

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

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (D) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2010

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)

A Delaware corporation

I.R.S. Employer Identification No. 41-1350192

250 Phillips Boulevard, Suite 290, Ewing, NJ 08618

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

Securities registered pursuant to section 12(b) of the Act:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock	NYSE Amex

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.  
YES  NO

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  
YES  NO

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

Aggregate market value of the voting and non-voting common stock held by nonaffiliates of the registrant as of June 30, 2010, was \$124,661,000 (based upon the last reported sale price of \$1.76 per share on June 30, 2010, on NYSE Amex).

There were 87,572,915 shares of common stock outstanding as of March 7, 2011.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for the registrant's 2011 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.

**ANTARES PHARMA, INC.**  
**FORM 10-K**  
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# PART I

## Item 1. BUSINESS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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 discussion of, 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 product developments with Teva Pharmaceutical Industries, Ltd. (“Teva”);
- 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 anticipated continued reliance on contract manufacturers to manufacture our products;
- our marketing and product development plans;
- our future cash flow and our ability to support our operations;
- our projected net loss for the year ending December 31, 2011;
- 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 an emerging pharma company that focuses on self-injection pharmaceutical products and technologies and topical gel-based products. Our subcutaneous injection technology platforms include Vibex™ disposable pressure-assisted auto injectors, Vision™ reusable needle-free injectors, and disposable multi-use pen injectors. In the injector area, we have a multi-product deal with Teva that includes Tev-Tropin® human growth hormone (“hGH”) and have partnerships with Ferring Pharmaceuticals BV (“Ferring”) and JCR Pharmaceuticals Co., Ltd. (“JCR”) that include their hGH products. In the gel-based area, we filed a new drug application (“NDA”) in December 2010 for Anturool®, an oxybutynin ATD™ gel for the treatment of overactive bladder (“OAB”). We also have a partnership with BioSante Pharmaceuticals, Inc. (“BioSante”) that includes LibiGel® (transdermal testosterone gel) in Phase 3 clinical development for the treatment of female sexual dysfunction (“FSD”), and Elestrin® (estradiol gel) for the treatment of moderate-to-severe

vasomotor symptoms associated with menopause, which is currently marketed in the U.S. Two of our technologies have generated United States Food and Drug Administration (“FDA”) approved products. Our products and product opportunities are summarized and briefly described below:

## Products

### Injection Devices

<i>Product</i>	<i>Indication</i>	<i>Partners</i>	<i>Concept</i>	<i>Prototype for Clinical Evaluation</i>	<i>Design Finalization</i>	<i>Regulatory Submission</i>	<i>Commercialization</i>
Tjet <sup>®</sup> Needle-free Injector	hGH	Teva					→
Zomajet <sup>®</sup> 2 Vision and Zomajet <sup>®</sup> Vision X Needle-free Injector	hGH	Ferring					→
Twin-Jector <sup>®</sup> EZ II Needle-free Injector	hGH	JCR					→
Medi-Jector Vision <sup>®</sup> Needle-free Injector	Insulin	None					→
Vibex <sup>™</sup> Auto Injector	Epinephrine	Teva				→	
Vibex <sup>™</sup> Auto Injector	Undisclosed Product	Teva				→	
Vibex <sup>™</sup> MTX Auto Injector	Methotrexate	None		→			
Disposable Pen Injector	Undisclosed Product #1	Teva		→			
Disposable Pen Injector	Undisclosed Product #2	Teva			→		

### Transdermal Delivery Gels

<i>Product</i>	<i>Indication</i>	<i>Partners</i>	<i>Formulation Development</i>	<i>Preclinical Testing</i>	<i>Clinical Phase</i>			<i>Regulatory Submission</i>	<i>Commercialization</i>
					<i>I</i>	<i>II</i>	<i>III</i>		
Estradiol ATD <sup>™</sup> (Elestrin <sup>®</sup> )	Hot flashes and vaginal atrophy hormone therapy	BioSante							→
Antural <sup>®</sup> (oxybutynin) ATD <sup>™</sup>	Overactive bladder syndrome	None					→		
Testosterone ATD <sup>™</sup> (LibiGel <sup>®</sup> for Women)	Female sexual dysfunction	BioSante					→		
Nestorone <sup>®</sup> /Estradiol ATD <sup>™</sup> Gel	Contraception	Population Council					→		
Undisclosed ATD <sup>™</sup> Gel	Undisclosed	Ferring		→					

### 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. Our current needle-free injector product is a reusable, variable-dose device engineered to last for two years and is designed for easy use, facilitating self-injection with a disposable syringe to assure safety and efficacy. The injector 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.

We have sold our needle-free injection system for use in more than 30 countries to deliver either human growth hormone (“hGH”) or insulin. The product is marketed by our partners for use with hGH as Tjet<sup>®</sup>, by Teva in the U.S.; Zomajet<sup>®</sup> 2 Vision and Zomajet<sup>®</sup> Vision X, by Ferring in Europe and Asia; and Twin-Jector<sup>®</sup> EZ II, by JCR in Japan, and is sold as the Medi-Jector VISION<sup>®</sup> over-the-counter (“OTC”) or by prescription in the U.S. for use by patients for insulin. We refer to our reusable needle-free injector as the Vision<sup>™</sup> and/or Tjet<sup>®</sup>.

- *Disposable pressure assisted auto injectors* employ the same basic technology developed for our needle-free devices, a controlled pressure delivery of drugs into the body utilizing a spring power source. Combining pressure with a hidden needle supports the design of a disposable, single-use injection system compatible with conventional glass drug containers. This system, the Vibex™, 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. In contrast to our 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.

### Transdermal Gel System

Our transdermal system consists of a unique formulation in semisolid dosage forms (gels) that delivers 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 system provides 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 system is known as our Advanced Transdermal Delivery (“ATD™”) gels.

### **History**

On January 31, 2001, we (Antares, formerly known as Medi-Ject Corporation, or Medi-Ject) completed a business combination to acquire the 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 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 Vision™ and Tjet®, which is marketed for use with insulin and human growth hormone. 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 the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

We have also developed variations of the needle-free injector by adding a 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 needle-free 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. We are also developing our own auto injector based product, Vibex™ MTX, for delivery of methotrexate for treatment of rheumatoid arthritis, for which we recently initiated a clinical study.

Our Pharma division is located both in the U.S. and in Muttenz, 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 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 in December 2010 we filed an NDA for Anturof<sup>®</sup>, 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, contraception, pain management and central nervous system therapies.

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).

### **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 portfolio includes disposable pressure assisted auto injection systems (Vibex<sup>™</sup>); disposable pen injection systems; reusable needle-free injection systems (Vision<sup>™</sup>) and transdermal Advanced ATD<sup>™</sup> gels.

### SELF-ADMINISTRATION OF INJECTABLE DRUGS

According to IMS Health, the worldwide market for injectable drugs including biologic drugs is estimated to be \$120 billion. Given the market success of several recent biologic drugs, pharmaceutical firms are increasingly reliant upon biologic drug candidates in their product pipelines, fueling growth expectations for the biologic drugs. Industry analysts project that biologics will account for 50% of the 100 top selling drugs by 2014, up from 28% in 2008.

Injectable drugs are often used in managing chronic medical conditions, presenting a need for repeated injections over time. Cost containment pressure by managed care combined with patient preferences for convenience and comfort are driving a change in the treatment setting from the health care facility to patients' homes. This trend is creating a shift from the injection being given by a doctor or nurse to self-administration by the patient or administration by a family member or other lay caregiver. This shift has produced a transition in how injectable drugs are configured to facilitate use by consumers. In many therapeutic categories pre-filled syringes and other injection systems offering greater ease-of-use and security for patients now exceed vials in unit volume, often at substantial unit price premium. These therapeutic categories and example products include:

<b>Condition</b>	<b>Products</b>
Diabetes	Humalog (Lilly), Novolog (Novo Nordisk), Apidra (Sanofi Aventis), Lantus (Sanofi Aventis), Levemir (Novo Nordisk), Byetta (Lilly)
Growth deficiency	Genotropin (Pfizer), Tev-Tropin (Teva), Humatrope (Lilly), Nutropin AQ (Roche), Noridropin (Novo Nordisk), Saizen/Serostem (EMD Serono), Omnitrope (Sandoz)
Rheumatoid Arthritis	Enbrel (Amgen, Pfizer), Humira (Abbott), Simponi (Centocor Ortho Biotech), Cimzia (UCB)
Multiple Sclerosis	Avonex (Biogen Idec), Betaseron (Bayer), Copaxone (Teva), Rebif (EMD Serono)
Chronic Hepatitis C	Intron-A (Merck), Pegasys (Roche), Peg-Intron (Merck)
Anemia/Neutropenia	Aranesp (Amgen), Neulasta (Amgen)
Migraine treatment	Imitrex (GSK, Par, Sandoz), Sumavel (Zogenix), Alsuma (Pfizer)

## Pressure Assisted Auto Injection

The most significant challenge beyond discovery of new molecules is how to effectively deliver them by means other than conventional needle and syringe. 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 parenteral drug delivery that continues to gain acceptance among the medical community. Encompassing a wide variety of sizes and designs, this technology operates by using pressure to force the drug, in solution or suspension, through 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 occur 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.

## **Our Injection Products**

### Vision™ / Tjet®

The Vision™/Tjet® 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 syringe, which acts as the pathway for the injectable drug through the skin and allows for easy viewing of the medication dose prior to injection. The device's primary advantages are 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 Vision™/Tjet® 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 Vision™/Tjet® is primarily used in the U.S., 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 2008, our partner, Teva, supported the filing of a supplemental new drug application (“sNDA”) to provide the Tjet® to hGH patients in the U.S. In June of 2009, the FDA approved the sNDA and in August of 2009 Teva launched the Tjet® device.

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. One of these agreements is for a product containing epinephrine and the other is for an undisclosed product. We are also developing a Vibex™ MTX auto injector for delivery of methotrexate for treatment of rheumatoid arthritis.

Disposable Pen Injector System

Our multi use, disposable pen injector complements our portfolio of single-use 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 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 for our pen injector device for two undisclosed products.

## 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 hormone therapy, 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 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, sometimes result in 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. Additionally, 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.

## Our Transdermal Products

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:

<b>Competitive Advantages of ATD™ Gel System</b>
<ul style="list-style-type: none"><li>• <b>Discrete</b></li><li>• <b>Easy application</b></li><li>• <b>Cosmetically appealing compared with patches</b></li><li>• <b>Reduced skin irritancy compared with patches</b></li><li>• <b>Application of once per day for most products</b></li><li>• <b>Potential for delivery of larger medication doses</b></li><li>• <b>Potential for delivery of multiple active drugs</b></li><li>• <b>Ability to be either systemic or topical</b></li></ul>

Our ATD™ gel products are being developed by both us and our pharmaceutical partner. The following is a summary of the products being developed/commercialized.

### Anturo!®

In December 2010 we filed an NDA for Anturo!®, our oxybutynin ATD™ gel for the treatment of OAB (overactive bladder). The NDA submission was supported by a Phase 3 clinical trial. In February 2011, we received a waiver of the \$1.5 million NDA filing fee. The FDA typically issues notice of acceptance within 60 days of issuing the fee waiver. We continue to seek a marketing partner to commercially launch Anturo!® if approved by the FDA.

### Elestrin®

Elestrin® is a transdermal estradiol gel for the treatment of moderate-to-severe vasomotor symptoms associated with menopause. We licensed the rights to Elestrin® in the U.S. and other markets to our partner BioSante through a license agreement under which we receive milestone payments and royalties. BioSante has sublicensed Elestrin® to Azur Pharma, who is currently marketing Elestrin® in the U.S.

### LibiGel®

LibiGel® is a transdermal testosterone gel for the treatment of female sexual dysfunction being developed by our partner BioSante. LibiGel® is currently in a Phase 3 clinical study. If LibiGel® is approved by the FDA, we are entitled to milestone and royalty payments from BioSante.

### Nestorone®

We have 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 compound and other proprietary information covering the compound, and our transdermal delivery gel technology. We are responsible for research and development activities as they relate to ATD formulation and manufacturing and the Population Council will be responsible for clinical trial design development and management. In 2010, we announced with the Population Council successful results from a dose-finding Phase II trial for the contraceptive gel. Together, we expect to identify a worldwide or regional commercial development partner as clinical data becomes available.

## Market Opportunity

### Needle-free Injectors / Auto Injectors / Pen Injectors

Our parenteral/device focus is specifically on the market for delivery of self-administered injectable drugs, comprised mainly of biological products. According to IMS Health, the fast-growing worldwide biologics market is estimated to be \$120 billion and biologics are among the strongest sources of growth for the pharmaceutical industry, with more than 28% of the R&D pipeline now dedicated to that segment. As biological drugs lose patent and market exclusivity, they become prime targets for follow-on biologics, also known as biosimilars. We estimate that self-administered injectable biologics represent well over half the market value of biologic products facing future competition from biosimilars. Since, by design, biosimilar molecules will be nearly identical to the innovator biologic, both the innovator and biosimilars manufacturers will seek other ways to differentiate their products in the market. We believe that manufacturers will look to proprietary self-administration devices, such as those offered by our injection device platforms, as a key way to compete in the market.

### Tjet<sup>®</sup> / Zomajet<sup>®</sup> (hGH)

In a May 2009 report, Greystone Associates estimated the worldwide hGH market in 2008 at \$2.8 billion. There is significant competition within the hGH market between major pharmaceutical companies such as Lilly, Roche, Pfizer, NovoNordisk and Merck Serono among others. Sandoz introduced Omnitrope as a lower cost biosimilar hGH in Europe in 2005 and the U.S. in 2006. However, despite a 25% lower price the product achieved only a 0.8% hGH market share by 2007. We believe that other product attributes, including patient comfort and ease-of-use, play a key role, along with price and promotion, in determining performance in the market. Our pharmaceutical partner in Europe, Ferring, has made significant inroads in the hGH market using our needle-free injector, marketed as the Zomajet<sup>®</sup> 2 Vision for their 4 mg formulation and Zomajet<sup>®</sup> Vision X for their 10 mg formulation, and we expect similar progress in the U.S. market with our partner Teva. Teva entered the hGH market without the benefit of an injection device and initially struggled to gain market share. Since the launch of the Tjet<sup>®</sup> needle-free device in late 2009, sales of Teva's hGH Tev-Tropin<sup>®</sup> have increased monthly. This early trend supports the notion that devices can increase patient use of a partner's brand of drug due to the benefits of a device.

### Vibex<sup>™</sup> MTX

Vibex<sup>™</sup> MTX is our proprietary methotrexate injection system in development for the treatment of rheumatoid arthritis. Rheumatoid arthritis is a chronic autoimmune disease in which an affected person's white blood cells (leukocytes) attack the synovial tissues surrounding the joints, resulting in pain, stiffness, swelling, joint damage, and loss of function of the joints. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) the incidence of rheumatoid arthritis is about 0.6 percent of the U.S. population (about 1.3 million people). The disease onset generally occurs between the ages of 25 to 50 years and is about twice as prevalent among women as among men. U.S. sales of pharmaceutical products to treat rheumatoid arthritis are approximately \$6.0 billion annually, according to a Cowen and Company report.

Methotrexate is the most commonly prescribed disease modifying anti-rheumatic drug (DMARD), used in an estimated 70% of rheumatoid arthritis patients. Methotrexate is started at a low dose, generally 7.5mg given orally, once-a-week, and titrated up for greater therapeutic effect, or until the patient incurs side effects. The maximum oral dose given is generally 20mg to 25mg per week. Studies have reported as many as 30% to 60% of patients experience gastrointestinal side effects with oral methotrexate, preventing further dose escalation or requiring discontinuation in some patients. Also, the extent of oral absorption of methotrexate varies considerably between patients and has been shown to decline with increasing doses, which may also contribute to insufficient therapeutic response even after dose escalation. Studies have shown that switching patients from oral to parenteral methotrexate improves absorption and has been associated with improved therapeutic response. Additionally, some studies have shown a lower incidence of gastrointestinal side effects in patients that were switched from oral to parenteral methotrexate.

We believe that Vibex<sup>™</sup> MTX offers physicians and patients an important alternative to oral methotrexate tablets and vials of the injectable form of the drug. Many patients who start on oral methotrexate fail to achieve adequate therapeutic results due in part to poor oral absorption or poor tolerability. Studies have demonstrated that

switching to a parenteral route of administration can improve absorption; however, fewer than 10% of patients on methotrexate are being prescribed the injectable form. Instead, patients who fail to achieve adequate response on oral methotrexate are often prescribed a biologic response modifier (biologic). The biologics have been demonstrated to improve the patient's therapeutic response when added to methotrexate. However, the biologics are expensive, typically costing in excess of \$20,000 per year (based on published manufacturers' direct prices), have their own limitations including increasing the risk of serious infections and certain malignancies and are not appropriate for all patients. Vibex™ MTX would offer physicians a convenient, practical and cost-effective option for administering parenteral methotrexate as an alternative to proceeding directly from oral methotrexate to biologics.

In an independent marketing survey of rheumatologists commissioned by Antares, the Vibex™ MTX product concept was well received with the majority of physicians expressing interest in having the product available as an option for their patients. Physicians surveyed cited the potential advantages of parenteral vs. oral methotrexate and the auto-injector system to improve patient acceptance of self-injection, while also assuring dosing accuracy, as specific advantages of prescribing the product.

