ANTARES PHARMA, INC.
Form 10-K
March 24, 2010

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

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009

[ ] 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:

Title of each class	Name of each exchange on which registered
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[X]

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[X]

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[X] 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[X] 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. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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 [X]

(Do not check if a smaller reporting company)

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

Aggregate market value of the voting and non-voting common stock held by nonaffiliates of the registrant as of June 30, 2009, was $49,908,000 (based upon the last reported sale price of $0.89 per share on June 30, 2009, on NYSE Amex).

There were 82,361,434 shares of common stock outstanding as of March 15, 2010.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2010 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

PART I

Item 1. BUSINESS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act 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," an 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, 2010;
- 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 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 and have partnerships with Ferring Pharmaceuticals BV ("Ferring") and JCR Pharmaceuticals Co., Ltd. ("JCR") that include their human growth hormone ("hGH") products. In the gel-based area, our

lead product candidate, Anturol®, an oxybutynin ATD™ gel for the treatment of overactive bladder ("OAB"), is currently under evaluation in a pivotal Phase 3 trial. 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 FDA approved products. Our products and product opportunities are summarized and briefly described below:

Products

Injection Devices

Transdermal Delivery Gels

Pressure Assisted Injection Devices

Our injection device platform features three main products: reusable needle-free injectors, disposable pressure assisted auto injectors and disposable pen injectors. Each is briefly described below:

- Reusable needle-free injectors deliver precise medication doses through high-speed, pressurized liquid penetration of the skin without a needle. 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. The associated sterile plastic disposables, needle-free syringes and adapters, are designed for use as appropriate for the drug and indication.

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®, by Teva in the U.S.; Zomajet® 2 Vision and Zomajet® Vision X, by Ferring in Europe and Asia; and Twin-Jector® EZ II, by JCR in Japan, and is sold as the Medi-Jector VISION® 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™ and/or Tjet®.

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

Our Parenteral Medicines (device) division is located in Minneapolis, Minnesota, where we develop and manufacture with partners novel pressure assisted injectors, with and without needles, which allow patients to self-inject drugs. We make a reusable, needle-free, spring-action injector device known as the Vision™ and Tjet®, which is legally 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 very small hidden needle to a pre-filled, single-use disposable injector, called the Vibex™ pressure assisted auto injection system. This system is an alternative to the 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.

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 United States Food and Drug Administration ("FDA") approved our first transdermal gel with a partner's drug product for the treatment of vasomotor symptoms in post-menopausal women. We are also developing our own transdermal gel-based products for the market and have recently completed enrollment in a pivotal Phase III safety and efficacy trial for Anturol®, our oxybutynin transdermal gel product for overactive bladder.

We believe that our transdermal gels minimize first pass liver metabolism, gastro intestinal effects and skin erythema. Other advantages include cosmetic elegance and ease of application as compared to transdermal patches and have potential applications in such therapeutic markets as hormone replacement, overactive bladder, contraception, pain management and central nervous system therapies.

We operate in the drug delivery sector of the pharmaceutical industry. Companies in this sector generally leverage technology and know-how in the area of drug formulation and product development to pharmaceutical manufacturers through licensing and development agreements while continuing to develop their own products for the marketplace. We also view many pharmaceutical and biotechnology companies as collaborators and primary customers. We have negotiated and executed licensing relationships in the needle-free devices segment in the U.S., Europe and Asia, the auto injector segment in the U.S. and Canada, the disposable pen injector segment worldwide, and the transdermal gels segment for which we have several development programs in place worldwide, including the United States and Europe. In addition, we continue to market our re-usable needle-free devices for the self administration of insulin in the U.S. market through distributors and have a non-exclusive license for our technology in the diabetes and obesity fields.

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

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 transdermal Advanced ATD™ gels; disposable pressure assisted auto injection systems (Vibex™); disposable pen injection systems; and reusable needle-free injection systems (Vision™).

