,608,050

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

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

Information required by this item will be set forth under the captions “Certain Relationships and Related Transactions” and “Corporate Governance” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Information required by this item will be set forth under the caption “Ratification of Selection of Independent Registered Public Accountants” in our definitive proxy statement for our 2009 annual meeting, and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

(1) Financial Statements - see Part II

(2) Financial Statement Schedules

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

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

(b) Exhibits

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

Exhibit No.	Description
3.1	Certificate of Incorporation (Filed as an exhibit to Schedule 14A on March 18, 2005 and incorporated herein by reference.)
3.2	Certificate of Amendment of Certificate of Incorporation (filed as exhibit 3.1 to Form 8-K on May 19, 2008 and incorporated herein by reference.)
3.3	Bylaws (Filed as an exhibit to Schedule 14A on March 18, 2005 and incorporated herein by reference.)
3.4	Amended and Restated Bylaws of Antares Pharma, Inc. adopted as of May 11, 2007 (Filed as exhibit 3.1 to Form 8-K on May 15, 2007 and incorporated herein by reference.)
4.1	Form of Certificate for Common Stock (Filed as an exhibit to Form S-1 on October 1, 1996 and incorporated herein by reference.)
4.2	Registration Rights Agreement with Permatec Holding AG dated January 31, 2001 (Filed as Exhibit 10.2 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
4.3	Warrant Agreement with Eli Lilly and Company dated September 12, 2003 (Filed as exhibit 10.60 to Form 8-K on September 18, 2003 and incorporated herein by reference.)

4.4	Registration Rights Agreement with Eli Lilly and Company dated September 12, 2003 (Filed as exhibit 10.61 to Form 8-K on September 18, 2003 and incorporated herein by reference.)
4.5	Stock Purchase Agreement with Sicor Pharmaceuticals, Inc., dated November 23, 2005 (Filed as exhibit 10.55 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
4.6	Form of Common Stock and Warrant Purchase Agreement, dated February 27, 2006 (Filed as exhibit 10.57 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
4.7	Form of Investors Rights Agreement, dated March 2, 2006 (Filed as exhibit 10.58 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
4.8	Form of Common Stock Purchase Warrant, dated March 2, 2006 (Filed as exhibit 10.59 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
4.9	Form of Common Stock Purchase Warrant and Related Schedule of Holders and Other Terms (Filed as exhibit 4.7 to Form S-3/A Registration Statement on May 16, 2006 and incorporated herein by reference.)
4.10	Registration Rights Agreement by and among Antares Pharma, Inc., MMV Financial Inc. and HSBC Capital (Canada) Inc., dated February 26, 2007 (Filed as exhibit 4.1 to Form 8-K on March 2, 2007 and incorporated herein by reference.)

4.11	Warrant for the Purchase of Shares of Common Stock issued by Antares Pharma, Inc. to MMV Financial Inc., dated February 26, 2007 (Filed as exhibit 4.2 to Form 8-K on March 2, 2007 and incorporated herein by reference.)
4.12	Warrant for the Purchase of Shares of Common Stock issued by Antares Pharma, Inc. to HSBC Capital (Canada) Inc., dated February 26, 2007 (Filed as exhibit 4.3 to Form 8-K on March 2, 2007 and incorporated herein by reference.)
4.13	Credit Agreement by and among Antares Pharma, Inc., MMV Financial Inc. and HSBC Capital (Canada) Inc., dated February 26, 2007 (Filed as exhibit 10.1 to Form 8-K on March 2, 2007 and incorporated herein by reference.)
4.14	First Amending Agreement Between Antares Pharma, Inc., MMV Financial Inc. and HSBC Capital (Canada) Inc., dated December 17, 2007 (Filed as exhibit 10.1 to Form 8-K on December 19, 2007 and incorporated herein by reference.)
4.15	Common Stock and Warrant Purchase Agreement, dated June 29, 2007, by and between Antares Pharma, Inc. and the Purchasers party thereto (Filed as exhibit 4.1 to Form 8-K on July 2, 2007 and incorporated herein by reference.)
4.16	Form of Investor Rights Agreement (Filed as exhibit 4.2 to Form 8-K on July 2, 2007 and incorporated herein by reference.)
4.17	Form of Warrant (Filed as exhibit 4.3 to Form 8-K on July 2, 2007 and incorporated herein by reference.)
10.0	Stock Purchase Agreement with Permatec Holding AG, Permatec Pharma AG, Permatec Technologie AG and Permatec NV with First and Second Amendments dated July 14, 2000 (Filed as an exhibit to Schedule 14A on December 28, 2000 and incorporated herein by reference.)
10.1	Third Amendment to Stock Purchase Agreement, dated January 31, 2001 (Filed as exhibit 10.1 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
10.2*	Agreement with Becton Dickinson dated January 1, 1999 (Filed as exhibit 10.24 to Form 10-K for the year ended December 31, 1998 and incorporated herein by reference.)
10.3*	License Agreement with Solvay Pharmaceuticals BV, dated June 9, 1999 (Filed as exhibit 10.33 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.4*	License Agreement with BioSante Pharmaceuticals, Inc., dated June 13, 2000 (Filed as exhibit 10.34 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.5*	Amendment No. 1 to License Agreement with BioSante Pharmaceuticals, Inc., dated May 20, 2001 (Filed as exhibit 10.35 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.6*	Amendment No. 2 to License Agreement with BioSante Pharmaceuticals, Inc., dated July 5, 2001 (Filed as exhibit 10.36 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.7*	Amendment No. 3 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 28, 2001 (Filed as exhibit 10.37 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.8*	Amendment No. 4 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 8, 2002 (Filed as exhibit 10.38 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.9*	License Agreement between Antares Pharma, Inc. and Ferring, dated January 21, 2003 (Filed as exhibit 10.47 to Form 8-K on February 20, 2003 and incorporated herein by reference.)
10.10	Securities and Exchange Agreement, dated September 12, 2003 (Filed as exhibit 10.57 to Form 8-K on September 15, 2003 and incorporated herein by reference.)
10.11*	Development and License Agreement, dated September 12, 2003, with Eli Lilly and Company (Filed as exhibit 10.59 to Form 8-K on September 18, 2003 and incorporated herein by reference.)