#### Vibex™ with Epinephrine

We have a license agreement with Teva for our Vibex™ system which we have designed for a product containing epinephrine and are currently scaling up the commercial tooling and molds for this product. According to IMS data, sales of the EpiPen® in the U.S. exceed \$250 million annually. The EpiPen® is the global market leader in the epinephrine auto injector market. Epinephrine is utilized for the treatment of severe allergic reactions (anaphylaxis) to insect venom, foods, drugs and other allergens as well as anaphylaxis to unknown substances or exercise-induced anaphylaxis.

#### Other Injectable Drugs

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 treatments for multiple sclerosis, migraine headaches, inflammatory diseases, impotence, infertility, AIDS and hepatitis. We 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 Cimzia® (UCB), Simponi® (Centocor Ortho Biotech), Enbrel® (Amgen, Pfizer) and Humira® (Abbott) for treatment of rheumatoid arthritis, Epogen® and Aranesp® (Amgen) for treatment of anemia, Forteo™ (Lilly) for treatment of osteoporosis, Intron® A (Merck) and Roferon® (Roche) for hepatitis C, Lantus® (sanofi aventis) and Byetta® (Lilly) for diabetes, Rebif® (EMD Serono) for multiple sclerosis, Copaxone® (Teva) for multiple sclerosis and Gonal-F® (EMD Serono) for fertility treatment.

We believe a significant portion of injectable products currently offered in vials could be replaced with user friendly injectors promoting better compliance and decreasing sharps concerns. Several manufacturers of injectable products have recently introduced convenient alternatives to vials, such as prefilled syringes and injector systems; and an increasing proportion of people who self-administer drugs are transitioning to prefilled syringes and other injector systems when offered. We believe that our injection technologies offer further improvements in convenience and comfort for patients self-administering injectable products and that our business model of working with pharmaceutical company partners has the potential for further market penetration. In addition to partnering with manufacturers of injectable products, we anticipate developing our own pharmaceutical products using our pressure assisted auto injectors in the future.

#### Anturol®

Anturol® is our oxybutynin ATD™ gel for the treatment of OAB (overactive bladder). According to IMS, the OAB market in the US was valued at \$2.0 billion, based on over 18 million prescriptions written in 2009. OAB is a condition marked by urinary urgency, which is a sudden need to urinate that can happen at any time whether or not the bladder is full. OAB is typically caused when the smooth muscle of the bladder undergoes involuntary

contractions and may result in uncontrolled leakage. OAB is defined as urgency, with or without incontinence and usually includes increased urinary voiding frequency and nocturia (waking up one or more times during the night to urinate). According to published reports it is estimated that more than 30 million Americans have OAB, and while it can happen at any age is more prevalent among older individuals. It is estimated, however, that half of the U.S. adults suffering from OAB either are too embarrassed to discuss the symptoms or are not aware that pharmacological treatment is available. 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. A goal of transdermal delivery is to minimize these common anticholinergic side effects. In December 2010 we filed an NDA for Anturol<sup>®</sup>.

### Elestrin<sup>®</sup> and LibiGel<sup>®</sup>

According to IMS Health, the U.S. hormone replacement market, including estrogens, progestogens, and estrogen-progestogen and estrogen-androgen combinations, was \$2.1 billion in 2008, up 3.7% from 2007 despite a slight decrease in the number of prescriptions. According to industry estimates, approximately six million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone therapy. IMS Health reported 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, was about \$260 million.

The U.S. market for transdermal testosterone therapies grew approximately 32 percent in 2009 to about \$930 million from \$700 million in 2008. Further growth in this sector may be achieved by the use of testosterone products in both male and female applications. We believe that a new market opportunity exists with the use of low dose testosterone for treatment of FSD, a disorder according to published reports that affects an estimated 40-55% of all women and for which no drug is currently approved in the U.S. Antares Pharma, along with its U.S. partner BioSante, has a low dose testosterone product named LibiGel<sup>®</sup>, which has completed Phase II testing for FSD and is currently in Phase III clinical trials. We have the exclusive rights in Europe and elsewhere outside the United States for LibiGel<sup>®</sup>. 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 Intrinsic<sup>®</sup> Patch, a testosterone transdermal patch for FSD.

### Nestorone<sup>®</sup> Gel (Contraception)

In 2009, the global contraceptives market was \$11.2 billion and is forecasted to grow to \$14.5 billion by 2016 according to a December 2010 report by GBI Research. Worldwide sales of hormonal contraceptives in 2008 were \$6.2 billion according to an October 2009 report by Datamonitor. Oral contraceptives account for about 86% of market with the remainder consisting of hormonal implants, injections and intra-uterine systems according to a 2007 report by Business Insights. Transdermal contraceptive systems provide women an attractive alternative to the pill by offering convenience and discretion. The Company is collaborating with the Population Council (an international, nonprofit research organization) to develop a novel hormonal contraceptive comprising a combination of the progestin Nestorone<sup>®</sup> and a form of estrogen, called 17 $\beta$ -estradiol (E2), which is chemically identical to the naturally occurring estrogen. This combination was chosen because of their potential for offering a superior tolerability and safety profile compared to other commonly used hormonal contraceptives. Nestorone is a novel synthetic progestin that has been shown to be highly effective at stopping ovulation at a low dose. It has no androgenic hormonal effects and has a good safety profile. It is not active when taken orally and is therefore especially appropriate for topical application. When delivered by the transdermal route, Estradiol (E2) has the advantage of being a much less potent estrogen than the commonly used contraceptive ethinyl estradiol (EE) and therefore may have a lower risk of causing venous thromboembolism.

## **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.

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

We believe transdermal gel formulations offer patients more choices and added convenience with no compromise of efficacy. Our ATD™ gel technology is based upon so-called GRAS (“Generally Recognized as Safe”) substances, meaning the toxicology profiles of the ingredients are known and widely used. We believe this approach has a major regulatory benefit and may reduce the cost and time of product development and approval.

Many drugs, including selected protein biopharmaceuticals, are degraded in the gastrointestinal tract and may only be administered through the skin by injection. 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 such as our injector platform 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. In March 2010, Congress passed the “Biologics Price Competition and Innovation Act” as part of the “Patient Protection and Affordable Care Act.” This legislation creates a pathway for regulatory approval, authorizing the FDA to establish criteria for review and approval of “biosimilar” and “interchangeable” biological products that are similar to the innovator biologic after patent and exclusivity expiration of the innovator product. The approval of biosimilar products is intended to reduce the cost of biological products by increasing competition just as the Hatch-Waxman legislation did by creating an abbreviated pathway for approval of generic drugs. In order to differentiate between different version of similar biologic agents, novel patented delivery systems are becoming more important to extend product proprietary position as well as secure patient preference.

Furthermore, 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.

Finally, when a drug loses patent protection, the branded version of the drug typically faces competition from generic alternatives. It may be possible to preserve market share by altering the delivery method, e.g., a single daily controlled release dosage form rather than two to four pills a day. We expect branded and specialty pharmaceutical companies will continue to seek differentiating drug delivery characteristics to defend against generic competition and to optimize convenience to patients. The altered delivery method may be an injection device or a novel 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.

## **Competition**

Competition in the transdermal delivery market includes companies like Watson Pharmaceuticals, Solvay, Acrux, NexMed, Inc., Auxillium, Inc., Endo Pharmaceuticals, Novavax, Inc. and many others. Competition in the disposable, single-use injector market includes, but is not limited to, Ypsomed AG, SHL Group AB, OwenMumford Ltd., West Pharmaceuticals, Becton Dickinson, Haselmeir GmbH, Elcam Medical and Vetter Pharma, while competition in the reusable needle-free injector market includes Bioject Medical Technologies Inc. and The Medical House PLC. Additionally, in the drug injection field we face competition from internal groups within large pharmaceutical companies as well as design houses which complete the design of devices for companies but don’t have manufacturing management capabilities.

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.

Competition in the methotrexate market includes tablets and parenteral forms that are currently marketed in the U.S. by several generic manufacturers, including Teva, Barr, Mylan, Roxane, Bedford Labs, APP Pharmaceuticals, and Hospira. In several European countries, Canada, and South Korea, Medac International or its licensees market methotrexate in prefilled syringes (Metoject®). Other commonly used pharmaceutical treatments for rheumatoid arthritis include analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, so-called disease modifying anti-rheumatic drugs (DMARDs) and biologic response modifiers. In addition to methotrexate, the DMARDs include azathioprine (Imuran®), cyclosporine (Neoral®), hydroxychloroquine (Plaquenil®), auranofin (Ridura®), leflunomide (Arava®) and sulfasalazine (Azulfidine®). The biologic response modifiers include etanercept (Enbrel®), adalimumab (Humira®), golimumab (Simponi®), tocilizumab (Actemra®), certolizumab (Cimzia®), infliximab (Remicoid®), abatacept (Orencia®), and rituximab (Rituxan®). They are often prescribed in combination with DMARDs such as methotrexate. Because biologics work by suppressing the immune system, they could be problematic for patients who are prone to frequent infection.

Competition in the OAB market includes Pfizer's Detrol® LA (tolterodine extended release capsules) (33% of RXs), followed closely by the generic forms of oxybutynin tablets (32%), GSK/Astellas' Vesicare® (sofenicin tablets) (17%), and Warner Chilcott's Enablex® (darifenacin extended release tablets) (9%). Other products in the category include Pfizer's Toviaz® (fesoteridine tablets), Allergan's Sanctura XR® (trospium extended release capsules), and Watson's transdermal products, Gelnique® (oxybutynin gel) and Oxytrol® (oxybutynin patch).

## Research and Development

We currently perform clinical development work primarily in our Ewing, NJ corporate location for our own portfolio of products. 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 above.

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

**Anturol®.** Anturol® (oxybutynin gel) is in development for the treatment of symptoms associated with OAB. Anturol's delivery system is based on our proprietary ATD™ Gel technology, which is a clear, odorless, hydroalcoholic gel that provides sustained 24 hour transdermal delivery of oxybutynin after a single, daily application. Oxybutynin belongs to the anticholinergic class of compounds and binds specifically to muscarinic receptors. These compounds relax smooth muscles, such as the detrusor muscle in the bladder, thus decreasing bladder contractions. When given orally, oxybutynin undergoes extensive first pass metabolism in the gut and liver to an active metabolite, desethyloxybutynin (DEO). DEO is thought to be a primary contributor to the anticholinergic side effects such as dry mouth and constipation associated with oral oxybutynin. By delivering oxybutynin transdermally, first-pass gastric and hepatic metabolism is avoided, which is believed to result in lower anticholinergic side effects compared to orally administered oxybutynin. These side effects are thought to account for a significant level of patient non-compliance among existing oral OAB treatments. We believe that Anturol® may improve the systemic availability of oxybutynin with relatively less formation of DEO, thus resulting in decreased incidence of adverse events relative to the rate experienced by patients taking comparable oral oxybutynin products. In addition, Anturol® may be more cosmetically appealing than oxybutynin patches, with less skin irritation.

In December 2010, we submitted a NDA for Anturol® with the FDA. The NDA submission, subject to acceptance by FDA, was supported by a Phase III clinical trial conducted under a Special Protocol Assessment (SPA) with FDA. The trial was a double blind, randomized, parallel placebo-controlled multi-center study that evaluated the efficacy and safety of Anturol® in over 600 subjects with overactive bladder. The primary objective of the study was to demonstrate that daily treatment of 56mg or 84mg dose of oxybutynin applied in the ATD™ Gel technology for 12 weeks was superior to placebo for the relief of OAB symptoms. The study met its primary

endpoint of a statistically significant reduction in urinary incontinence episodes for both doses studied (56 mg daily or 84 mg daily,  $p=0.028$  and  $0.033$  respectively).

Secondary end points in the Phase III study included changes from baseline in average daily urinary frequency, void volume, patient perceptions, as well as safety and tolerability including skin irritation. Although not the basis for approval, the 84 mg dose provided highly statistically significant results for the secondary end points of urinary frequency and volume while the 56 mg dose did not reach statistical significance. Additionally, Anturol<sup>®</sup> was well tolerated in the study. No serious adverse events related to the treatment were reported. Anticholinergic side effects such as dry mouth and constipation were low and CNS (central nervous system) side effects were comparable to placebo. Treatment-related adverse events that resulted in study discontinuation during the double-blind period were low and similar for both the treatment and placebo groups.

In addition, an Open Label Extension (“OLE”) to the Phase III study evaluating long term safety was successfully completed in the fourth quarter of 2010. The OLE portion of the study was a 24-week, multi-center evaluation of the safety of topically administered oxybutynin gel (84 mg oxybutynin). There were 77 patients enrolled in the OLE portion of the study. The administration of 84 mg oxybutynin was safe and well tolerated and there were no clinically meaningful changes in vital signs, laboratory values, or ECG examinations over the course of the 24 weeks. These results are similar to those observed in the 84 mg oxybutynin treatment group in the double-blind portion of the study.

We are currently awaiting the determination by the FDA if the NDA was accepted for filing after having received a waiver of the \$1.5 million user fee in February 2011.

***Device Development Projects.*** We are engaged in research and development activities related to our Vibex<sup>™</sup> disposable pressure assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex<sup>™</sup> system for a product containing epinephrine and for an undisclosed product and for our pen injector device for two undisclosed products. We are also developing a Vibex<sup>™</sup> MTX auto injector for delivery of methotrexate for treatment of rheumatoid arthritis. Our pressure assisted auto injectors are designed to deliver drugs by injection from single dose prefilled syringes. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. 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 following is a summary of the development stage for the four products in development with Teva.

#### Vibex<sup>™</sup> with Epinephrine

We have designed the Vibex<sup>™</sup> for a product containing epinephrine and are currently scaling up the commercial tooling and molds for this product. During 2009, we received approximately \$4,000,000 from Teva for this tooling as well as other development work for this program. In 2010, we recognized revenue of approximately \$1,500,000 for work performed for Teva. From a regulatory standpoint Teva filed this product as an ANDA, and the FDA accepted the filing as such. Currently, Teva is conducting its own development work on the drug. An amendment to the ANDA is expected to be filed with the FDA and then the FDA is expected to complete its review of the ANDA, the timing of which is completely dependent on the FDA.

#### Vibex<sup>™</sup> undisclosed product

We have designed the Vibex<sup>™</sup> for the second undisclosed product and have completed the majority of the commercial tooling and molds for the product. From a regulatory standpoint Teva filed the product as an abbreviated new drug application (“ANDA”) and the FDA rejected the filing as such. The FDA’s rejection was based primarily on the opinion that the device was sufficiently different than the innovator’s device not to warrant an ANDA. We redesigned the device to address the FDA’s concern of device similarity and submitted the new device to the FDA. During 2010 the FDA reactivated the ANDA file and is currently completing its review of the ANDA.



### Disposable pen injector #1

We have designed the pen injector and provided clinical supplies for the first pen injector product to Teva. We have not completed any commercial tooling to date. From a regulatory standpoint Teva has conducted a bioequivalence study for the product and determined the appropriate regulatory pathway is a 505(b)(2). The FDA has requested additional clinical work be conducted in support of the filing. Teva is currently determining the clinical design and cost for this program.

### Disposable pen injector #2

We are currently working on prototype designs for the second pen injector product. Teva believes the regulatory pathway for this product is an ANDA pathway. Currently Teva has initiated the development program and is expecting to file an ANDA in the next 12 to 18 months.

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 2011, but the timing and extent of near-term future development will be dependent on decisions made by Teva.

### Vibex™ MTX

Vibex™ MTX is our proprietary, wholly owned methotrexate injection system designed for rapid self-administration. Vibex™ MTX is engineered to enable patients to self-inject reliably, comfortably, and conveniently at home. It is designed to enhance safe use with an integrated, shielded needle and lockout system which prevents accidental needle sticks after use. We have conducted in vivo pre-clinical studies which demonstrated reproducible pharmacokinetics and good injection site tolerance when methotrexate was delivered using the Vibex™ technology. In December 2010 we filed an investigational new drug (“IND”) application with the FDA and in February 2011 the first patient was dosed in a clinical study which will evaluate several dose strengths delivered with the Vibex™ MTX system versus a conventional needle and syringe. Vibex™ MTX is protected by several issued and pending patents.

See Research and Development Programs 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.

## **Manufacturing**

We do not have the facilities or capabilities to commercially manufacture any of our products and 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 Anturool® 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 Anturool® gel in a manner that may meet FDA requirements. The FDA has not approved the manufacturing processes for Anturool® at Patheon at this time. We have completed commercial scale up activities associated with Anturool® manufacturing required for the NDA. We anticipate the FDA will perform a site visit of Patheon during 2011 in connection with the review of the Anturool® NDA.

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 needle-free device for all of our partners. 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.

We have contracted with Uman Pharma (Montreal, Canada) to supply clinical and commercial quantities of methotrexate for the U.S and Canadian markets for our Vibex™ MTX product.

## Sales and Marketing

We expect to currently market most of our products through other more established pharmaceutical 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 will consider developing commercial capabilities.