SELF-ADMINISTRATION OF INJECTABLE BIOLOGIC DRUGS

Injectable biologic drugs generated a reported $125 billion in global revenue in 2008. 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.

Biological 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:

Condition	Products
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), Noridtropin (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)

Pressure Assisted Auto Injection

The most significant challenge beyond discovery of new molecules is how to effectively deliver them by means other than conventional injection technology. The majority of these molecules have not, to date, been amenable to oral administration due to a combination of several factors, including breakdown in the gastrointestinal tract, fundamentally poor absorption, or high first pass liver metabolism. Pulmonary delivery of these molecules, as an alternative to injections, has also been pursued without commercial success. Many companies have expended considerable effort in searching for less invasive ways to deliver such molecules that may allow them to achieve higher market acceptance, particularly for those requiring patient self-administration.

Pressure assisted auto injection is a form of 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 for two undisclosed products, and we are currently developing a proprietary product using the Vibex™ in the area of pain management.

Disposable Pen Injector System

Our most recently developed product, the pen injector, complements our portfolio of pressure assisted auto injector devices. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the 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.

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

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

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:

Competitive Advantages of ATD™ Gel System

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

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

Anturol®

Our lead product candidate, Anturol®, is an oxybutynin ATD™ gel for the treatment of OAB (overactive bladder), and is currently under evaluation in a pivotal Phase 3 trial. Enrollment in the trial was completed in March of 2010 and we expect to file a new drug application ("NDA") in 2010. We intend to seek a marketing partner to help fund the development of Anturol® and to commercially launch Anturol® 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.

Ropinirole

We have a worldwide product development and license agreement with Jazz Pharmaceuticals ("Jazz") for Ropinerole which is being developed to treat a central nervous system ("CNS") disorder that will utilize our transdermal gel delivery technology ATD™. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by us under certain circumstances.

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 a September 2008 Deutsche Bank Global Market Research Report, U.S. sales of biological drugs in 2007 were approximately $42 billion. The same report states that $25 billion worth of these drugs are losing patent exclusivity between now and 2016, making them prime targets for follow-on biologics. Self-administered injectable biologics account for the main portion—over $22 billion—of those facing future competition from follow-on biologics. Since, by design, follow-on biologic molecules will be nearly identical to the innovator biologic, both the innovator and follow-on manufacturers will seek other ways to differentiate their products in the market. We believe that manufacturers will look to proprietary advantages in the designs of the self-administration devices, such as those offered by our injection device platforms, as a key way to compete in the market.

In a May 2009 report, Greystone Associates estimated the worldwide hGH market in 2008 at $2.8 billion. The hGH market has significant competition with 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® 2 Vision for their 4 mg formulation and Zomajet® 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® needle-free device in late

2009, sales of Teva's hGH Tev-Tropin® 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.

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®

According to a March 2010 Cowen Therapeutic Outlook Report, the worldwide market for urinary incontinence was $2.1 billion in 2009 and is estimated to be $2.3 billion by 2014. During this period, new treatments of overactive bladder (OAB) are expected to grow from $0.9 billion to $2.0 billion, offset by generic erosion of older brands such as Detrol LA (Pfizer). It is estimated 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 clinical trials other transdermal gel and patch oxybutynin products have reported an incidence of anticholinergic side effects comparable to placebo. We have recently completed enrollment in a Phase III study of Anturol® oxybutynin gel to treat urinary incontinence.

Elestrin® and LibiGel®

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.

According to IMS Health, the U.S. market for transdermal testosterone therapies grew approximately 22 percent in 2007 to $624 million from $510 million in 2006. 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®, 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®. As evidenced in Europe, we believe that global patient demand

for transdermal hormone therapy products will continue to increase. Evidence of this belief is the commercial launch, in France, Italy, Spain, U.K., Germany and others, by Proctor and Gamble of the Intrinsa® Patch, a testosterone transdermal patch for FSD.

Nestorone® Gel (Contraception)

Worldwide sales of hormonal contraceptives in 2008 was $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® and a form of estrogen, called 17 -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.