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10.12	Second Amendment to the Development and License Agreement with Eli Lily and Company dated March 20, 2008 (Filed as Exhibit 10.1 to Form 10-Q for the Quarter Ended March 31, 2008 and incorporated herein by reference.)
10.13	Office lease with The Trustees Under the Will and of the Estate of James Campbell, Deceased, dated February 19, 2004 (Filed as exhibit 10.65 to Form 10-K for the year ended December 31, 2003 and incorporated herein by reference.)
10.14	Form of Indemnification Agreement, dated February 11, 2008, between Antares Pharma, Inc. and each of its directors and executive officers (Filed as exhibit 10.1 to Form 8-K on February 13, 2008 and incorporated herein by reference.)
10.15+	Amended and Restated Employment Agreement, dated March 11, 2008, with Jack E. Stover (Filed as exhibit 10.1 to Form 8-K on March 12, 2008 and incorporated herein by reference.)
10.16+	Amended and Restated Employment Agreement with Jack E. Stover, dated May 13, 2008 (Filed as Exhibit 10.1 to Form 10-Q for the Quarter Ended June 30, 2008 and incorporated herein by reference.)
10.17*	Development Supply Agreement, dated June 22, 2005 (Filed as exhibit 10.0 to Form 10-Q for the quarter ended June 30, 2005 and incorporated herein by reference.)
10.18*	License Development and Supply Agreement with Sicor Pharmaceuticals, Inc., dated November 23, 2005 (Filed as exhibit 10.54 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
10.19+	Senior Management Agreement by and between Antares Pharma, Inc. and Robert F. Apple, dated February 9, 2006 (Filed as exhibit 10.1 to Form 8-K on February 14, 2006 and incorporated herein by reference.)
10.20+	Amendment to Senior Management Agreement with Robert F. Apple, dated November 12, 2008. (Filed as Exhibit 10.1 to Form 10-Q for the Quarter Ended September 30, 2008 and incorporated herein by reference.)
10.21+	Employment agreement with Peter Sadowski, Ph.D., dated October 13, 2006 (Filed as exhibit 10.1 to Form 8-K on October 16, 2006 and incorporated herein by reference.)
10.22+	Amendment to Employment Agreement with Peter Sadowski, Ph. D., dated November 12,2008 (Filed as Exhibit 10.2 to Form 10-Q for the Quarter Ended September 30, 2008 and incorporated herein by reference.)
10.23+	Employment agreement with Dario Carrara, dated October 13, 2006 (Filed as exhibit 10.2 to Form 8-K on October 16, 2006 and incorporated herein by reference.)
10.24	Amendment to Employment Agreement with Dario Carrara, dated November 12,2008 (Filed as Exhibit 10.3 to Form 10-Q for the Quarter Ended September 30, 2008 and incorporated herein by reference.)
10.25+	Employment Agreement, dated July 7, 2008 by and between Antares Pharma, Inc. and Dr. Paul K. Wotton (Filed as Exhibit 10.1 to Form 8-K on July 7, 2008 and incorporated herein by reference.)
10.26	Lease Agreement, dated as of May 15, 2006, between the Company and 250 Phillips Associates LLC (Filed as exhibit 10.2 to From 10-Q for the quarter ended June 30, 2006 and incorporated herein by reference.)
10.27	Antares Pharma, Inc. 2008 Equity Compensation Plan (filed as exhibit 10.1 to Form 8-K on May 19, 2008 and incorporated herein by reference.)
21.1	Subsidiaries of the Registrant
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm
31.1	Section 302 CEO Certification
31.2	Section 302 CFO Certification
32.1	Section 906 CEO Certification
32.2	Section 906 CFO Certification

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report to be signed on its behalf by the undersigned thereunto duly authorized, in the City of Ewing, State of New Jersey, on March 24, 2009.

ANTARES PHARMA, INC.

/s/Paul K. Wotton

Dr. Paul K. Wotton

President and Chief Executive Officer

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this annual report has been signed by the following persons on behalf of the registrant in the capacities indicated on March 24, 2009.

Signature	Title
/s/Paul K. Wotton Dr. Paul K. Wotton	President and Chief Executive Officer, Director (Principal Executive Officer)
/s/Robert F. Apple Robert F. Apple	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
/s/Leonard S. Jacob Dr. Leonard S. Jacob	Director, Chairman of the Board
/s/Thomas J. Garrity Thomas J. Garrity	Director
/s/Jacques Gonella	Director

Dr. Jacques Gonella

/s/Anton G. Gueth Anton G. Gueth	Director
/s/Rajesh Shrotriya Dr. Rajesh Shrotriya	Director