During 2010, 2009 and 2008, international revenue accounted for approximately 48%, 47% and 74% of total revenue. Europe accounted for 94%, 94% and 93% of international revenue in 2010, 2009 and 2008, with the remainder coming primarily from Asia. Ferring accounted for 45%, 39% and 60% of our worldwide revenues in 2010, 2009 and 2008. Teva accounted for 44%, 38% and 2% of our worldwide revenues in 2010, 2009 and 2008 and BioSante accounted for 4%, 2% and 12% of our worldwide revenues in 2010, 2009 and 2008. Revenue from Ferring and Teva resulted from sales of injection devices and related disposable components for their hGH formulations. Revenue from Teva also included development revenue related to license agreements with Teva for our Vibex™ system and for our pen injector device. In 2008, 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 Results of Operations – Revenues in Part II, Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – for a discussion of our products and services revenues and Note 13 to the Consolidated Financial Statements for revenues by geographic area.

## Collaborative Arrangements and License Agreements

The following table describes existing pharmaceutical and device relationships and license agreements:

Partner	Drug	Market Segment	Product
Ferring	hGH (Zomacton®) (4mg formulation)	Growth Retardation (U.S., Europe, Asia & Pacific)	Needle Free Zomajet® 2 Vision
Ferring	hGH (Zomacton®) (10 mg formulation)	Growth Retardation (U.S., Europe, Asia & Pacific)	Needle Free Zomajet® Vision X
Teva	hGH (Tev-Tropin®)	Growth Retardation (United States)	Needle Free Tjet®
JCR	hGH	Growth Retardation (Japan)	Needle Free Twin-Jector® EZ II
Teva	Epinephrine	Anaphylaxis (U.S. and Canada)	Auto Injector Disposable Device
Teva	Undisclosed Product	Undisclosed (United States)	Auto Injector Disposable Device
Teva	Undisclosed Product #1	Undisclosed (North America, Europe & others)	Disposable Pen Injector Device
Teva	Undisclosed Product #2	Undisclosed (North America, Europe & others)	Disposable Pen Injector Device
BioSante	Estradiol (Elestrin®)	Hormone replacement therapy (North America, other countries)	ATD™ Gel
	Testosterone (LibiGel®)	Female sexual dysfunction (North America, other countries)	ATD™ Gel
Population Council	Nestorone®/Estradiol NestraGel™	Contraception (Worldwide)	ATD™ Gel
Ferring	Undisclosed	Undisclosed (Worldwide)	ATD™ Gel

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 an upfront payment 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<sup>®</sup>. BioSante received an upfront payment from Bradley which triggered a payment to us of \$875,000. In December 2006, the FDA approved Elestrin<sup>®</sup> for marketing 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<sup>®</sup>. Bradley was acquired by Nycomed Inc. in February 2008 and returned Elestrin<sup>®</sup> to BioSante. In December 2008, Elestrin<sup>®</sup> 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<sup>®</sup> as well as potential sales-based milestone payments.

BioSante is developing LibiGel<sup>®</sup>, a transdermal testosterone gel for the treatment of female sexual dysfunction. LibiGel<sup>®</sup> is currently in a Phase 3 clinical study. If LibiGel<sup>®</sup> is approved by the FDA, we are entitled to royalty payments from sales of LibiGel<sup>®</sup> and 25% of any upfront or milestone payments received by BioSante.

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 2004, JCR initiated a campaign to broaden its marketing efforts for human growth hormone under a purchase agreement with our needle free injector.

In November 2005, we signed an agreement with Teva, under which Teva is obligated to purchase all of its injection delivery device requirements from us for an undisclosed product to be marketed in the United States. Teva 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 Teva. Pursuant to the agreement; Teva is obligated to purchase all of its delivery device requirements from us for an epinephrine auto injector product to be marketed in the United States and Canada. We received an upfront cash payment, and will receive 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 2009 the agreement was again amended providing for payment of capital equipment and other development work.

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<sup>®</sup>, by using the Population Council’s patented compound 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 have received milestone fees and royalty payments on Teva's net sales of hGH, as well as a purchase price for each device sold.

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. In January 2011, this agreement was amended to provide payments to us for capital equipment and other development work, some of which was initiated in the fourth quarter of 2010.

In November 2009 we entered into a license agreement with Ferring under which we licensed certain of our patents and agreed to transfer know-how for our transdermal gel technology for certain pharmaceutical products. Under this agreement, we received an upfront payment, milestone payments and will receive additional milestone payments as certain defined milestones are achieved.

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.

### **Seasonality of Business**

We do not believe our business, either device or pharmaceutical, is subject to seasonality. We are subject to and affected by the business practices of our pharmaceutical/device partners. Inventory practices of our partners may subject us to product sales fluctuations quarter to quarter or year over year. Additionally, development revenue we derive from our partners is subject to fluctuation based on the number of programs being conducted by our partners as well as delays or lack of funding for those programs.

### **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 2026. In addition to issued patents and patent applications, we are also protected by trade secrets in all of our technologies.

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.

### **Government Regulation**

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, manufacturing shut downs, 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. 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. Phase II involves studies in a limited patient population, typically patients with the conditions needing treatment, to evaluate preliminarily the efficacy of the product for specific, targeted indications; determine dosage tolerance and optimal dosage; and identify possible adverse effects and safety risks.

Pivotal or Phase III adequate and well-controlled trials are undertaken in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for the purpose of registering the new drug. The FDA may suspend or terminate clinical trials at any point in this process if it concludes that patients are being

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

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

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.

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 drug equivalent can be marketed. We seek approval for such products by submitting an ANDA to the FDA. When processing an ANDA, the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. "Bioavailability" indicates the extent of absorption of a drug product in the blood stream. "Bioequivalence" 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.

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.

Our drug products such as Anturo<sup>®</sup> gel and Nestorone<sup>®</sup> gel, as well as our products being developed by our partners are subject to the above regulations. Anturo<sup>®</sup> and Nestorone<sup>®</sup> will be subject to the NDA process. Device combination products developed by us, such as Vibex<sup>™</sup> MTX, and being developed by our partner Teva are subject to the sNDA, ANDA and 505(b)(2) regulations cited above, as well as the device approval process below.

### 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 an NDA, 505(b)(2) or a Product License Application (“PLA”). Combination drug/device products raise unique scientific, technical and regulatory issues. The FDA has established an Office of Combination Products (“OCP”) to address the challenges associated with the review and regulation of combination products. The OCP assists in determining strategies for the approval of drug/delivery combinations and assuring 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.

An 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; an 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 Vision<sup>™</sup> 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 an sNDA 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. Teva launched the Tjet<sup>®</sup> device in August of 2009 for use in delivery of Teva's form of hGH, Tev-Tropin<sup>®</sup>, following the approval of the hGH sNDA in June 2009.

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 (a certification indicating that a product has met EU consumer safety, health or environmental requirements) 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.

## **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 4, 2011, we had 21 full-time employees, of whom 20 are in the United States. Of the 21 employees, 13 are primarily involved in research, development and manufacturing activities, two are primarily involved in business development and commercialization, with the remainder engaged in executive and administrative capacities. Although we believe that we are appropriately sized to focus on our mission, we intend to add personnel with specialized expertise, as needed.

We believe that we have been successful to date in attracting skilled and experienced scientific and business professionals. We consider our employee relations to be good, and none of our employees are represented by any labor union or other collective bargaining unit.

## **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.antaespharma.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 the “Company,” “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 \$6,091,198 and \$10,290,752 in the fiscal years ended 2010 and 2009, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2010 of \$136,973,795. 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 2009, we completed a registered direct offering of our common stock and warrants in which we received aggregate gross proceeds of \$8,500,000. In September of 2009, we received gross proceeds of \$3,000,000 from an additional registered direct offering of common stock and warrants. In September 2009, we used approximately \$3,000,000 of the stock sales proceeds to pay down an existing credit facility. In addition, we received proceeds from warrant and stock option exercises of \$2,463,419 and \$105,622 in 2010 and 2009, respectively. If additional capital is needed in the near term to support operations, economic and market conditions may make it difficult to raise additional funds through debt or equity financings.

At December 31, 2010 we had cash and cash equivalents of \$9,847,813. 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 at least the next 12 months, we may need to pursue a financing or reduce expenditures as necessary to meet our cash requirements. 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 personnel reductions or curtail or discontinue development programs. 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.

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:

- timing of our partners’ development, regulatory and commercialization plans;
- the demand for our technologies from current and future biotechnology and pharmaceutical partners;
- our ability to manufacture products efficiently, at the appropriate commercial scale, and with the required quality;
- our ability to increase and continue to outsource manufacturing capacity to allow for new product introductions;
- the level of product competition and of price competition;
- 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 ability to obtain regulatory approvals;
- our ability to attract the right personnel to execute our plans;
- our ability to develop, maintain or acquire patent positions;
- our ability to control costs; and
- general economic conditions.

*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 such as Teva 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. 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 the FDA, potentially delaying product launches.

*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, 2010, we derived approximately 45% of our revenue from Ferring and 44% from Teva. For the year ended December 31, 2009, we derived approximately 39% of our revenue from Ferring and 38% from Teva. The revenue from Ferring was primarily product sales and royalties. The revenue from Teva was product sales, royalties and license and development revenue.

The loss of either 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. To date we have received FDA approval of one of those products, the Tjet<sup>®</sup> needle-free device for use with hGH. Teva is currently marketing the Tjet<sup>®</sup> device to its patients and we expect product sales and royalties from this product into the future. Although certain upfront and milestone payments have been received for the other programs with Teva, timelines have been extended and there can be no assurance that there ever will be commercial sales or future milestone payments under these other agreements.

In June 2000, we entered into an exclusive agreement to license four applications of our drug-delivery technology to BioSante. BioSante is using the licensed technology for the development of hormone replacement therapy products that include LibiGel<sup>®</sup> (transdermal testosterone gel) in Phase 3 clinical development for the treatment of FSD, and Elestrin<sup>®</sup> (estradiol gel) for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, and currently marketed in the U.S. Under the agreement an upfront payment, development milestones and royalties on product sales are to be paid to us. We also receive a portion of any sublicense fees received by BioSante. Although certain payments from sublicense arrangements have been received and royalties for Elestrin<sup>®</sup> have been received, there can be no assurance that we will ever receive payments of any kind in connection with LibiGel<sup>®</sup>.

*Part of our business model is to be 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 develop on our own. 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 are currently developing Vibex™ MTX with a view to potentially market this product ourselves. There is no guarantee the clinical development will be successful or if successful that we will market the product effectively.

*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 Anturool<sup>®</sup>, which is currently in development for overactive bladder, or any other of our future drug candidates. We must contract with manufacturers to produce Anturool<sup>®</sup> according to government regulations. Our future development and delivery of our product candidates depends on the timely, profitable and competitive performance of these manufacturers. A limited number of manufacturers exist which are capable of manufacturing our product candidates. We may fail to contract with the necessary manufacturers or we may contract with manufactures on terms that may not be favorable to us. Our manufacturers must obtain FDA approval for their manufacturing processes, and we have no control over this approval process. 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 and commercial quantities of Anturool<sup>®</sup> 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 and commercial quantities of Anturool<sup>®</sup> in a manner that meets FDA requirements. The FDA has not yet approved the manufacturing processes of Patheon for Anturool<sup>®</sup>. 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 Anturool<sup>®</sup> gel or oxybutynin.

We have contracted with Uman Pharma (Montreal, Canada) to supply clinical and commercial quantities of syringes containing methotrexate for the U.S and Canadian markets. Uman Pharma contracts with a commercial supplier of pharmaceutical chemicals to supply them with methotrexate. If Uman Pharma or its supplier of methotrexate fails to achieve or maintain compliance with FDA standards, our development timelines could be delayed since we do not currently have approved secondary manufacturers.

*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 may necessitate 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 needle-free devices and certain related disposable

component parts for our partners Teva, Ferring and JCR. 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.

*If transdermal gels do not achieve greater market acceptance, we may be unable to continue to sell them.*

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 such as the testosterone replacement market. 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 marketing of this potential product. However, we may be unsuccessful in partnering Anturol® which may delay or affect the timing of the potential product launch due to availability of resources if Anturol® is ultimately approved by the FDA.

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

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<sup>®</sup>, for which we receive royalties from our partner based on any commercial sales, was launched in June 2007. Since it is not our product, we have no way of knowing at this time if health insurance companies' reimbursement has negatively impacted patient use of Elestrin<sup>®</sup>. The sales of Elestrin<sup>®</sup> continue to be modest.

Our Tjet<sup>®</sup> device was launched in the U.S. in 2009 for use with hGH by Teva. Although Teva currently provides the device and disposables at no cost to the patient, the amount of health insurance reimbursement of Teva's hGH, Tev-Tropin<sup>®</sup>, has a direct impact on the device product sales and royalty due from Teva to us.

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

One of our business pathways requires us to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use and marketing of drug delivery technologies with specific drug therapies. Under these arrangements, the partner companies typically assist us in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. Our licensees may also be responsible for distribution and marketing of the technologies for these drug therapies either worldwide or in specific territories. We are currently a party to a number of such agreements, all of which are currently in varying stages of development. We may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product) and thus, would not receive the fees expected from such arrangements, related future royalties or product sales. Moreover, there can be no assurance that we will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of our drug delivery technologies. In such event, our business, results of operations and financial condition could be adversely affected, and our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability. As a result of our collaborative agreements, we are dependent upon the development, data collection and marketing efforts of our licensees. The amount and timing of resources such licensees devote to these efforts are not within our control, and such licensees could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug or drug device covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales of our drug delivery technology. We are relying on partners such as Teva, Ferring and BioSante 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.

*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, injector device 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. 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, Ipsomed, Owen Mumford, Elcam, SHL, Bioject Medical Technologies, Inc., Auxillium, Aradigm, Zogenix, Inc., NexMed, Inc. and West Pharmaceuticals, 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<sup>®</sup>) for OAB in January 2008 and in January 2009 Gelnique was approved by the FDA. Watson's launch of their oxybutynin gel is well ahead of Anturol's potential launch which may limit the success of Anturol<sup>®</sup> 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 have 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<sup>®</sup>). 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<sup>®</sup> is approved, we may be delayed in our marketing of Anturol<sup>®</sup> or incur significant expenses defending our patent position which may adversely affect the potential market value of Anturol<sup>®</sup>.

In November 2008, Meridian Medical Technologies ("Meridian") received U.S. Patent 7,449,012 ("the '012 patent") relating to a specific type of auto injector for use with epinephrine. The '012 patent is set to expire in September 2025. The '012 patent was listed in FDA's Orange Book in July 2009 under the EpiPen<sup>®</sup> NDA. On July 21, 2009, Meridian and King Pharmaceuticals, Inc. ("King") received a copy of Paragraph IV certification from Teva giving notice that it had filed an ANDA to commercialize an epinephrine injectable product and referring to our auto injector device and challenging the validity and alleging non-infringement of the '012 patent. On August 28, 2009, King and Meridian filed suit against Teva in the U.S. District Court for the District of Delaware asserting its '012 patent. On October 21, 2009, Teva filed its answer asserting non-infringement and invalidity of the '012 patent. A claim construction hearing is set for September 15, 2011 and trial is currently set for February 16, 2012. The parties are in the midst of fact discovery.

In September 2010, King received U.S. Patent No. 7,794,432 ("the '432 patent") relating to certain features of an auto injector for use with epinephrine. The '432 patent is set to expire in September 2025. The '432 patent was listed in FDA's Orange Book in September 2010 under the EpiPen<sup>®</sup> NDA.

In November 2010, Meridian and King received a copy of Paragraph IV certification from Teva challenging the validity and alleging non-infringement of the '432 patent. King and Meridian filed an amended complaint, in the same litigation as the '012 patent, adding the '432 patent. On January 28, 2011, Teva filed its answer asserting non-infringement and invalidity of the '432 patent. We understand that Teva is challenging both the '012 and '432 patents in litigation, but litigation inherently presents risk and there can be no assurance that Teva will prevail in the litigation or that the result will not have a material adverse effect on our potential launch of this product or revenues.

*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, particularly in the product development area. 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 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.

*If we or our third-party manufacturer are unable to supply Ferring with our devices pursuant to our current device 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.

### **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 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<sup>®</sup> for the treatment of overactive bladder (OAB). Anturol<sup>®</sup> is the anticholinergic oxybutynin delivered by our proprietary ATD<sup>™</sup> 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.

Under a special protocol assessment (“SPA”) with the FDA (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 an NDA) we have conducted a pivotal safety and efficacy trial of Anturol<sup>®</sup> for OAB. The three arm study enrolled approximately 600 patients for a 12-week clinical trial. The randomized, double-blind, placebo controlled, multi-center trial principally evaluated the efficacy of Anturol<sup>®</sup> when administered topically once daily for 12 weeks. The primary end point of the trial was 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. In March of 2010 we announced that enrollment in the Phase III study was complete. In July 2010, we announced positive results from the Phase III study. The study met its primary endpoint of a statistically significant reduction in urinary incontinence episodes for both doses studied (56 mg daily or 84 mg daily). In addition, an Open Label Extension study, evaluating long term safety was successfully completed in Q4 2010. In December 2010, we announced the filing of an NDA with the FDA. In February 2011, we received a waiver of the \$1.5 million NDA filing fee. The FDA typically issues notice of acceptance within 60 days of issuing the fee waiver. However, there is no assurance the FDA will accept the filing of the NDA. Additionally, the acceptance of the NDA (if accepted) does not ensure the FDA will accept the results of the trial. The FDA may require further studies for approval. We may never receive FDA approval for Anturol<sup>®</sup> and without FDA approval we cannot market or sell Anturol<sup>®</sup> in the U.S. 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 may be 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 December 2008, one of our device partners, Teva, filed an ANDA for their epinephrine product. The ANDA submission was accepted by the FDA. Teva is in the process of completing the work required for the submission. The submission of the ANDA does not ensure that the FDA will approve the filing and without FDA approval we cannot market or sell our injector for use with this drug product in the U.S.