Ropinirole Gel

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

Current treatments for CNS disorders vary in effectiveness, but there are many conditions for which there are few safe and effective drugs. Cowen & Co. estimates that nearly $41 billion was spent in 2009 on prescription CNS drugs. They estimate that another $6.7 billion was spent in 2009 on pain management prescriptions consisting primarily of opioid drugs and nonsteroidal anti-inflammatory drugs. Many CNS and chronic pain drugs merely treat the symptoms and do not provide cures. According to the World Health Organization, diseases of the CNS will constitute an increasing medical need in this century, attributable to an exponential increase of these diseases after the age of 65 combined with an aging population. Ropinirole and Pramipexole are products being used for CNS disorders, particularly parkinsons disease and Restless Leg Syndrome (RLS). Oral therapies for RLS such as Ropinirole and Pramipexole generated U.S. sales of $660 million in 2007 prior to introduction of generic versions of the products.

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

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., 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.

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

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

Summary of Clinical Data

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

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

In October 2007, we announced that the first patients were dosed in the pivotal trial designed to evaluate efficacy of Anturol® when administered topically once daily for 12 weeks in patients predominantly with urge incontinence episodes. The randomized, double-blind, parallel, placebo controlled, multi-center trial is to involve 600 patients (200 per arm) using two dose strengths (selected from the Phase II clinical trial) versus a placebo. The primary end point of the trial will be efficacy against the placebo defined as the reduction in the number of urinary incontinence episodes experienced. Secondary end points include changes from baseline in urinary urgency, average daily urinary frequency, patient perceptions as well as safety and tolerability including skin irritation. Enrollment was completed in March of 2010 with an expected NDA filing time, if data is successful, in the fourth quarter of 2010.

Device Development Projects. We are engaged in research and development activities related to our Vibex™ disposable pressure assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex™ system for two undisclosed products and for our pen injector device for two undisclosed products. Our pressure assisted auto injectors are designed to deliver drugs by injection from single dose prefilled syringes. The 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™ undisclosed product #1

We have designed the Vibex™ for the first undisclosed product 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. 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 as well as

conducting user studies with the device. 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™ undisclosed product #2

We have designed the Vibex™ 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 believe we can redesign the device to address the FDA's concern of device similarity and are currently working on the redesign.

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 a safety study be conducted in support of the filing. Teva is currently determining the clinical design and cost for this program.

Disposable pen injector #2

We have early prototype designs for the second pen injector product. Teva believes the regulatory pathway is an ANDA pathway. Currently Teva is designing the development program.

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 2010, but the timing and extent of near-term future development will be dependent on decisions made by Teva.

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

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 2009, 2008 and 2007, international revenue accounted for approximately 47%, 74% and 55% of total revenue. Europe accounted for 94%, 93% and 91% of international revenue in 2009, 2008 and 2007, with the remainder coming primarily from Asia. Ferring accounted for 39%, 60% and 39% of our worldwide revenues in 2009, 2008 and 2007. BioSante accounted for 2%, 12% and 36% and JCR accounted for 2%, 5% and 4% of our worldwide revenues in 2009, 2008 and 2007. Revenue from Ferring and JCR resulted from sales of injection devices and related disposable components for their hGH formulations. In 2008 and 2007, the BioSante revenue resulted primarily from license fees and milestone payments related to Elestrin®, received under a sublicense arrangement related to an existing license agreement with BioSante.