In 2007, our partner Teva filed a second injector device with an undisclosed product as an ANDA and the FDA rejected such filing. The FDA's rejection was based primarily on the opinion that the device was sufficiently different than the innovator's device not to warrant an ANDA. We redesigned the device to address the FDA's concern of device similarity and submitted the new device to the FDA. During 2010 the FDA reactivated the ANDA file and is currently completing its review of the ANDA. The reactivation of the ANDA does not ensure that the FDA will approve the filing and without FDA approval we cannot market or sell our injector for use with this drug product in the U.S.

As part of our device regulatory strategy, we have filed two MAFs with the FDA. These MAFs are reviewed as part of a product application review. Amendments are made to the MAFs 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 drug/device combination 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 drug/device combination products 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 drug/device combination 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. 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 and drug/device combination 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 the 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. Such was the case for the approval of our needle-free device for use with hGH. The approval process took much more time than contemplated, which resulted in lost revenues.

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 4, 2011, we have warrants outstanding that are exercisable, at prices ranging from \$0.80 per share to \$3.78 per share, for an aggregate of approximately 10,900,000 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 7,500,000 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 4, 2011, our officers and directors beneficially owned an aggregate of approximately 16,800,000 shares (or approximately 18%) of our outstanding 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, laboratory and manufacturing space in Plymouth, a suburb of Minneapolis, Minnesota. The lease will terminate in August 2016. We believe the facilities will be sufficient to meet our requirements through the lease period at this location.

We also lease a small amount of office space in Muttenz, Switzerland. The lease is month-to-month and requires a three month notice prior to termination. 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. (REMOVED AND RESERVED).*

## 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 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.

	<u>High</u>	<u>Low</u>
<b>2010:</b>		
First Quarter	\$ 1.55	\$ 1.07
Second Quarter	\$ 2.00	\$ 1.42
Third Quarter	\$ 1.85	\$ 1.32
Fourth Quarter	\$ 1.79	\$ 1.36
<b>2009:</b>		
First Quarter	\$ 0.48	\$ 0.36
Second Quarter	\$ 1.06	\$ 0.40
Third Quarter	\$ 1.21	\$ 0.76
Fourth Quarter	\$ 1.27	\$ 1.07

#### Common Shareholders

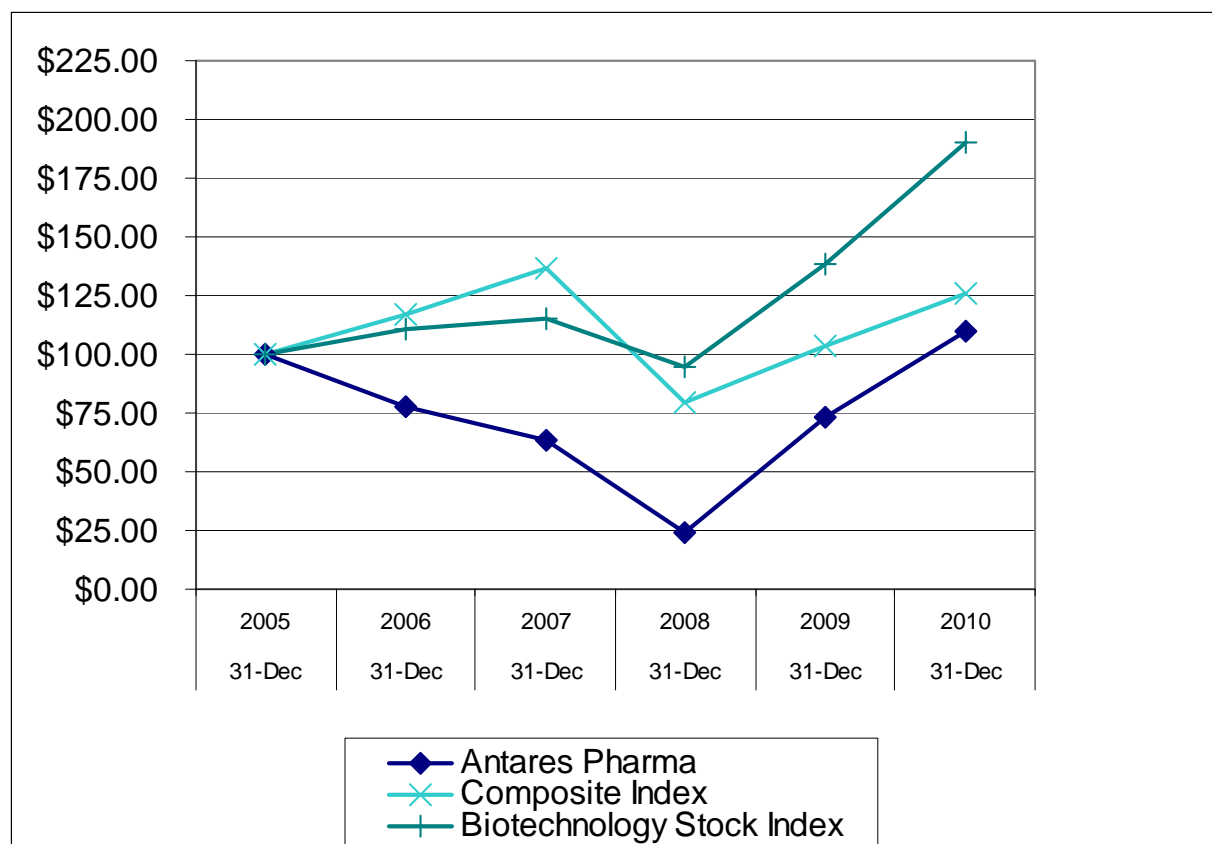
As of March 4, 2011, we had 98 shareholders of record of our common stock as well as approximately 3,000 shareholders in street name.

#### 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.

## 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, 2005, through December 31, 2010. 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, 2005 (based upon the closing price of each). Total Return assumes reinvestment of dividends.



	December 31, 2005	December 31, 2006	December 31, 2007	December 31, 2008	December 31, 2009	December 31, 2010
Antares Pharma, Inc.	\$ 100.00	\$ 77.42	\$ 63.23	\$ 23.87	\$ 73.55	\$ 109.68
Amex Composite Index	100.00	116.90	136.98	79.45	103.74	125.54
Amex Biotechnology Stock Index	100.00	110.77	115.51	95.04	138.36	190.57



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).

	<u>At December 31,</u>				
	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 9,848	\$ 13,559	\$ 13,096	\$ 9,759	\$ 2,706
Short-term investments	-	-	-	16,301	4,953
Working capital	5,804	8,307	7,537	21,891	5,979
Total assets	15,141	19,143	19,911	30,217	11,534
Long-term liabilities, less current maturities	1,843	2,051	5,297	7,295	3,556
Accumulated deficit	(136,974)	(130,883)	(120,592)	(107,901)	(99,322)
Total stockholders' equity	6,627	8,851	7,243	17,499	5,080
	<u>Year Ended December 31,</u>				
	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
<b>Statement of Operations Data:</b>					
Product sales	\$ 5,774	\$ 3,506	\$ 3,350	\$ 3,211	\$ 2,195
Development revenue	2,127	2,607	541	956	594
Licensing fees	2,856	1,595	1,238	3,231	1,254
Royalties	<u>2,062</u>	<u>603</u>	<u>532</u>	<u>459</u>	<u>225</u>
Revenues	<u>12,819</u>	<u>8,311</u>	<u>5,661</u>	<u>7,857</u>	<u>4,268</u>
Cost of revenues (1)	4,273	4,140	2,020	3,442	1,556
Research and development	8,803	7,903	7,866	5,362	3,778
Sales, marketing and business development	1,035	1,051	1,625	1,641	1,350
General and administrative (2)	<u>4,734</u>	<u>4,911</u>	<u>6,348</u>	<u>6,058</u>	<u>5,861</u>
Operating expenses	<u>14,572</u>	<u>13,865</u>	<u>15,839</u>	<u>13,061</u>	<u>10,989</u>
Operating loss	(6,026)	(9,694)	(12,198)	(8,646)	(8,277)
Net other income (expense)	<u>(65)</u>	<u>(597)</u>	<u>(492)</u>	<u>67</u>	<u>177</u>
Net loss	(6,091)	(10,291)	(12,690)	(8,579)	(8,100)
Deemed dividend to warrant holder	-	-	-	-	(99)
Net loss applicable to common shares	<u>\$ (6,091)</u>	<u>\$ (10,291)</u>	<u>\$ (12,690)</u>	<u>\$ (8,579)</u>	<u>\$ (8,199)</u>
Net loss per common share (3) (4)	<u>\$ (0.07)</u>	<u>\$ (0.14)</u>	<u>\$ (0.19)</u>	<u>\$ (0.14)</u>	<u>\$ (0.16)</u>
Weighted average number of common shares	<u>83,170</u>	<u>73,489</u>	<u>67,233</u>	<u>59,605</u>	<u>51,582</u>

(1) In 2007 we recorded non-cash impairment of prepaid license discount and related charges of \$1,439.

(2) In 2007 and 2006 we recorded non-cash patent impairment charges of \$296 and \$139, 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" and "Forward-Looking Statements in Management's Discussion and Analysis."*

**Forward-Looking Statements in Management's Discussion and Analysis**

Management's discussion and analysis of the significant changes in the consolidated results of operations, financial condition and cash flows of the Company is set forth below. Certain statements in this report may be considered to be "forward-looking statements" as that term is defined in the U.S. Private Securities Litigation Reform Act of 1995, such as statements that include the words "expect," "estimate," "project," "anticipate," "should," "intend," "probability," "risk," "target," "objective" and other words and terms of similar meaning in connection with any discussion of, 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:

- the impact of new accounting pronouncements;
- our expectations regarding the product development, manufacturing and partnering of Anturo1®;
- our expectations regarding continued product development with Teva;
- our plans regarding potential manufacturing and marketing partners;
- our future cash flow;
- our expectations regarding the year ending December 31, 2011; and
- our ability to raise additional financing, reduce expenses or generate funds in light of our current and projected level of operations and general economic conditions.

The words "may," "will," "expect," "intend," "anticipate," "estimate," "believe," "continue," and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements involve known and unknown risks, uncertainties and achievements, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

- delays in product introduction and marketing or interruptions in supply;
- our ability to partner Anturo1®;
- a decrease in business from our major customers and partners;
- our inability to compete successfully against new and existing competitors or to leverage our marketing capabilities and our research and development capabilities;
- our inability to obtain additional financing, reduce expenses or generate funds when necessary;

- our inability to attract and retain key personnel;
- adverse economic and political conditions; and
- our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers.

In addition, you should refer to the “Risk Factors” section of this Form 10-K report for a discussion of other factors that may cause our actual results to differ materially from those described by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained in this report will prove to be accurate and, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

We encourage readers of this report to understand forward-looking statements to be strategic objectives rather than absolute targets of future performance. Forward-looking statements speak only as of the date they are made. We do not intend to update publicly any forward-looking statements to reflect circumstances or events that occur after the date the forward-looking statements are made or to reflect the occurrence of unanticipated events except as required by law. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, if at all.

The following discussion and analysis, the purpose of which is to provide investors and others with information that we believe to be necessary for an understanding of our financial condition, changes in financial condition and results of operations, should be read in conjunction with the financial statements, notes and other information contained in this report.

## **Overview**

Antares Pharma, Inc. is an emerging pharma company that focuses on self-injection pharmaceutical products and technologies and topical gel-based products. Our subcutaneous and intramuscular injection technology platforms include Vibex™ disposable pressure-assisted auto injectors, Vision™ reusable needle-free injectors, and disposable multi-use pen injectors. We currently view pharmaceutical and biotechnology companies as our primary customers.

In the injector area, we have licensed our reusable needle-free injection device for use with hGH to Teva, Ferring and JCR. In August 2009, we announced that Teva launched its Tjet® injector system, which uses our needle-free device to administer Teva’s Tev-Tropin® brand hGH. Primarily as a result of the Teva launch, our product sales increased to approximately \$5,800,000 in 2010 compared to \$3,500,000 in 2009 and our royalties increased to approximately \$2,100,000 in 2010 compared to \$600,000 in 2009. We have also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories. In 2009, we received a payment of \$4,076,375 from Teva for tooling and for an advance for the design, development and purchase of additional tooling and automation equipment, all of which is related to a fixed, single-dose, disposable injector product containing epinephrine using our Vibex™ auto injector platform. In addition, we continue to support existing customers of our reusable needle-free devices for the administration of insulin in the U.S. market through distributors.

In the gel-based area, we filed an NDA in December 2010 for AnturoI®<sup>®</sup>, an oxybutynin ATD™ gel for the treatment of OAB. The NDA submission was supported by a Phase 3 clinical trial. Spending on this program was approximately \$4,900,000 in 2010 and was approximately \$13,800,000 over the last three years. We also have a partnership with BioSante that includes LibiGel® (transdermal testosterone gel) in Phase 3 clinical development for the treatment of FSD, and Elestrin® (estradiol gel) currently marketed in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

We have operating facilities in the U.S. and Switzerland. Our U.S. operation manufactures and markets our reusable needle-free injection devices and related disposables, and develops our 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. Our Pharma division is located both in the U.S. and in Muttenz,

Switzerland, where pharmaceutical products are developed utilizing our transdermal systems. Our corporate offices are located in Ewing, New Jersey.

In order to better position ourselves to take advantage of potential growth opportunities and to fund future operations, during 2009 we raised additional capital and took steps to reduce our monthly cash obligations. In the third quarter of 2009, we raised gross proceeds of \$11,500,000 through the sale of shares of our common stock and warrants. We used approximately \$3,000,000 of these proceeds to pay off the remaining balance of our credit facility, eliminating our monthly debt service requirements. In the fourth quarter of 2009, we reduced our monthly overhead when we entered into an Asset Purchase Agreement with Ferring. Under this agreement, Ferring assumed responsibility for all of our facility and equipment lease obligations in connection with our operations in Switzerland, and the majority of our employees at that location were hired by Ferring effective January 1, 2010. Subsequent to the Ferring agreement we entered into a month-to-month facility lease agreement at a new Swiss location in a much smaller space at a significantly reduced monthly rate.

We have reported net losses of \$6,091,198, \$10,290,752 and \$12,690,453 in the fiscal years ended 2010, 2009 and 2008, respectively. We have accumulated aggregate net losses from the inception of business through December 31, 2010 of \$136,973,795. At December 31, 2010 we had a cash balance of \$9,847,813. In the first quarter of 2011, we received proceeds of \$4,863,201 in connection with the exercise of warrants to purchase 3,242,134 shares of our common. We believe that the combination of our current cash balance, the proceeds recently received from the exercise of warrants, our projected product sales, product development revenue, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 12 months.

### **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. In the third quarter of 2009, we elected early adoption of Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2009-13, "Revenue Arrangements with Multiple Deliverables" ("ASU 2009-13") with retrospective application to January 1, 2009. ASU 2009-13, which amended FASB ASC 605-25, "Multiple-Element Arrangements," is effective for arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, but allows for early adoption. ASU 2009-13 requires a vendor to allocate revenue to each unit of accounting in arrangements involving multiple deliverables. It changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when vendor specific objective evidence or third party evidence of selling price is not available. As discussed further in Note 12 to our consolidated financial statements, adoption of this accounting pronouncement in 2009 resulted in the recognition of revenue deferred in prior years of \$481,833 and the recognition of costs previously deferred of \$615,256 in connection with one of our License, Development and Supply Agreements with Teva that became subject to the new accounting pronouncement after a material modification to the agreement occurred. As a result of adoption of ASU 2009-13, deferred revenues and deferred costs associated with this agreement with Teva will be recognized as revenues and expenses earlier than would otherwise have occurred. We also expect revenues and expenses generated in connection with future multiple

element arrangements will often be recognized over shorter periods than would have occurred prior to adoption of ASU 2009-13.

We have a number of arrangements that were not affected by adoption of ASU 2009-13, and the accounting for these arrangements will continue under the prior accounting standards unless an arrangement is materially modified, as defined in the new accounting standard. The prior accounting standards address 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 or inability to establish objective evidence of fair value for the deliverable portions of the contracts significantly impacted the time period over which revenues are being recognized. For instance, if there was no objective fair value of undelivered elements of a contract, then we were 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.

We have deferred significant revenue amounts (\$4,922,656 at December 31, 2010) 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 recognize 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 on reported revenues, and is not meant to be a substitute for accounting or presentation requirements under U.S. generally accepted accounting principles.

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Product sales	\$ 5,773,734	\$ 3,506,510	\$ 3,349,532
Development fees	1,496,161	5,095,125	1,481,254
Licensing fees and milestone payments	974,925	2,272,047	762,500
Royalties	<u>2,061,703</u>	<u>602,816</u>	<u>314,189</u>
Billings received and/or accrued per contract terms	10,306,523	11,476,498	5,907,475
Deferred billings received and/or accrued	(1,240,089)	(6,633,477)	(1,387,380)
Deferred revenue recognized	<u>3,752,264</u>	<u>3,468,041</u>	<u>1,140,616</u>
Total revenue as reported	<u>\$12,818,698</u>	<u>\$ 8,311,062</u>	<u>\$ 5,660,711</u>

#### *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 or asset group. 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.

Each year we 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 are anticipated. No impairment charges were recognized in 2010, 2009 or 2008. The gross carrying amount and accumulated amortization of patents, which are our only intangible assets subject to amortization, were \$1,752,636 and \$949,210, respectively, at

December 31, 2010 and were \$1,665,519 and \$923,120, respectively, at December 31, 2009. The Company's estimated aggregate patent amortization expense for the next five years is \$68,000, \$80,000, \$78,000, \$78,000 and \$78,000 in 2011, 2012, 2013, 2014 and 2015, respectively.

We have \$1,095,355 of goodwill recorded as of December 31, 2010 that relates to our Minnesota operations. We evaluate the carrying amount of goodwill on December 31 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 reporting unit to the carrying amount, including goodwill. If the carrying amount of the Minnesota reporting unit 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 reporting unit 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 reporting unit 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.

In evaluating whether the fair value of the Minnesota reporting unit was below its carrying amount, we used the market capitalization of the Company at December 31, 2010, which was approximately \$143 million, to calculate an estimate of fair value of the Minnesota reporting unit. We determined that the percentage of the total market capitalization of the Company at December 31, 2010 attributable to the Minnesota reporting unit would have to be unreasonably low before the fair value of the Minnesota reporting unit would be less than its carrying amount. In making this determination, we evaluated the activity at the Minnesota reporting unit compared to the total Company activity, and considered the source and potential value of agreements currently in place, the source of recent product sales and development revenue growth, the source of total Company revenue and the source of cash generating activities. After performing the market capitalization analysis and concluding that the fair value of the Minnesota reporting unit was not below its carrying amount, we determined that no further detailed determination of fair value was required.

Our evaluation of goodwill completed during 2010, 2009 and 2008 resulted in no impairment losses.

## **Results of Operations**

*Years Ended December 31, 2010, 2009 and 2008*

### *Revenues*

Total revenue was \$12,818,698, \$8,311,062 and \$5,660,711 for the years ended December 31, 2010, 2009 and 2008, respectively.

Product sales were \$5,773,734, \$3,506,510 and \$3,349,532 for the years ended December 31, 2010, 2009 and 2008, respectively. Product sales include sales of reusable needle-free injector devices and disposable components, and repairs. Our product sales are generated primarily from sales to Ferring and Teva. Ferring uses our needle-free injector with their 4mg and 10mg hGH formulations marketed as Zomajet<sup>®</sup> 2 Vision and Zomajet<sup>®</sup> Vision X, respectively, in Europe and Asia. Teva launched our Tjet<sup>®</sup> needle-free device with their hGH Tev-Tropin<sup>®</sup> in the U.S. in August of 2009. In 2010, 2009 and 2008, revenue from sales of needle-free injector devices totaled \$1,613,988, \$1,291,250 and \$1,045,296, respectively. Sales of disposable components in 2010, 2009 and 2008 totaled \$4,052,206, \$2,131,525 and \$2,201,076, respectively. The 2010 increase in device sales was due to increases in sales to Teva, Ferring and JCR. The 2010 increase in sales of disposable components was primarily a result of an increase in sales to Teva of approximately \$1,050,000 in the first full year of sales following their 2009 launch of our Tjet<sup>®</sup> device, along with an increase of approximately \$790,000 in sales to Ferring. The 2009 increase in device sales and decrease in sales of disposable components was primarily a result of the combination of first year sales to Teva and a decrease in sales to Ferring. In 2009, device sales to Teva exceeded the decrease in device sales

to Ferring, while the decrease in sales of disposable components to Ferring exceeded sales of disposable components to Teva.

Development revenue was \$2,127,033, \$2,606,516 and \$540,557 for the years ended December 31, 2010, 2009 and 2008, respectively. The 2010 and 2009 development revenue was primarily due to auto injector development work under a License, Development and Supply agreement with Teva originally signed in July 2006. In 2009, in connection with an amendment to this License, Development and Supply Agreement, Teva purchased tooling in process from us that had a carrying value of approximately \$1,200,000 and paid us in advance for the design, development and purchase of additional tooling and automation equipment. We received a payment under this amendment in the amount of \$4,076,375, all of which was initially recorded as deferred revenue. Approximately \$1,400,000 and \$1,600,000 of the development revenue recognized in 2010 and 2009, respectively, was related to work done under this Teva agreement, as amended. In 2010, approximately \$250,000 of revenue was recognized in connection with a pen injector development program with Teva. The balance of the revenue in 2010 and 2009 and nearly all of the 2008 revenue was attributable primarily to projects related to our proprietary ATD™ gel technology.

Licensing revenue was \$2,856,228, \$1,595,220 and \$1,238,211 for the years ended December 31, 2010, 2009 and 2008, respectively. The 2010 licensing revenue was primarily due to recognition of revenue deferred in 2009 under an Exclusive License Agreement with Ferring, along with a sales based milestone payment from Teva and milestone payments received from BioSante. Licensing revenue recognized in 2010 and 2009 included approximately \$75,000 and \$350,000, respectively, that had been previously deferred and represents a portion of payments received from Teva under a License, Development and Supply Agreement for a product utilizing our auto injector technology. This revenue was recognized as a result of adopting a new revenue recognition accounting standard, as described in Note 12 to the consolidated financial statements. The licensing revenue in 2009 also included a milestone payment received from Teva in connection with Teva's launch of our Tjet needle-free device with their hGH Tev-Tropin®. In addition, in 2009 we recognized licensing revenue of approximately \$315,000 in connection with a License Agreement with Ferring executed in November 2009, described in more detail in Note 11 to the consolidated financial statements, which included an upfront payment and milestone payments. Also in 2009, approximately \$338,000 of a previously deferred license fee related to our oral disintegrating tablet technology was recognized after the customer terminated the agreement due to technical challenges with their drug molecule. The licensing revenue in 2008 included \$462,500 received under a sublicense arrangement related to an existing license agreement with BioSante related to Elestrin®. 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 \$2,061,703, \$602,816 and \$532,411 for the years ended December 31, 2010, 2009 and 2008, respectively. The increase in royalties in 2010 was due primarily to first year royalties of \$1,404,053 received from Teva in connection with sales of their hGH Tev-Tropin®. Nearly all remaining royalty revenue in 2010 and nearly all royalty revenue in years prior to 2010 was generated under the license agreement with Ferring 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. Royalty revenue in each year also included royalties from JCR on sales of hGH and royalties from BioSante on sales of Elestrin®.

#### *Cost of Revenues and Gross Margins*

The costs of product sales are primarily related to reusable injection devices and disposable components. Cost of product sales were \$2,799,253, \$1,813,385 and \$1,889,317 for the years ended December 31, 2010, 2009 and 2008, respectively, representing gross margins of 52%, 48% and 44%, respectively. Approximately 3% of the gross margin increase in 2010 from 2009 was due to a higher sales volume absorbing overhead costs that were approximately the same each year and 1% of the gross margin increase was due to increased selling prices. The gross margin increase in 2009 from 2008 was primarily due to a 2.8% change resulting from an inventory write-down in 2008, along with a combined impact of 1.2% relating to other factors including selling price increases, changes in the mix of products sold, and variations in exchange rates between the Euro and U.S. Dollar which can affect our gross margins realized on a portion of our product sales to Ferring.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. Cost of development revenue was \$1,473,957, \$2,326,449 and \$130,268 for the years ended December 31, 2010, 2009 and 2008, respectively. The 2010 and 2009 development costs were primarily related to a License, Development and Supply Agreement with Teva for a product utilizing our auto injector technology. Approximately \$246,000 and \$615,000 of the development costs in 2010 and 2009, respectively, were costs deferred prior to 2009 and recognized after adoption of the new revenue recognition accounting standard, as described in Note 12 to our consolidated financial statements. Development costs that were being deferred in connection with the Teva agreement were related to both licensing and development revenue that had been deferred. An additional \$1,000,000 and \$1,300,000 of development costs were recognized in 2010 and 2009, respectively, in connection with revenue recognized related to the Teva agreement. The remaining development costs in 2010 were costs recognized in connection with revenue recognized under a pen injector development program with Teva and projects related to our proprietary ATD™ gel technology. The remaining development costs in 2009 and the development costs in 2008 were attributable primarily to projects related to our proprietary ATD™ gel technology.

### *Research and Development*

The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development. Our most significant projects currently include the following:

- Anturool® oxybutynin gel for treatment of OAB;
- Vibex™ auto injector for delivery of epinephrine for emergency treatment of allergic reactions; and
- Vibex™ MTX auto injector for delivery of methotrexate for treatment of rheumatoid arthritis.

Research and development expenses were \$8,802,502, \$7,902,486 and \$7,866,499 for the years ended December 31, 2010, 2009 and 2008. 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 our transdermal gel products, primarily Anturool®. Expenses associated with the Anturool® Phase III study were approximately \$4,900,000, \$5,200,000 and \$3,800,000 in the years ended December 31, 2010, 2009 and 2008, respectively. The increase in total research and development expenses in 2010 compared to 2009 was due primarily to our Vibex™ MTX development program, other internally funded auto injector development projects and increases in personnel costs due to the addition of two employees. The 2010 expenses were partially offset by the receipt of approximately \$430,000 from the qualifying therapeutic discovery grant program under section 48D of the internal revenue code. Although the total research and development expense in 2009 increased only slightly compared to 2008, the costs directly associated with the Phase III study of Anturool® increased by approximately \$1,400,000, while costs associated with certain other projects decreased.

### *Sales, Marketing and Business Development*

Sales, marketing and business development expenses were \$1,035,017, \$1,051,030 and \$1,624,599 for the years ended December 31, 2010, 2009 and 2008. In 2010, decreases in business development expenses in connection with our Swiss operations as a result of the transaction with Ferring at the end of 2009 were offset by the addition of a senior level business development employee in January of 2010. The decrease in 2009 is primarily due to reductions in payroll costs associated with headcount reductions.

### *General and Administrative*

General and administrative expenses were \$4,734,427, \$4,911,356 and \$6,347,997 for the years ended December 31, 2010, 2009 and 2008. Expense decreases associated with the Swiss operations as a result of the transaction with Ferring at the end of 2009 of approximately \$400,000 were partially offset by increases in other payroll expenses and directors' compensation. The decrease in 2009 compared to 2008 was mainly due to the expense in 2008 associated with a separation agreement with our former Chief Executive Officer, and the hiring of the new Chief Executive Officer in October 2008. The decrease in 2009 compared to 2008 was also impacted by a decrease in overhead costs and patent related expenses.



### *Other Income (Expense)*

Other expense, net, was (\$64,740), (\$597,108) and (\$492,484) for the years ended December 31, 2010, 2009 and 2008. The 2010 net expense was primarily due to \$85,994 of expense that was recognized upon dissolution of one of our foreign subsidiaries in connection with removing the applicable cumulative translation adjustment from other comprehensive income. In 2009, interest income decreased to \$27,270 from \$553,061 in 2008, due to a reduction in market interest rates received on invested funds and a lower average cash balance. Interest expense decreased in 2009 to \$633,459 from \$1,021,675 in 2008 due primarily to a lower average principal balance of our credit facility in 2009 compared to 2008 and due to the retirement of our credit facility in 2009.

### **Liquidity and Capital Resources**

We have reported net losses of \$6,091,198, \$10,290,752 and \$12,690,453 in the fiscal years ended 2010, 2009 and 2008. We have accumulated aggregate net losses from the inception of business through December 31, 2010 of \$136,973,795. 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 2009 we raised additional capital and took steps to reduce our monthly cash obligations.

In July 2009, we raised gross proceeds of \$8,500,000 in a registered direct offering through the sale of shares of our common stock and warrants. We sold a total of 10,625,000 units, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.4 of a share of common stock (or a total of 4,250,000 shares), at a purchase price of \$0.80 per unit. The warrants became exercisable six months after issuance at \$1.00 per share and will expire five years from the date of issuance.

In September 2009, we raised gross proceeds of \$3,000,000 through the sale of 2,727,273 units to certain institutional investors, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.4 of a share of common stock (or a total of 1,090,909 shares), at a purchase price of \$1.10 per unit. The warrants became exercisable six months after issuance at \$1.15 per share and will expire five years from the date of issuance.

The proceeds from the sale of common stock and warrants in September 2009 were used to pay off the remaining balance of our credit facility, reducing our monthly debt service requirements. The credit facility had originated in 2007, when we received gross proceeds of \$7,500,000 in two tranches of \$5,000,000 and \$2,500,000 to help fund working capital needs. The per annum interest rate was 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 was forty-two months from February 2007 and (ii) with respect to the second tranche was thirty-six months from December 2007.

In the fourth quarter of 2009, we reduced our monthly overhead when we entered into an Asset Purchase Agreement with Ferring. Under this agreement, Ferring assumed responsibility for all of our facility and equipment lease obligations in connection with our operations in Switzerland, and the majority of our employees at that location were hired by Ferring effective January 1, 2010. Subsequent to the Ferring agreement we entered into a month-to-month facility lease agreement at a new Swiss location in a much smaller space at a significantly reduced monthly rate.

In 2010, we received proceeds of \$2,463,419 in connection with exercises of options and warrants to purchase shares of our common stock, which resulted in the issuance of 2,176,785 shares of our common stock.

In the first quarter of 2011, we received proceeds of \$4,863,201 in connection with the exercise of warrants to purchase 3,242,134 shares of our common stock. These warrants had an exercise price of \$1.50 and were exercised prior to their expiration date of March 2, 2011. There were 3,502,016 warrants with an exercise price of \$1.50 that expired unexercised on March 2, 2011.

At December 31, 2010 we had cash and cash equivalents of \$9,847,813. We believe that the combination of our current cash and cash equivalents balance and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 12 months. We do not currently have any bank credit lines. In the future, if we need additional financing and are

unable to obtain such financing when needed, or obtain it on favorable terms, we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

#### *Net Cash Used in Operating Activities*

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, general and administrative costs, research and development projects and sales, marketing and business development activities. Net cash used in operating activities was \$6,079,370, \$5,099,560 and \$10,324,412 for the years ended December 31, 2010, 2009 and 2008. Net operating cash outflows were primarily the result of net losses of \$6,091,198, \$10,290,752 and \$12,690,453 in 2010, 2009 and 2008, adjusted by noncash expenses and changes in operating assets and liabilities.

In 2010, the net loss decreased by \$4,199,554 to \$6,091,198 from \$10,290,752 in 2009 primarily as a result of an increase in product gross profit of \$1,281,356, licensing and development gross profit of \$1,634,017, and royalties of \$1,458,887.

In 2009, the net loss decreased by \$2,399,701 to \$10,290,752 from \$12,690,453 in 2008 primarily as a result of an increase in gross profit of \$530,102 and decreases in general and administrative expenses of \$1,436,641 and sales marketing and business development expenses of \$573,569.

Noncash expenses totaled \$1,556,824, \$1,554,876 and \$1,713,321 in 2010, 2009 and 2008. In 2010, a decrease in amortization of debt discount and issuance costs of \$206,519 was offset by increases in stock based compensation of \$118,698 and loss on dissolution of foreign subsidiary of \$85,994. The decrease in 2009 compared to 2008 was primarily due to reductions in depreciation and amortization of \$56,936 and amortization of debt discount and issuance costs of \$63,028 and a gain on disposal of equipment, molds, furniture and fixtures of \$70,506.

In 2010, the change in operating assets and liabilities used cash of \$1,544,996. This use of cash was mainly due to a decrease in deferred revenue of \$2,438,733, partially offset by an increase in accrued expenses and other current liabilities of \$716,160 and changes in other operating assets and liabilities of \$196,629. Deferred revenue decreased primarily due to recognition of amounts received from Teva and Ferring in 2009 which had been recorded as deferred revenue at the end of 2009. Accrued expenses and other current liabilities increased primarily due to timing of normal operating activities.

In 2009, the change in operating assets and liabilities generated cash of \$3,636,316. This was mainly the result of payments received from Teva and Ferring under license and development agreements, much of which was recorded as deferred revenue which increased by \$3,171,277 in 2009. Other operating assets and liabilities changed by a net of \$465,039, with the most significant change being a decrease in deferred costs of \$1,099,072 due mainly to costs recognized in connection with development revenue recognized under a License, Development and Supply Agreement with Teva for a product utilizing our auto injector technology.

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 Anturo<sup>®</sup>. 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 Anturo<sup>®</sup>. 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.