See 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 significant existing pharmaceutical and device relationships and license agreements:

Partner	Drug	Market Segment	Product
Ferring	hGH (4mg formulation)	Growth Retardation (U.S., Europe, Asia & Pacific)	Needle Free Zomajet® 2 Vision
Ferring	hGH (10 mg formulation)	Growth Retardation (U.S., Europe, Asia & Pacific)	Needle Free Zomajet® Vision X
Teva	hGH	Growth Retardation (United States)	Needle Free Tjet®
JCR	hGH	Growth Retardation (Japan)	Needle Free Twin-Jector® EZ II
Teva	Undisclosed Product #1	Undisclosed (U.S. and Canada)	Auto Injector Disposable Device
Teva	Undisclosed Product #2	Undisclosed (United States)	Auto Injector Disposable Device
Teva	Undisclosed Product #3	Undisclosed (North America, Europe & others)	Disposable Pen Injector Device
Teva	Undisclosed Product #4	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
Jazz Pharmaceuticals	Ropinirole	Central Nervous System (Worldwide)	ATD™ Gel
Population Council	Nestorone®/Estradiol	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 $1 million upon execution of the agreement and is also required to make royalty payments once commercial sales of the products have begun. The royalty payments are based on a percentage of sales of the products and must be paid for a period of 10 years following the first commercial sale of the products, or when the last patent for the products expires, whichever is later. The agreement also provides for milestone payments to us upon the occurrence of certain events related to regulatory filings and approvals. In November 2006, BioSante entered into a sublicense and marketing agreement with Bradley Pharmaceuticals, Inc. ("Bradley") for Elestrin® (formerly Bio-E-Gel). BioSante received an upfront payment from Bradley which triggered a payment to us of $875,000. In December 2006, the FDA approved Elestrin® 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®. Bradley was acquired by Nycomed Inc. in February 2008 and returned Elestrin® to BioSante. In December 2008, Elestrin® was sublicensed to Azur Pharmaceuticals ("Azur") and subsequently relaunched in 2009. As a result of the sublicense agreement with Azur, we received payments from BioSante of $462,500 in December 2008. In addition, we will receive royalties on sales of Elestrin® as well as potential sales-based milestone payments.

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

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

In July 2006, we entered into an exclusive License Development and Supply Agreement with Sicor Pharmaceuticals Inc., an affiliate of Teva. Pursuant to the agreement; the affiliate is obligated to purchase all of its delivery device requirements from us for an undisclosed product to be marketed in the United States and Canada. We received an upfront cash payment, and will receive milestone fees, a negotiated purchase price for each device sold, as well as royalties on sales of their product. In December 2008, this agreement was amended to include development work that was outside the scope of the original agreement, resulting in additional payments to us. In 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®, 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 will receive milestone fees and a royalty payment on Teva's net sales of hGH, as well as a purchase price for each device sold.

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

In 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 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 and will receive 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 2023. In addition to issued patents and patent applications, we are also protected by trade secrets in all of our technology platforms.

Some of our technology is developed on our behalf by independent outside contractors. To protect the rights of our proprietary know-how and technology, Company policy requires all employees and consultants with access to proprietary information to execute confidentiality agreements prohibiting the disclosure of confidential information to anyone outside the Company. These agreements also require disclosure and assignment to us of discoveries and inventions made by such individuals while devoted to Company-sponsored activities. Companies with which we have

entered into development agreements have the right to certain technology developed in connection with such agreements.

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, injunctive actions and civil or criminal actions or penalties.

Drug Approval Process

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

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

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

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

Clinical trials are conducted according to protocols that detail matters such as a description of the condition to be treated, the objectives of the study, a description of the patient population eligible for the study and the parameters to be used to monitor safety and efficacy. Each protocol must be submitted to the FDA as part of the IND. Protocols

must be conducted in accordance with FDA regulations concerning good clinical practices to ensure the quality and integrity of clinical trial results and data. Failure to adhere to good clinical practices and the protocols may result in FDA rejection of clinical trial results and data, and may delay or prevent the FDA from approving the drug for commercial use.

Clinical trials are typically conducted in three sequential Phases, which may overlap. During Phase I, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, distribution,

metabolism and excretion. Phase I studies are often conducted with healthy volunteers depending on the drug being tested; however, in oncology, Phase I trials are more often conducted in cancer patients. Phase II involves studies in a limited patient population, typically patients with the conditions needing treatment, to:

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

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

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

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 Anturol® gel and Nestorone® gel, as well as our products being developed by our partners are subject to the above regulations. Anturol® and Nestorone® will be subject to the NDA process. Device combination products developed and currently being developed by our partner Teva are subject to the sNDA, ANDA and 505(b)(2) regulations cited above.