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

In 2010, cash used in investing activities was \$182,916, consisting of additions to patent rights of \$122,720, purchases of equipment, molds, furniture and fixtures of \$89,293, and net of proceeds from sales of equipment, molds, furniture and fixtures of \$29,097. In 2009, cash used in investing activities was \$12,584, consisting of

additions to patent rights of \$176,541, purchases of equipment, molds, furniture and fixtures of \$11,043, and net of proceeds from sales of equipment, molds, furniture and fixtures of \$175,000. Investing activities in 2008 were comprised primarily of short-term investment purchases and maturities. All short-term investments were commercial paper or U.S. government agency discount notes that matured within six to twelve months of purchase and were classified as held-to-maturity because we had 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. Investing activities in 2008 also included additions to patent rights of \$177,425 and purchases of equipment, molds, furniture and fixtures of \$1,379,344. The 2008 purchases of equipment, molds, furniture and fixtures were primarily for tooling and production equipment related to commercial injector device deals with Teva.

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

Net cash provided by (used in) financing activities totaled \$2,463,419, \$5,606,808 and \$(808,641) for the years ended December 31, 2010, 2009 and 2008. In 2010, we received proceeds from exercise of warrants and stock options of \$2,463,419. In 2009, we received net proceeds of \$10,527,650 from the sale of common stock and warrants, we made payments on long term debt of \$5,026,464 and we received \$105,622 from the exercise of warrants and stock options. In 2008, principal payments on long term debt totaled \$2,128,591 and proceeds received from the exercise of warrants totaled \$1,319,950.

Our contractual cash obligations at December 31, 2010 are associated with operating leases and are summarized in the following table:

	<b>Payment Due by Period</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>4-5 years</b>	<b>After 5 years</b>
Total contractual cash obligations	<u>\$ 581,463</u>	<u>\$ 187,371</u>	<u>\$ 252,907</u>	<u>\$141,185</u>	<u>\$ -</u>

#### *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 2010, our research and development activities were primarily related to Anturool<sup>®</sup> and device development projects.

**Anturool<sup>®</sup>.** In December 2010 we filed a NDA with the FDA for Anturool<sup>®</sup> Gel for the treatment of OAB (overactive bladder). In July 2010, we completed a Phase III pivotal trial designed to evaluate the efficacy of Anturool<sup>®</sup> 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 involved approximately 600 patients (200 per arm) using two dose strengths (selected from a Phase II clinical trial) versus a placebo. In addition, an Open Label Extension study evaluating long term safety was completed in the fourth quarter of 2010. There is no assurance that the FDA will accept our NDA or that the FDA will ultimately approve Anturool<sup>®</sup>, and without FDA approval we cannot market or sell Anturool<sup>®</sup> in the U.S.

We have also incurred significant costs related to Anturool<sup>®</sup> manufacturing development. We have contracted with Patheon, Inc. ("Patheon"), a manufacturing development company, to supply clinical and commercial quantities of Anturool<sup>®</sup>. With Patheon, we have completed limited commercial scale up activities associated with Anturool<sup>®</sup> manufacturing.

As of December 31, 2010, we have incurred total external costs of approximately \$17,800,000 in connection with our Anturool<sup>®</sup> research and development, of which approximately \$4,900,000 was incurred in 2010.

We intend to seek a marketing partner to commercially launch Anturo<sup>®</sup> if approved by the FDA. To date, we have not entered into an agreement with a marketing partner.

**Device Development Projects.** We are engaged in research and development activities related to our Vibex<sup>™</sup> disposable pressure-assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex<sup>™</sup> system for use with epinephrine and an undisclosed product and for our pen injector device for two undisclosed products. We are also developing a Vibex<sup>™</sup> MTX auto injector for delivery of methotrexate for treatment of rheumatoid arthritis. 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. Our development programs consist of the 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.

In the second quarter of 2010 we entered into an agreement with Uman Pharma under which both companies will invest jointly to develop and commercialize Vibex<sup>™</sup> MTX. We will lead the clinical development program and FDA regulatory submissions, and will retain rights to commercialize the Vibex<sup>™</sup> MTX product outside of Canada. Uman Pharma will perform formulation development and manufacturing activities to support the registration of Vibex<sup>™</sup> MTX and supply methotrexate in prefilled syringes to us for the U.S. market. Uman Pharma received an exclusive license to commercialize the Vibex<sup>™</sup> MTX product in Canada. The companies intend to work together to commercialize the Vibex<sup>™</sup> MTX product in other territories.

As of December 31, 2010, we have incurred total external costs of approximately \$6,400,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately \$2,000,000 was incurred in 2010. Of this amount, approximately \$700,000 was incurred in connection with our Vibex<sup>™</sup> MTX development program. We expect spending on this program to be approximately \$2,000,000 in 2011. As of December 31, 2010, approximately \$4,400,000 of the total costs of \$6,400,000 was initially deferred, of which approximately \$3,100,000 has been recognized as cost of sales and \$1,300,000 remains deferred. This remaining deferred balance will be recognized as cost of sales 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 2011, but the timing and extent of near-term future development will be dependent on certain decisions made by Teva. In 2009, we received a payment from Teva in the amount of \$4,076,375 in connection with an amendment to a License, Development and Supply Agreement signed in July 2006 related to a fixed, single-dose, disposable injector product containing epinephrine using our Vibex<sup>™</sup> auto injector platform. Although this payment and certain upfront and milestone payments have been received from Teva, there have been no commercial sales from the auto injector or pen injector programs, 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 Anturo<sup>®</sup> 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 \$3,200,000 for the year ended December 31, 2010.

### **Recently Issued Accounting Pronouncements**

In April 2010, the FASB issued authoritative guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The recent guidance discusses the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. The guidance is effective

for fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. This guidance is effective for us on January 1, 2011. We are currently evaluating the impact, if any; this guidance will have our consolidated financial statements.

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

Our primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with the licensing agreement entered into in January 2003 with Ferring, which established pricing in Euros for products sold under the supply agreement and for all royalties. In March 2007, we amended the 2003 agreement with Ferring, establishing prices in U.S. dollars rather than Euros for certain products, reducing the exchange rate risk. Most of our sales and licensing fees are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. We do not currently use derivative financial instruments to hedge against exchange rate risk. Because exposure increases as intercompany balances grow, we will continue to evaluate the need to initiate hedging programs to mitigate the impact of foreign exchange rate fluctuations on intercompany balances. The effect of foreign exchange rate fluctuations on our financial results for the years ended December 31, 2010, 2009 and 2008 was not material.

*Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.*

**ANTARES PHARMA, INC.  
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## Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
Antares Pharma, Inc.:

We have audited the accompanying consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2010 and 2009, 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, 2010. We also have audited the Company's internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Annual Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) 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. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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, 2010 and 2009, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles. Also in our opinion, Antares Pharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

As disclosed in notes 2 and 12 to the consolidated financial statements, the Company adopted Financial Accounting Standards Board Accounting Standards Update 2009-13 *Revenue Arrangements with Multiple Deliverables*, in the third quarter of 2009 with retrospective application to January 1, 2009.

/s/ KPMG LLP

Minneapolis, Minnesota  
March 14, 2011



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

	<u>December 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 9,847,813	\$ 13,559,088
Accounts receivable	1,245,560	1,542,272
Inventories	272,463	329,553
Deferred costs	915,689	963,053
Prepaid expenses and other current assets	<u>193,985</u>	<u>155,255</u>
Total current assets	12,475,510	16,549,221
Equipment, molds, furniture and fixtures, net	327,535	317,310
Patent rights, net	803,426	742,399
Goodwill	1,095,355	1,095,355
Deferred costs	408,250	408,250
Other assets	<u>31,226</u>	<u>30,838</u>
Total Assets	<u>\$ 15,141,302</u>	<u>\$ 19,143,373</u>
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 1,773,259	\$ 1,882,158
Accrued expenses and other liabilities	1,818,769	1,048,619
Deferred revenue	<u>3,080,062</u>	<u>5,311,516</u>
Total current liabilities	6,672,090	8,242,293
Deferred revenue – long term	<u>1,842,594</u>	<u>2,050,550</u>
Total liabilities	<u>8,514,684</u>	<u>10,292,843</u>
Stockholders' Equity:		
Preferred Stock: \$0.01 par; authorized 3,000,000 shares, none outstanding	-	-
Common Stock: \$0.01 par; authorized 150,000,000 shares; 84,157,865 and 81,799,541 issued and outstanding at December 31, 2010 and 2009, respectively	841,579	817,995
Additional paid-in capital	143,318,671	139,614,459
Accumulated deficit	(136,973,795)	(130,882,597)
Accumulated other comprehensive loss	<u>(559,837)</u>	<u>(699,327)</u>
Total Liabilities and Stockholders' Equity	<u>\$ 15,141,302</u>	<u>\$ 19,143,373</u>

See accompanying notes to consolidated financial statements.

**ANTARES PHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Revenue:			
Product sales	\$ 5,773,734	\$ 3,506,510	\$ 3,349,532
Development revenue	2,127,033	2,606,516	540,557
Licensing revenue	2,856,228	1,595,220	1,238,211
Royalties	2,061,703	602,816	532,411
Total revenue	<u>12,818,698</u>	<u>8,311,062</u>	<u>5,660,711</u>
Cost of revenue:			
Cost of product sales	2,799,253	1,813,385	1,889,317
Cost of development and licensing revenue	1,473,957	2,326,449	130,268
Total cost of revenue	<u>4,273,210</u>	<u>4,139,834</u>	<u>2,019,585</u>
Gross profit	<u>8,545,488</u>	<u>4,171,228</u>	<u>3,641,126</u>
Operating expenses:			
Research and development	8,802,502	7,902,486	7,866,499
Sales, marketing and business development	1,035,017	1,051,030	1,624,599
General and administrative	4,734,427	4,911,356	6,347,997
	<u>14,571,946</u>	<u>13,864,872</u>	<u>15,839,095</u>
Operating loss	<u>(6,026,458)</u>	<u>(9,693,644)</u>	<u>(12,197,969)</u>
Other income (expense):			
Interest income	30,675	27,270	553,061
Interest expense	(4,464)	(633,459)	(1,021,675)
Foreign exchange gains (losses)	(31,525)	(40,861)	17,001
Other, net	(59,426)	49,942	(40,871)
	<u>(64,740)</u>	<u>(597,108)</u>	<u>(492,484)</u>
Net loss	<u>\$ (6,091,198)</u>	<u>\$ (10,290,752)</u>	<u>\$ (12,690,453)</u>
Basic and diluted net loss per common share	<u>\$ (0.07)</u>	<u>\$ (0.14)</u>	<u>\$ (0.19)</u>
Basic and diluted weighted average common shares outstanding	<u>83,170,297</u>	<u>73,488,507</u>	<u>67,232,889</u>

See accompanying notes to consolidated financial statements.

**ANTARES PHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS**  
**Years Ended December 31, 2008, 2009 and 2010**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Number of Shares	Amount				
<b>December 31, 2007</b>	<b>65,529,666</b>	<b>\$ 655,296</b>	<b>\$ 125,430,653</b>	<b>\$ (107,901,392)</b>	<b>\$ (685,266)</b>	<b>\$ 17,499,291</b>
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)
<b>December 31, 2008</b>	<b>68,049,666</b>	<b>680,496</b>	<b>127,926,205</b>	<b>(120,591,845)</b>	<b>(771,591)</b>	<b>7,243,265</b>
Issuance of common stock	13,352,273	133,523	10,394,127	-	-	10,527,650
Exercise of warrants and options	152,082	1,521	104,101	-	-	105,622
Stock-based compensation	245,520	2,455	1,190,026	-	-	1,192,481
Net loss	-	-	-	(10,290,752)	-	(10,290,752)
Translation adjustments	-	-	-	-	72,264	72,264
Comprehensive loss	-	-	-	-	-	(10,218,488)
<b>December 31, 2009</b>	<b>81,799,541</b>	<b>817,995</b>	<b>139,614,459</b>	<b>(130,882,597)</b>	<b>(699,327)</b>	<b>8,850,530</b>
Exercise of warrants and options	2,176,785	21,769	2,441,650	-	-	2,463,419
Stock-based compensation	181,539	1,815	1,262,562	-	-	1,264,377
Net loss	-	-	-	(6,091,198)	-	(6,091,198)
Dissolution of foreign subsidiary	-	-	-	-	85,994	85,994
Translation adjustments	-	-	-	-	53,496	53,496
Comprehensive loss	-	-	-	-	-	(5,951,708)
<b>December 31, 2010</b>	<b>84,157,865</b>	<b>\$ 841,579</b>	<b>\$ 143,318,671</b>	<b>\$ (136,973,795)</b>	<b>\$ (559,837)</b>	<b>\$ 6,626,618</b>

See accompanying notes to consolidated financial statements.

**ANTARES PHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		
	2010	2009	2008
Cash flows from operating activities:			
Net loss	\$ (6,091,198)	\$ (10,290,752)	\$ (12,690,453)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on dissolution of foreign subsidiary	85,994	-	-
Depreciation and amortization	188,750	226,384	283,320
Gain on sale of equipment, molds, furniture and fixtures	(29,097)	(70,506)	-
Stock-based compensation expense	1,311,177	1,192,479	1,160,454
Amortization of debt discount and issuance costs	-	206,519	269,547
Changes in operating assets and liabilities:			
Accounts receivable	214,279	(239,440)	(853,964)
Inventories	57,090	(147,515)	(56,629)
Prepaid expenses and other current assets	(40,338)	130,761	659,726
Deferred costs	47,364	1,099,072	(740,276)
Other assets	(9)	147,734	(562)
Accounts payable	(100,809)	(201,161)	1,195,006
Accrued expenses and other current liabilities	716,160	(324,412)	(105,298)
Deferred revenue	(2,438,733)	3,171,277	554,717
Net cash used in operating activities	<u>(6,079,370)</u>	<u>(5,099,560)</u>	<u>(10,324,412)</u>
Cash flows from investing activities:			
Proceeds from maturity of short-term investments	-	-	16,015,057
Proceeds from sales of equipment, molds, furniture and fixtures	29,097	175,000	-
Additions to patent rights	(122,720)	(176,541)	(177,425)
Purchases of equipment, molds, furniture and fixtures	(89,293)	(11,043)	(1,379,344)
Net cash provided by (used in) investing activities	<u>(182,916)</u>	<u>(12,584)</u>	<u>14,458,288</u>
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	-	10,527,650	-
Proceeds from exercise of warrants and stock options	2,463,419	105,622	1,319,950
Principal payments on notes payable	-	(5,026,464)	(2,128,591)
Net cash provided by (used in) financing activities	<u>2,463,419</u>	<u>5,606,808</u>	<u>(808,641)</u>
Effect of exchange rate changes on cash and cash equivalents	<u>87,592</u>	<u>(31,874)</u>	<u>12,139</u>
Net increase (decrease) in cash and cash equivalents	(3,711,275)	462,790	3,337,374
Cash and cash equivalents:			
Beginning of year	<u>13,559,088</u>	<u>13,096,298</u>	<u>9,758,924</u>
End of year	<u>\$ 9,847,813</u>	<u>\$ 13,559,088</u>	<u>\$ 13,096,298</u>

See accompanying notes to consolidated financial statements.

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

**1. Description of Business**

Antares Pharma, Inc. (the “Company” or “Antares”) is an emerging pharma company that focuses on self-injection pharmaceutical products and technologies and topical gel-based products. The Company’s subcutaneous and intramuscular injection technology platforms include Vibex™ disposable pressure-assisted auto injectors, Vision™ reusable needle-free injectors, and disposable multi-use pen injectors. Pharmaceutical and biotechnology companies are viewed as the Company’s primary customers.

In the injector area, the Company has licensed its reusable needle-free injection device for use with human growth hormone to Teva Pharmaceutical Industries, Ltd. (“Teva”), Ferring Pharmaceuticals BV (“Ferring”) and JCR Pharmaceuticals Co., Ltd. (“JCR”). In August 2009, the Company announced that Teva launched its Tjet® injector system, which uses the Company’s needle-free device to administer Teva’s Tev-Tropin® brand human growth hormone. The Company has also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories. In 2009, the Company received a payment of \$4,076,375 from Teva for tooling and for an advance for the design, development and purchase of additional tooling and automation equipment, all of which is related to a fixed, single-dose, disposable injector product containing epinephrine using the Company’s Vibex™ auto injector platform. In addition, the Company continues to support existing customers of its reusable needle-free devices for the administration of insulin in the U.S. market through distributors.

In the gel-based area, in December 2010 the Company filed an NDA for its lead product candidate, AnturoI®, an oxybutynin ATD™ gel for the treatment of OAB (overactive bladder). The Company also has a partnership with BioSante Pharmaceuticals, Inc. (“BioSante”) that includes LibiGel® (transdermal testosterone gel) in Phase 3 clinical development for the treatment of female sexual dysfunction (FSD), and Elestrin® (estradiol gel) currently marketed in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

The Company has operating facilities in the U.S. and Switzerland. The U.S. operation manufactures and markets the Company’s reusable needle-free injection devices and related disposables, and develops its 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. The Company’s Pharma division is located both in the U.S. and in Muttenz, Switzerland, where pharmaceutical products are developed utilizing the Company’s transdermal systems. The Company’s corporate offices are located in Ewing, New Jersey.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying consolidated financial statements include the accounts of Antares Pharma, Inc. and its two wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. In December 2010 the Company dissolved one of its three wholly-owned subsidiaries, which had an insignificant impact on the consolidated financial statements in 2010 and in prior years.