Device Approval Process

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

Drug delivery systems such as injectors may be legally marketed as a medical device or may be evaluated as part of the drug approval process such as a NDA or a Product License Application ("PLA"). Combination drug/device products raise unique scientific, technical and regulatory issues. The FDA has established an Office of Combination Products ("OCP") to address the challenges associated with the review and regulation of combination products. The OCP assists in determining strategies for the approval of drug/delivery combinations and assuring agreement within the FDA on review responsibilities. To the extent permitted under the FD&C Act and current FDA policy, we intend to seek regulatory review for drug delivery systems for use in specific drug applications under the medical device provisions, rather than under the new drug provisions, of the FD&C Act. Device regulatory filings could take the form of a PMN, PMA, or the filing of a device master file ("MAF"). In some cases, the device specific information may need to be filed as part of the drug approval submission, and in those cases we will seek agreement from the Agency for review of the device portion of the submission by the Center for Devices and Radiological Health ("CDRH") under the medical device provisions of the law.

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

such a filing. We intend to pursue such strategies as permitted by the law and as directed by the FDA either through guidance documents or discussions.

In addition to submission when a device is being introduced into the market for the first time, a PMN is also required when the manufacturer makes a change or modification to a previously marketed device that could significantly affect safety or effectiveness, or where there is a major change or modification in the intended use or in

the manufacture of the device. When any change or modification is made in a device or its intended use, the manufacturer is expected to make the initial determination as to whether the change or modification is of a kind that would necessitate the filing of a new 510(k) notification. The Vision™ injection system is a legally marketed device under Section 510(k) of the FD&C Act for insulin. In the future we or our partners may submit additional 510(k) notifications with regard to further device design improvements and uses with additional drug therapies.

If the FDA concludes that any or all of our new injectors must be handled under the new drug provisions of the FD&C Act, substantially greater regulatory requirements and approval times will be imposed. Use of a modified new product with a previously unapproved new drug likely will be handled as part of the NDA for the new drug itself. Under these circumstances, the device component will be handled as a drug accessory and will be approved, if ever, only when the NDA itself is approved. Our injectors may be required to be approved as a combination drug/device product under a 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, a pharmaceutical partner of ours, filed a sNDA with the FDA for hGH for use with our Tjet® device in July 2008. The sNDA was approved in June of 2009. Teva launched the Tjet® device in August of 2009 for use in delivery of Teva's form of hGH, Tev-Tropin®.

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 15, 2010, we had 19 full-time employees, of whom 17 are in the United States. Of the 19 employees, 10 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.antarespharma.com). We make available free of charge on or through our Internet website our annual

reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after electronically filing those documents with or furnishing them to the SEC. The information on our website is not incorporated into and is not a part of this annual report.

Item 1A. RISK FACTORS

The following "risk factors" contain important information about us and our business and should be read in their entirety. Additional risks and uncertainties not known to us or that we now believe to be not material could also impair our business. If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline and you could lose all of your investment. In this Section, the terms 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 $10,290,752 and $12,690,453 in the fiscal years ended 2009 and 2008, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2009 of $130,882,597. In addition, we expect to report a net loss for the year ending December 31, 2010. 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 $105,622 and $1,319,950 in 2009 and 2008, respectively. If additional capital is needed in the near term to support operations, the current economic and market conditions may make it difficult to raise additional funds through debt or equity financings.