*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.

*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, the Company has determined that the Swiss Franc is the functional currency for its foreign subsidiaries. The reporting currency for the Company is the United States Dollar (“USD”). The financial statements of the Company’s 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. In December 2010, the Company dissolved one of its foreign subsidiaries and recognized approximately \$86,000 of expense in connection with removing the applicable cumulative translation adjustment from other comprehensive income. 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.

#### *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. The Company’s accounts receivable balance is typically due from its large pharmaceutical customers such as Teva, Ferring and JCR, and at December 31, 2010, over 93% of the accounts receivable balance was due from these three organizations. These companies have historically paid timely and have been financially stable organizations. Due to the nature of the accounts receivable balance, the Company believes the risk of doubtful accounts is minimal. 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. The allowance for doubtful accounts balance was \$10,000 at December 31, 2010 and 2009.

#### *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 lesser of the lease term or estimated useful life, and the related obligations are recorded as liabilities. Lease amortization is included in depreciation expense. Depreciation expense was \$79,908, \$135,411 and \$158,864 for the years ended December 31, 2010, 2009 and 2008, respectively.

#### *Goodwill*

The Company has \$1,095,355 of goodwill recorded as of December 31, 2010 that relates to the Minnesota reporting unit. The Company evaluates the carrying amount of goodwill on December 31 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 reporting unit exceeded its fair value, then the amount of the impairment loss would 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 reporting unit 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 reporting unit 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.

In evaluating whether the fair value of the Minnesota reporting unit was below its carrying amount, the Company used the market capitalization of the Company at December 31, 2010, which was approximately \$143 million, to calculate an estimate of fair value of the Minnesota reporting unit. The Company determined that the percentage of the total market capitalization of the Company at December 31, 2010 attributable to the Minnesota reporting unit would have to be unreasonably low before the fair value of the Minnesota reporting unit would be less than its carrying amount. In making this determination, the Company evaluated the activity at the Minnesota reporting unit compared to the total Company activity, and considered the source and potential value of agreements currently in place, the source of recent product sales and development revenue growth, the source of total Company revenue and the source of cash generating activities. After performing the market capitalization analysis and concluding that the fair value of the Minnesota reporting unit was not below its carrying amount, the Company determined that no further detailed determination of fair value was required.

The Company's evaluation of goodwill completed during 2010, 2009 and 2008 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 five 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, 2010, 2009 and 2008 was \$108,842, \$99,313 and \$124,455, 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 or asset group. 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.

Each year the Company 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 anticipated. No impairment charges were recognized in 2010, 2009 or 2008. The gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, were \$1,752,636 and \$949,210, respectively, at December 31, 2010 and were \$1,665,519 and \$923,120, respectively, at December 31, 2009. The Company's estimated aggregate patent amortization expense for the next five years is \$68,000, \$80,000, \$78,000, \$78,000 and \$78,000 in 2011, 2012, 2013, 2014 and 2015, respectively.

### *Fair Value of Financial Instruments*

Cash and cash equivalents are stated at cost, which approximates fair value.

### *Revenue Recognition*

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

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

Licensing revenue recognition requires significant management judgment to evaluate the effective terms of agreements, the Company's performance commitments and determination of fair value of the various deliverables under the arrangement. In the third quarter of 2009, the Company elected early adoption of Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2009-13, "Revenue Arrangements with Multiple Deliverables" ("ASU 2009-13"). ASU 2009-13, which amended FASB ASC 605-25, "Multiple-Element Arrangements," is effective for arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, but allows for early adoption. ASU 2009-13 requires a vendor to allocate revenue to each unit of accounting in arrangements involving multiple deliverables. It changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when vendor specific objective evidence or third party evidence of selling price is not available. As a result of adoption of ASU 2009-13, deferred revenues and deferred costs associated with one License, Development and Supply Agreement with Teva are being recognized as revenues and expenses earlier than would otherwise have occurred. Revenues and expenses generated in connection with future multiple element arrangements will likely often be recognized over shorter periods than would have occurred prior to adoption of ASU 2009-13. The impact of adoption of ASU 2009-13 is discussed further in Note 12 to the consolidated financial statements.

The Company has a number of arrangements that were not affected by adoption of ASU 2009-13, and the accounting for these arrangements will continue under the prior accounting standards unless an arrangement is materially modified, as defined in the new accounting standard. The prior accounting standards address when and, if so, how an arrangement involving multiple deliverables should be divided into separate units of accounting. In some arrangements, the different revenue-generating activities (deliverables) are sufficiently separable, and there exists sufficient evidence of their fair values to separately account for some or all of the deliverables (that is, there are separate units of accounting). In other arrangements, some or all of the deliverables are not independently functional, or there is not sufficient evidence of their fair values to account for them separately. The ability or inability to establish objective evidence of fair value for the deliverable portions of the contracts significantly impacted the time period over which revenues are being recognized. For instance, if there was no objective fair value of undelivered elements of a contract, then a multi-deliverable contract was required to be treated as one unit of accounting, resulting in all revenue being deferred and recognized over the entire contract period.

At December 31, 2010, \$4,922,656 of non-refundable cash payments received have been recorded as deferred revenue in cases where 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.



### *Stock-Based Compensation*

The Company records compensation expense associated with share based awards granted to employees at the fair value of the award on the date of grant. The expense is recognized over the period during which an employee is required to provide services in exchange for the award.

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.

Stock-based instruments granted to nonemployees are recorded at their fair value on the measurement 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:

	<u>Balance at Beginning of Year</u>	<u>Provisions</u>	<u>Claims</u>	<u>Balance at End of Year</u>
2010	\$ 20,000	\$ 3,210	\$ (3,210)	\$ 20,000
2009	\$ 20,000	\$ 13,129	\$ (13,129)	\$ 20,000

### *Research and Development*

Research and development costs are expensed as incurred.

### *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 net deferred tax asset balance for all years presented.

### *Net Loss Per Share*

Basic net loss per share 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 net loss per share is computed similar to basic net loss per share except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of stock options and warrants, 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. 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, 2010, 2009 and 2008, excluded from dilutive loss per share as their effect is anti-dilutive, are as follows:

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Stock options and warrants	25,342,935	26,635,093	26,268,701

#### *New Accounting Pronouncements*

In January 2010, the FASB issued ASU 2010-06, Fair Value Measurements and Disclosures (Topic 820), “Improving Disclosures about Fair Value Measurements.” ASU 2010-06 requires new disclosures about significant transfers in and out of Level 1 and Level 2 fair value measurements and the reasons for such transfers and in the reconciliation for Level 3 fair value measurements to disclose separately information about purchases, sales, issuances and settlements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements in the reconciliation for Level 3 fair value measurements. Those disclosures will be effective for fiscal years beginning after December 15, 2010. The adoption of ASU 2010-06 did not have an impact on the Company’s consolidated financial statements.

In the third quarter of 2009, the Company elected early adoption of FASB ASU 2009-13, “Revenue Arrangements with Multiple Deliverables.” ASU 2009-13, which amended FASB ASC 605-25, “Multiple-Element Arrangements,” is effective for arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, but allows for early adoption. ASU 2009-13 requires a vendor to allocate revenue to each unit of accounting in arrangements involving multiple deliverables based on the relative selling price of each deliverable. It also changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when more objective evidence of selling price is not available. The impact of adopting this pronouncement is discussed in Note 12 to the consolidated financial statements.

### **3. Liquidity**

The Company has reported net losses of \$6,091,198, \$10,290,752 and \$12,690,453 in the fiscal years ended 2010, 2009 and 2008, respectively, and the Company has accumulated aggregate net losses from the inception of business through December 31, 2010 of \$136,973,795. 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.

In order to be in a better position to take advantage of potential growth opportunities and to fund future operations, during 2009 the Company raised additional capital and took steps to reduce its monthly cash obligations. In the third quarter of 2009, the Company raised gross proceeds of \$11,500,000 through the sale of shares of its common stock and warrants. Approximately \$3,000,000 of the proceeds was used to pay off the remaining balance of the Company’s credit facility, eliminating the monthly debt service requirements. In the fourth quarter of 2009, the Company reduced its monthly overhead when it entered into an Asset Purchase Agreement with Ferring. Under this agreement, Ferring assumed responsibility for all of the Company’s facility and equipment lease obligations in connection with its operations in Switzerland, and the majority of the Company’s employees at that location were hired by Ferring effective January 1, 2010. Subsequent to the Ferring agreement, the Company entered into a month-to-month facility lease agreement at a new Swiss location in a much smaller space at a significantly reduced monthly rate.

At December 31, 2010, the Company had cash and cash equivalents of \$9,847,813. The Company believes that the combination of the current cash and cash equivalents balance and the projected product sales, product development revenue, license revenues, milestone payments and royalties will provide sufficient funds to support operations for at least the next 12 months.

#### 4. Composition of Certain Financial Statement Captions

	<u>December 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
Inventories:		
Raw material	\$ 231,424	\$ 250,718
Finished goods	41,039	78,835
	<u>\$ 272,463</u>	<u>\$ 329,553</u>
Equipment, molds, furniture and fixtures:		
Furniture, fixtures and office equipment	\$ 749,216	\$ 713,809
Production molds and equipment	1,365,137	1,348,701
Molds and tooling in process	146,245	105,800
Less accumulated depreciation	<u>(1,933,063)</u>	<u>(1,851,000)</u>
	<u>\$ 327,535</u>	<u>\$ 317,310</u>
Patent rights:		
Patent rights	\$ 1,752,636	\$ 1,665,519
Less accumulated amortization	<u>(949,210)</u>	<u>(923,120)</u>
	<u>\$ 803,426</u>	<u>\$ 742,399</u>
Accrued expenses and other liabilities:		
Accrued employee compensation and benefits	\$ 628,887	\$ 490,773
Accrued clinical trial costs	649,207	15,000
Other liabilities	540,675	542,846
	<u>\$ 1,818,769</u>	<u>\$ 1,048,619</u>

#### 5. Notes Payable

In September 2009, the remaining balance of the Company's credit facility was paid off with the proceeds from the sale of common stock and warrants. Total interest expense related to the credit facility was \$620,304 and \$996,832 in 2009 and 2008, respectively, of which \$206,519 and \$269,546 in 2009 and 2008, respectively, was noncash interest consisting of amortization of debt discount and debt issuance costs.

#### 6. Leases

The Company has non-cancelable operating leases for its corporate headquarters facility in Ewing, New Jersey, and its office, research and development facility in Minneapolis, MN. The leases require payment of all executory costs such as maintenance and property taxes. The Company also leases certain equipment and furniture under various operating leases. The Company had no equipment under capital leases at December 31, 2010 or 2009, as these leases were assumed by Ferring in the Asset Purchase Agreement discussed in Note 11 to the consolidated financial statements.

Rent expense, net, incurred for the years ended December 31, 2010, 2009 and 2008 was \$228,087, \$378,425 and \$395,031, respectively.

Future minimum lease payments under operating leases as of December 31, 2010 were as follows:

	<u>Amount</u>
2011	\$ 178,442
2012	88,577
2013	81,470
2014	82,859
2015	84,248
Thereafter	56,937
Total future minimum lease payments	<u>\$ 572,533</u>

## 7. Income Taxes

The Company incurred losses for both book and tax purposes for all applicable jurisdictions in each of the years in the three-year period ended December 31, 2010, 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, 2010. Effective tax rates differ from statutory income tax rates in the years ended December 31, 2010, 2009 and 2008 as follows:

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(2.1)	(0.3)	(0.4)
Valuation allowance increase	18.3	4.6	17.2
Effect of foreign operations	(0.9)	17.4	16.4
Expiration of unused net operating loss and credit carryforwards	21.2	10.2	1.7
Nondeductible items	(0.7)	1.9	1.7
Other	(1.8)	0.2	(2.6)
	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

Deferred tax assets as of December 31, 2010 and 2009 consist of the following:

	<u>2010</u>	<u>2009</u>
Net operating loss carryforward – U.S.	\$ 16,839,000	\$ 16,060,000
Net operating loss carryforward – Switzerland	7,358,000	7,261,000
Research and development tax credit carryforward	1,209,000	909,000
Deferred revenue	1,459,000	785,000
Depreciation and amortization	81,000	119,000
Stock-based compensation	1,328,000	1,189,000
Other	823,000	876,000
	<u>29,097,000</u>	<u>27,199,000</u>
Less valuation allowance	<u>(29,097,000)</u>	<u>(27,199,000)</u>
	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance for deferred tax assets as of December 31, 2010 and 2009 was \$29,097,000 and \$27,199,000, respectively. The net change in the total valuation allowance for the years ended December 31, 2010 and 2009 was an increase of \$1,898,000 and \$719,000, 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, 2010, of approximately \$45,500,000, 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 2011 through 2030, with approximately \$10,710,000 expiring over the next three years. Additionally, the Company has a research credit carryforward of approximately \$1,209,000. These credits expire in years 2011 through 2030.

The Company also has a Swiss net operating loss carryforward at December 31, 2010, of approximately \$54,500,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2011 through 2017, with approximately \$22,758,000 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 Permtec, 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.

As of December 31, 2010 and 2009, there were no unrecognized tax benefits. Accordingly, a tabular reconciliation from beginning to ending periods is not provided. The Company will 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.

The Company does not anticipate that the total amount of unrecognized tax benefits will change significantly in the next twelve months.

The Company is subject to federal examinations for the years 2007 forward. There are no tax examinations currently in progress.

## **8. Stockholders' Equity**

### *Common Stock*

In July 2009, the Company raised gross proceeds of \$8,500,000 in a registered direct offering through the sale of shares of its common stock and warrants. The Company sold a total of 10,625,000 units, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.4 of a share of common stock (or a total of 4,250,000 shares), at a purchase price of \$0.80 per unit. The warrants became exercisable six months after issuance at \$1.00 per share and will expire five years from the date of issuance.

In September 2009, the Company raised gross proceeds of \$3,000,000 through the sale of 2,727,273 units to certain institutional investors, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.4 of a share of common stock (or a total of 1,090,909 shares), at a purchase price of \$1.10 per unit. The warrants became exercisable six months after issuance at \$1.15 per share and will expire five years from the date of issuance.

Warrant and stock option exercises during 2010, 2009 and 2008 resulted in proceeds of \$2,463,419, \$105,622 and \$1,319,950, respectively, and in the issuance of 2,176,785, 152,082 and 2,400,000 shares of common stock, respectively.

### *Stock Options and Warrants*

The Company's 2008 Equity Compensation 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. During 2010, the shareholders approved an amendment to the Plan to increase the maximum number of shares authorized for issuance by 1,500,000 to 11,500,000 from 10,000,000. As of December 31, 2010, the Plan had 1,430,882 shares available for grant. The number of shares available for grant does not take into consideration potential stock awards that could result in the issuance of shares of common stock if certain performance conditions are met, discussed under "Stock Awards" below. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the Plan as of December 31, 2010 and the changes during the year then ended is as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price (\$)</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value (\$)</u>
Outstanding at December 31, 2009	8,339,684	1.13		
Granted/Issued	1,277,487	1.51		
Exercised	(1,566,435)	0.99		772,006
Cancelled	(392,860)	2.00		
Outstanding at December 31, 2010	<u>7,657,876</u>	<u>1.18</u>	<u>7.2</u>	<u>4,514,194</u>
Exercisable at December 31, 2010	<u>5,559,083</u>	<u>1.19</u>	<u>6.5</u>	<u>3,332,001</u>

As of December 31, 2010, there was approximately \$1,100,000 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 2010, 2009 and 2008 was approximately \$952,000, \$973,000 and \$1,076,000, respectively. In 2010, 2009 and 2008, expense included approximately \$62,000, \$54,000 and \$65,000, respectively, recognized due to modifications of option terms for employees whose employment with the Company ended in those years. The per share weighted average fair value of options granted during 2010, 2009 and 2008 was estimated as \$0.78, \$0.52, \$0.40, 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.

	<u>December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Risk-free interest rate	1.7%	2.2%	2.9%
Annualized volatility	60.0%	72.0%	70.0%
Weighted average expected life, in years	5.0	5.0	5.0
Expected dividend yield	0.0%	0.0%	0.0%

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, 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
Granted/Issued	1,245,936	0.90	5,500,909	1.02
Exercised	(72,082)	0.77	(80,000)	1.00
Cancelled	(890,826)	1.38	(5,337,545)	1.27
Outstanding at December 31, 2009	8,339,684	1.13	18,295,409	1.56
Granted/Issued	1,277,487	1.51	-	-
Exercised	(1,566,435)	0.99	(610,350)	1.50
Cancelled	(392,860)	2.00	-	-
Outstanding at December 31, 2010	<u>7,657,876</u>	1.18	<u>17,685,059</u>	1.56

The following table summarizes information concerning currently outstanding and exercisable options and warrants by price range at December 31, 2010:

Price Range	Outstanding			Exercisable	
	Number of Shares Outstanding	Weighted Average Remaining Life In Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
<b>Option Plans:</b>					
\$ 0.37 to 0.53	1,846,094	8.0	\$ 0.49	1,416,372	\$ 0.49
0.70 to 0.96	1,214,190	7.5	0.84	995,869	0.84
1.01 to 1.50	2,242,259	7.0	1.25	1,561,509	1.28
1.51 to 1.77	2,186,619	7.1	1.61	1,416,619	1.64
4.56	168,714	0.9	4.56	168,714	4.56
	<u>7,657,876</u>	7.2	1.18	<u>5,559,083</u>	1.19
<b>Warrants:</b>					
\$ 0.80 to 1.15	6,140,909	3.3	1.00	6,140,909	1.00
1.50	6,744,150	0.2	1.50	6,744,150	1.50
2.00	3,800,000	1.5	2.00	3,800,000	2.00
3.78	1,000,000	2.5	3.78	1,000,000	3.78
	<u>17,685,059</u>	1.7	1.56	<u>17,685,059</u>	1.56
<b>Total Options &amp; Warrants</b>	<u>25,342,935</u>	3.4	1.45	<u>23,244,142</u>	1.47

In the first quarter of 2011, 3,242,134 warrants with an exercise price of \$1.50 were exercised resulting in proceeds to the Company of \$4,863,201. The remaining 3,502,016 warrants with an exercise price of \$1.50 expired unexercised.