At December 31, 2009 we had cash and cash equivalents of $13,559,088. Although the combination of our current cash and cash equivalents balance and projected product sales, product development, license revenues, milestone payments and royalties may provide us with sufficient funds to support operations for the next 12 months, we may need to pursue a financing or reduce expenditures as necessary to meet our cash requirements over the next 12 months. If we do obtain such financing, we cannot assure that the amount or the terms of such financing will be as attractive as we may desire. If we are unable to obtain such financing when needed, or if the amount of such financing is not sufficient, it may be necessary for us to take significant cost saving measures or generate funding in ways that may negatively affect our business in the future. To reduce expenses, we may be forced to make personnel reductions, eliminate departments 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. Generally speaking, in the near term, we do not intend to have a direct marketing channel to consumers for our drug delivery products or technologies except through current distributor agreements in the United States for our insulin delivery device. Therefore, the success of the marketing organizations of our pharmaceutical company partners, as well as the level of priority assigned to the marketing of the products by these entities, which may differ from our priorities, will determine the success of the products incorporating our technologies. Competition in this market could also force us to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability.

Additionally, there is no assurance that regulatory filings by our partners in the U.S. will be deemed sufficient by 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, 2009, we derived approximately 39% of our revenue from Ferring and 38% from Teva. For the year ended December 31, 2008, we derived approximately 60% of our revenue from Ferring and 12% of our revenue from BioSante. The revenue from Ferring was primarily product sales and royalties. The revenue from Teva was license and development revenue and product sales. The revenue from BioSante was primarily milestone based and will likely not be recurring in the near future.

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

We have entered into four license, development and/or supply agreements for five potential products since November of 2005 with Teva or an affiliate of Teva. To date we have received FDA approval of one of those products, the Tjet® needle-free device for use with hGH. Teva is currently marketing the Tjet® 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 July 2007, we entered into a worldwide product development and license agreement with Jazz. Under the agreement an upfront payment, development milestones, and royalties on product sales are to be paid to us under certain circumstances. The development program conducted by Jazz is currently on hold and we may never receive any compensation other than the upfront payment earned at agreement execution and other development revenue.

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® (transdermal testosterone gel) in Phase 3 clinical development for the treatment of FSD, and Elestrin® (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.

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.

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.

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

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

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

26

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.

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

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

- advantages over alternative drug delivery systems or similar products from other companies;
- demonstrated clinical efficacy, safety and enhanced patient compliance;
- cost-effectiveness;

- convenience and ease of use of injectors and transdermal gels;
- marketing and distribution support; and
- successful launch of our pharmaceutical partners products which utilize our devices.

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

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

Because transdermal gels are not a widely understood method of drug delivery, our potential partners and consumers may have little experience with such products. Our assumption of higher value may not be shared by the potential partner and consumer. To date, transdermal gels have gained successful entry into only a limited number of markets 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 development and 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®, for which we receive royalties from our partner based on any commercial sales, was launched in June 2007. We have no way of knowing at this time if health insurance companies' reimbursement has negatively impacted patient use of Elestrin®.

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

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

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

We currently hold numerous patents and numerous patent applications pending in the U.S. and other countries. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain their own patents that may have an adverse effect on our ability to conduct business, or are able to otherwise circumvent our patents. Additionally, our technologies are complex and one patent may not be sufficient to protect our products where a series of patents may be needed. Further, we may not have the necessary financial resources to enforce or defend our patents or patent applications. In addition, any patent applications we may have made or may make relating to inventions for our actual or potential products, processes and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for our inventions.

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

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

Third parties may claim that the manufacture, use or sale of our drug delivery technologies infringe their patent rights. If such claims are asserted, we may have to seek licenses, defend infringement actions or challenge the validity of those patents in the patent office or the courts. If we cannot avoid infringement or obtain required licenses on acceptable terms, we may not be able to continue to develop and commercialize our product candidates. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property. If we are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by patents of others. Even if we were able to prevail, any litigation could be costly

and time-consuming and could divert the attention of our management and key personnel from our business operations. We may not have identified, or be able to identify in the future, United States or foreign patents that pose a risk of potential infringement claims. Furthermore, in the event a patent infringement suit is brought against us, the development, manufacture or potential sale of product candidates

claimed to infringe on a third party's intellectual property may have to stop or be delayed. Ultimately, we may be unable to commercialize some of our product candidates as a result of patent infringement claims, which could harm our business.