#### 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 1,530,000 shares of common stock upon the occurrence of various triggering events. Of these shares, 57,954, 135,227 and 22,727 were awarded in 2010, 2009 and 2008, respectively. At December 31, 2010, 539,727 shares remain as potential awards. A total of approximately \$104,000, \$133,000 and \$11,000 in compensation

expense was recorded in 2010, 2009 and 2008, respectively, in connection with the shares awarded and others considered probable of achievement.

In 2010, five members of executive management received stock awards totaling 170,768 shares of common stock. Of these shares, 25,000 vested immediately, 25,000 will vest on February 22, 2011 and 120,768 will vest on February 22, 2013. In 2008, four executive management members received stock awards totaling 180,000 shares of common stock which vest in equal annual installments over a three year period. Of these shares, 60,000 vested in 2010 and 60,000 vested in 2009. 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 \$153,000, \$49,000 and \$28,000 in 2010, 2009 and 2008, respectively. As of December 31, 2010, there was approximately \$152,000 of total unrecognized compensation cost related to nonvested stock awards that is expected to be recognized over a weighted average period of approximately 1.7 years. The per share weighted average fair value of the shares granted in 2010 and 2008 was \$1.30 and \$0.82, respectively.

In addition to the shares granted to executive management, in 2010, 2009 and 2008 a total of 71,563, 48,019 and 35,294 shares of common stock, respectively, were granted to directors and employees as part of annual compensation or bonuses. Expense recognized in connection with these shares was \$102,575, \$37,125 and \$22,500 in 2010, 2009 and 2008, respectively.

## **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, 2010, 2009 and 2008, the Company elected to make contributions to the plan totaling \$92,153, \$72,537 and \$61,180, respectively.

## **10. Supplemental Disclosures of Cash Flow Information**

Cash paid for interest during the years ended December 31, 2010, 2009 and 2008 was \$4,464, \$476,907 and \$677,456, respectively.

## **11. License Agreements**

### *Teva License Development and Supply Agreements*

In December 2007, the Company entered into a license, development and supply agreement with Teva under which the Company 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 the Company under certain circumstances. Based on an analysis under accounting literature applicable at the time of the agreement, the entire arrangement was considered a single unit of accounting. Therefore, payments received and development costs incurred were deferred and were to be recognized from the start of manufacturing through the end of the initial contract period. In January 2011, this license, development and supply agreement was amended. The Company has determined that the changes to the agreement as a result of the amendment are a material modification to the agreement. Because the agreement was materially modified, the Company is re-evaluating the accounting under ASU 2009-13, which will impact the Company's financial results for 2011.

In September 2006, the Company entered into a Supply Agreement with Teva. Pursuant to the agreement, Teva is obligated to purchase all of its needle-free delivery device requirements from Antares for 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 was recognized as revenue over the development period. The milestone fees and royalties will be recognized as revenue when earned.



In 2009, Teva launched the Company's Tjet needle-free device with their hGH Tev-Tropin<sup>®</sup>. In 2010 and 2009, the Company received milestone payments from Teva in connection with this agreement.

In July 2006, the Company entered into an exclusive License Development and Supply Agreement with Teva. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from Antares for an auto injector product containing epinephrine 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. As discussed in Note 12 to the consolidated financial statements, in the third quarter of 2009 this agreement was amended and the accounting for the revenue and costs under this agreement was changed.

In November 2005, the Company signed an agreement with Teva, under which Teva is obligated to purchase all of its injection delivery device requirements from Antares for an undisclosed product to be marketed in the United States. Teva 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, Teva purchased 400,000 shares of Antares common stock at a per share price of \$1.25. Antares granted Teva certain registration rights with respect to the purchased shares of common stock. Based on an analysis under accounting literature applicable at the time of the agreement, 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.

#### *Ferring Agreements*

On November 6, 2009, the Company entered into an Exclusive License Agreement with Ferring, under which the Company licensed certain of its patents and agreed to transfer know-how for its transdermal gel technology for certain pharmaceutical products. This agreement has no impact on Antares' current licenses, the transdermal clinical pipeline, or marketed products, including Anturof<sup>®</sup>, LibiGel<sup>®</sup>, Nestorone, and Elestrin<sup>®</sup>. Also on November 6, 2009, in tandem with the execution of the Exclusive License Agreement, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Ferring. Pursuant to the terms and conditions of the Purchase Agreement, Ferring purchased from the Company all of the assets, including equipment, fixtures, fittings and inventory, located at the Company's research and development facility located in Allschwil, Switzerland (the "Facility"). Further pursuant to the terms and conditions of the Purchase Agreement, Ferring assumed the contractual obligations related to the Facility, including the real property lease for the Facility, and continued to employ the employees working at the Facility. The Company also entered into a Consultancy Services Agreement with Ferring for a period of 12 months, under which the Company provided services in connection with development of certain pharmaceutical products under the Exclusive License Agreement. Under these agreements the Company received upfront license fees, payments for assets and payments for services rendered under the consultancy agreement. In addition, the Company will receive milestone payments as certain defined milestones are achieved and received monthly payments over the term of the consultancy agreement.

Although there are three separate agreements with Ferring, they were all entered into at essentially the same time and therefore are presumed to have been negotiated as a package. This package of arrangements was evaluated as a single arrangement for purposes of applying the applicable accounting standard. Payments received under the Exclusive License Agreement were recognized over the 12 month period of the Consultancy Services Agreement, as this is the period of time the Company was involved in development. Milestone payments received in connection with milestones reached after the services agreement has ended will be recognized when the milestone payment is received. The amount received from Ferring for the assets sold resulted in a gain, which was recorded in other income.

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 also pays 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 was 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 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 144-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.

In November 2006, BioSante entered into a sublicense and marketing agreement with Bradley Pharmaceuticals, Inc. for Elestrin<sup>®</sup> (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a sublicense payment to the Company. In December 2006 the FDA approved for marketing Elestrin<sup>®</sup> in the United States triggering additional sublicense payments to the Company. In 2008, BioSante reacquired the rights to Elestrin<sup>®</sup> and entered into new marketing agreements in December 2008, triggering further sublicense payments to the Company. 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 were recognized as revenue when received. In addition, the Company has received royalties on sales of Elestrin<sup>®</sup>, which have been recognized as revenue when received.

#### *Jazz License Agreement*

In July 2007, we entered into a worldwide product development and license agreement with Jazz Pharmaceuticals (“Jazz”) for a product being developed to treat a CNS (central nervous system) disorder that would utilize our transdermal gel delivery technology. Under the agreement, an upfront payment, development milestones, and royalties on product sales were to be received by us under certain circumstances. The upfront payment was

being recognized as revenue over the development period. In 2010 Jazz discontinued development of this product; therefore the remaining deferred balance of the upfront payment was recognized as revenue.

#### *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 utilized our oral disintegrating tablet delivery technology. Under the agreement, an upfront payment, development milestones, and royalties on product sales were to be received by us under certain circumstances. The upfront payment was being recognized as revenue over the development period. In 2009, we recognized revenue of approximately \$338,000 representing the unrecognized portion of previously deferred payments received in connection with this agreement after the customer terminated the agreement due to technical challenges with their drug molecule.

## **12. Revenue Recognition**

As discussed in Note 2, in 2009 the Company elected early adoption of ASU 2009-13. The Company elected to adopt ASU 2009-13 on a prospective basis, with retrospective application to January 1, 2009.

During the third quarter of 2009, the Company amended the License, Development and Supply Agreement with Teva originally entered into in July of 2006. Under the terms of the amendment, the Company received a payment of \$4,076,375 from Teva for tooling in process that had a carrying value of approximately \$1,200,000 and for an advance for the design, development and purchase of additional tooling and automation equipment, all of which is related to an undisclosed, fixed, single-dose, disposable injector product using the Company's Vibex™ auto injector platform. The changes to the agreement related to this payment along with various other changes to the original terms resulted in a material modification to the agreement. Because the agreement was materially modified, the accounting was re-evaluated under ASU 2009-13, and the provisions of ASU 2009-13 were applied as if they were applicable from inception of the agreement. The re-evaluation resulted in the agreement being separated into three units of accounting and resulted in changes to both the method of revenue recognition and the period over which revenue will be recognized. Under the new accounting, the original license fee and milestone payments received will be recognized as revenue over the development period, the \$4,076,375 payment received will be recognized as revenue as various tools and equipment are completed and delivered, and revenue during the manufacturing period will be recognized as devices are sold and royalties are earned. The accounting literature applicable at the time of the original agreement required the entire arrangement to be considered a single unit of accounting. Therefore, the payments received and the development costs incurred were being deferred and would have been recognized from the start of manufacturing through the end of the initial contract period. For the year ended December 31, 2009, the adoption of ASU 2009-13 resulted in the recognition of revenue previously deferred of \$481,833 and the recognition of costs previously deferred of \$615,256. Also, tooling in process of approximately \$1,200,000 sold to Teva was reclassified from equipment, molds, furniture and fixtures to deferred costs and was recognized as cost of sales upon revenue recognition. Adoption of ASU 2009-13 had no impact on the accounting for any of the Company's other revenue arrangements containing multiple deliverables.

## **13. Segment Information and Significant Customers**

The Company has one operating segment, drug delivery, which includes the development of drug delivery transdermal 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 total assets located in two countries as follows:

	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
United States of America	\$14,353,760	\$17,384,011
Switzerland	787,542	1,759,362
	<u>\$15,141,302</u>	<u>\$19,143,373</u>

Revenues by customer location are summarized as follows:

	<u>For the Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
United States of America	\$ 6,627,689	\$4,427,822	\$1,451,092
Europe	5,797,385	3,668,941	3,899,115
Other	393,624	214,299	310,504
	<u>\$ 12,818,698</u>	<u>\$8,311,062</u>	<u>\$5,660,711</u>

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

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Ferring	\$5,758,290	\$3,247,758	\$3,383,071
Teva	5,693,853	3,134,830	90,905
BioSante	518,768	206,820	668,853

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

	<u>2010</u>	<u>2009</u>
Ferring	\$ 501,923	\$1,325,436
Teva	393,551	121,810

#### 14. Quarterly Financial Data (unaudited)

	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
<b>2010:</b>				
Total revenues	\$ 3,364,086	\$ 3,050,987	\$ 3,122,060	\$ 3,281,565
Gross profit	2,049,107	2,055,026	2,042,546	2,398,810
Net loss	(1,608,943)	(1,552,254)	(1,631,400)	(1,298,602)
Net loss per common share (1)	(0.02)	(0.02)	(0.02)	(0.02)
Weighted average shares	82,265,477	82,912,179	83,615,043	83,861,667
<b>2009:</b>				
Total revenues	\$ 2,365,070	\$ 1,709,566	\$ 1,654,783	\$ 2,581,643
Gross profit	1,275,900	1,010,400	898,428	986,500
Net loss	(2,775,355)	(2,284,413)	(2,824,384)	(2,406,600)
Net loss per common share (1)	(0.04)	(0.03)	(0.04)	(0.03)
Weighted average shares	68,049,666	68,101,137	75,870,525	81,755,905

(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.*

*Evaluation of disclosure controls and procedures.*

The Company's management evaluated, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, the effectiveness of its disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed in reports that the Company files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

*Management's annual report on internal control over financial reporting.*

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's management has assessed the effectiveness of internal control over financial reporting as of December 31, 2010. This assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework.

The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of the Company's assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and board of directors; and
- (3) 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. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on the Company's assessment using the COSO criteria, management has concluded that its internal control over financial reporting was effective as of December 31, 2010 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. The Company's independent registered public accounting firm, KPMG LLP, has issued an audit report on the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appears on page 53 of this Form 10-K.

*Changes in internal control over financial reporting.*

There was no change in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

*Item 9B. OTHER INFORMATION.*

None.

## 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 2011 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 2011 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for our 2011 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 2011 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.antaespharma.com](http://www.antaespharma.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 2011 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 2011 annual meeting, and is incorporated herein by reference.

The following table provides information for our equity compensation plans as of December 31, 2010:

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding shares reflected in the first column)</u>
Equity compensation plans approved by security holders	7,657,876	\$ 1.18	1,430,882

*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 2011 annual meeting, and is incorporated herein by reference.

*Item 14. PRINCIPAL ACCOUNTING 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 2011 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 of Antares Pharma, Inc. (Filed as exhibit 4.1 to Form S-3 on April 12, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 19, 2008 and incorporated herein by reference.)
3.3	Amended and Restated By-laws of Antares Pharma, Inc. (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/A on August 15, 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 Sior 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	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.)
4.10	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.)
4.11	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.)

- 4.12 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.)
- 4.13 Form of Investor Rights Agreement (Filed as exhibit 4.2 to Form 8-K on July 2, 2007 and incorporated herein by reference.)
- 4.14 Form of Warrant (Filed as exhibit 4.3 to Form 8-K on July 2, 2007 and incorporated herein by reference.)
- 4.15 Form of Warrant to Purchase Common Stock (Filed as Exhibit 4.1 to Form 8-K on July 24, 2009 and incorporated herein by reference.)
- 4.16 Form of Warrant to Purchase Common Stock (Filed as Exhibit 4.1 to Form 8-K on September 18, 2009 and incorporated herein by reference.)
- 4.17 Form of Subscription Agreement, by and between Antares Pharma, Inc. and the investor party thereto (Filed as Exhibit 10.2 to Form 8-K filed on July 24, 2009 and incorporated herein by reference.)
- 4.18 Form of Subscription Agreement, by and between Antares Pharma, Inc. and the investor party thereto (Filed as Exhibit 10.1 to Form 8-K filed on September 18, 2009 and incorporated herein by reference.)
- 4.19+ Antares Pharma, Inc. 2008 Equity Compensation Plan, as amended (Filed as exhibit 4.1 to Form S-8 on June 11, 2010 and incorporated herein by reference.)
- 10.0 Stock Purchase Agreement with Permaterc Holding AG, Permaterc Pharma AG, Permaterc Technologie AG and Permaterc NV with First and Second Amendments dated July 14, 2000 (Filed as an exhibit to Schedule 14A on December 28, 2000 and incorporated herein by reference.)
- 10.1 Third Amendment to Stock Purchase Agreement, dated January 31, 2001 (Filed as exhibit 10.1 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
- 10.2\* Agreement with Becton Dickinson dated January 1, 1999 (Filed as exhibit 10.24 to Form 10-K for the year ended December 31, 1998 and incorporated herein by reference.)
- 10.3\* 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.)
- 10.4\* 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.)
- 10.5\* 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.)
- 10.6\* 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.)
- 10.7\* 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.)
- 10.8\* 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.)
- 10.9 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.)
- 10.10 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.)
- 10.11 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.)
- 10.12\* Development Supply Agreement, dated June 22, 2005 (Filed as exhibit 10.69 to Form 10-Q for the quarter ended June 30, 2005 and incorporated herein by reference.)

- 10.13\* 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.)
- 10.14+ 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.)
- 10.15+ 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.)
- 10.16+ 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.)
- 10.17+ 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.)
- 10.18+ 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.)
- 10.19 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.)
- 10.20 First Amendment to Lease Agreement between James Campbell Company LLC and Antares Pharma, Inc., dated November 2, 2010. #
- 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.
- # Filed herewith.

## 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 14, 2011.

### 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 14, 2011.

<u>Signature</u>	<u>Title</u>
<u>/s/Paul K. Wotton</u> Dr. Paul K. Wotton	President and Chief Executive Officer, Director (Principal Executive Officer)
<u>/s/Robert F. Apple</u> Robert F. Apple	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
<u>/s/Leonard S. Jacob</u> Dr. Leonard S. Jacob	Director, Chairman of the Board
<u>/s/Thomas J. Garrity</u> Thomas J. Garrity	Director
<u>/s/Jacques Gonella</u> Dr. Jacques Gonella	Director
<u>/s/Anton G. Gueth</u> Anton G. Gueth	Director
<u>/s/Rajesh Shrotriya</u> Dr. Rajesh Shrotriya	Director
<u>/s/Eamonn P. Hobbs</u> Eamonn P. Hobbs	Director