We are aware of two related U.S. patents issued to Watson Pharmaceuticals relating to a gel formulation of oxybutynin (Gelnique®). We believe that we do not infringe these patents and that they should not have been granted. We may seek to invalidate these patents but there can be no assurance that we will prevail. If the patents are determined to be valid and if Anturol® is approved, we may be delayed in our marketing of Anturol® or incur significant expenses defending our patent position which may adversely affect the potential market value of Anturol®.

We are aware that one of our partners has been sued for infringement by another party related to a potential product incorporating one of our devices. We believe the claim has no merit but we have no assurance that our partner will prevail in the suit, which could result in significant litigation cost, product launch delay or ultimately the abandonment of the potential product incorporating our device.

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

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

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

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

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

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

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

We might attempt to acquire products or businesses that we believe are a strategic complement to our business model. We might encounter operating difficulties and expenditures relating to integrating an acquired product or business. These acquisitions might require significant management attention that would otherwise be available for ongoing development of our business. In addition, we might never realize the anticipated benefits of any acquisition.

We might also make dilutive issuances of equity securities, incur debt or experience a decrease in cash available for our operations, or incur contingent liabilities and/or amortization expenses relating to goodwill and other intangible assets, in connection with future acquisitions.

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

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

Risks Related to General Economic Conditions

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

The global credit markets have experienced significant dislocations and liquidity disruptions. These circumstances have materially impacted liquidity in the financial markets. Continued uncertainty in the financial markets may negatively impact our ability to access additional financing, which could negatively affect our ability to fund our current operations as well as our future development and our business could be adversely affected. A prolonged downturn in the financial markets may cause us to seek alternative sources of potentially less attractive financing, and may require us to adjust our business plan accordingly.

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

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

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

Risks Related to Regulatory Matters

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

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

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

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

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

In February 2006, we announced the results of our Phase II dose ranging study for our ATD™ oxybutynin gel product Anturol®. The study was an open label, single period, randomized study using 48 healthy subjects and three different doses of Anturol® over a 20 day period. Our overall conclusions of the study were positive. The FDA however, may not concur with our analysis of the data.

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

In October 2007, we announced the first patient dosing in a pivotal safety and efficacy trial of Anturol® for OAB. The three arm study will enroll approximately 600 patients for a 12-week clinical trial. The randomized, double-blind, placebo controlled, multi-center trial will principally evaluate the efficacy of Anturol® when administered topically once daily for 12 weeks. The primary end point of the trial will be efficacy against the placebo defined as the reduction in the number of urinary incontinence episodes experienced. Secondary end points include changes from baseline in urinary urgency, average daily urinary frequency, patient perceptions as well as safety and tolerability. In March of 2010 we announced that enrollment in the Phase III study was complete. The completion of enrollment of the trial does not ensure success of the trial. Anturol® may prove to not be efficacious and may not beat placebo or may have undesired side effects not previously experienced. Additionally, the FDA may require further studies for approval. Any of these potential outcomes could have a negative impact on the value of our stock price.

We are also developing, with our partners, injection devices for use with our partner's drugs. The regulatory path for approval of such combination products maybe subject to review by several centers within the FDA and although precedent and guidance exists for the requirements for such combination products, there is no assurance that the FDA will not change what it requires or how it reviews such submissions. Human clinical testing may be required by the FDA in order to commercialize these devices and there can be no assurance that such trials will be successful. Such changes in review processes or the requirement for clinical studies could delay anticipated launch dates or be at a cost which makes launching the device cost prohibitive for our partners. Such delay or failure to launch these devices could adversely affect our revenues and future profitability.

In December 2008, one of our device partners, Teva, filed an ANDA for their undisclosed 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.

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

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

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

Drug delivery systems such as injectors are reviewed by the FDA and may be legally marketed as a medical device or may be evaluated as part of the drug approval process. Combination drug/device products raise unique scientific, technical and regulatory issues. The FDA has established 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.