ANTARES PHARMA, INC.
Form 10-K
March 13, 2013
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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, 2012

¨ **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**
100 Princeton South, Suite 300, Ewing, NJ 08628

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	**NASDAQ Capital Market**

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 x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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, 2012, was $339,582,000 (based upon the last reported sale price of $3.63 per share on June 30, 2012, on the NASDAQ Capital Market).

There were 126,170,879 shares of common stock outstanding as of March 8, 2013.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant s 2013 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.

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PART I

Item 1. BUSINESS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties. You should not place undue reliance on those statements because they are subject to numerous uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as anticipate, will, estimate, expect, project, intend, should, plan, believe, hope, and other words and terms of similar meaning in 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 development and potential U.S. Food and Drug Administration (FDA) approval of OTREXUP (methotrexate injection);
- our expectations regarding product developments with Teva Pharmaceutical Industries, Ltd. (Teva);
- our expectations regarding commercialization of Gelnique 3% (oxybutynin gel) by Actavis, Inc. (Actavis), formerly Watson Pharmaceuticals, Inc. (Watson);
- our expectations regarding product development and potential FDA approval of Vibex QS T (testosterone injection);
- our expectations regarding product development and potential FDA approval of Vibex Sumatriptan (sumatriptan injection);
- our expectations regarding product development and potential FDA approval of Vibex Epinephrine (epinephrine injection);
- 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, 2013;

our ability to raise additional funds, if needed; 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.

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Overview

Antares Pharma, Inc. (Antares, we, our, us or the Company) is an emerging specialty pharmaceutical company that focuses on developing an commercializing self-administered parenteral pharmaceutical products and technologies and topical gel-based products. We have numerous partnerships with pharmaceutical companies as well as multiple internal product development programs. Our lead product candidate, OTREXUP , is our proprietary combination product comprised of a pre-filled methotrexate syringe and our Medi-Jet self-injection system for the treatment of moderate to severe rheumatoid arthritis (RA). On December 17, 2012 we announced submission of a New Drug Application (NDA) for OTREXUP and then on February 27, 2013 announced the FDA acceptance of that filing for review. The Prescription Drug User Fee Act (PDUFA) goal date for FDA approval is October 14, 2013. We have worldwide marketing rights for OTREXUP and have provided Uman Pharma (Uman) an exclusive license to commercialize the product in Canada. Our strategy is to potentially commercialize OTREXUP in the U.S. ourselves and to enter into licensing or distribution agreements for commercialization outside the U.S.

We have developed both subcutaneous and intramuscular injection technology systems which include Vibex disposable pressure-assisted auto injectors, Vision reusable needle-free injectors, and disposable multi-use pen injectors. We have licensed our reusable needle-free injection device for use with human growth hormone (hGH) to Teva, Ferring Pharmaceuticals BV (Ferring) and JCR Pharmaceuticals Co., Ltd. (JCR), with Teva and Ferring being two of our primary customers. Teva markets our needle-free injection device as the Tjet® injector system to administer their 5mg Tev-Tropin® brand hGH promoted in the U.S. and Ferring commercialized our needle-free injection system with their 4mg and 10mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. We have also licensed both the Vibex disposable auto injector and pen injection devices to Teva for use in certain fields and territories and we are engaged in product development activities for Teva utilizing these devices. In addition to development of products with partners, we are developing OTREXUP for the treatment of rheumatoid arthritis, poly-articular-course juvenile RA and psoriasis and are also preparing to initiate clinical development of Vibex QS T for testosterone replacement therapy.

In the gel-based products area, we received FDA approval in December 2011 for our oxybutynin gel product, Gelnique 3% , for the treatment of overactive bladder (OAB). We have a licensing agreement with Actavis (formerly Watson Pharmaceuticals) under which Actavis is currently marketing Gelnique 3% in the U.S. In January 2012, we entered into a licensing agreement with Daewoong Pharmaceuticals (Daewoong) under which Daewoong will commercialize our oxybutynin gel 3% product, once approved in South Korea. Our gel portfolio of products also includes Elestrin® (estradiol gel) currently marketed by Meda Pharmaceuticals (Meda) in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

Our products and product opportunities are summarized and briefly described below:

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History

On January 31, 2001, we (Antares, formerly known as Medi-Ject Corporation, or Medi-Ject) completed a business combination to acquire the operating subsidiaries of Permatec Holding AG (Permatec), headquartered in Basel, Switzerland. Medi-Ject was at that time, focused on delivering drugs across the skin using needle-free technology, and Permatec specialized in delivering drugs across the skin using gel technologies. 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 Products Group is located in Minneapolis, Minnesota, where we develop and manufacture for ourselves and with partners novel pressure assisted injectors, with and without needles, which allow patients to self-inject drugs. We make a reusable, needle-free, spring-action injector device known as the Vision and Tjet®, which is marketed for use with human growth hormone and insulin. We have had success in achieving distribution of our device for use with hGH through licenses to pharmaceutical partners, and it has resulted in continuing market growth and, we believe, a high degree of customer satisfaction. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

We have also developed variations of the needle-free injector by adding a small shielded 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 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., Europe and Canada with Teva. We are also developing the Medi-Jet auto injector for our product OTREXUP , for delivery of methotrexate for treatment of rheumatoid arthritis, and the Vibex QuickShot T (QS T) for testosterone replacement therapy.

Our Product Development Group is located in Ewing, New Jersey, where our gel based products were developed as well as our internal drug/device combination products. Several licensing agreements with pharmaceutical companies of various sizes have led to successful development of FDA approved products. In 2006, the FDA approved our first transdermal gel (Elestrin®) with a partner s drug product for the treatment of vasomotor symptoms in post-menopausal women. In December 2011, we received FDA approval for our topical oxybutynin gel product, Gelnique 3% , for the treatment of OAB. In April 2012, our licensee, Actavis, launched Gelnique 3% in the U.S.

Our Product Development Group also heads the clinical, regulatory and commercial development of our internal drug/device combination products. In 2012 we completed a successful clinical development program and filed an NDA with the FDA for OTREXUP for rheumatoid arthritis. Additionally, a pre-IND meeting was held with the FDA as part of preparing to initiate clinical development of Vibex QS T for testosterone replacement therapy.

We are a Delaware corporation with principal executive offices located at 100 Princeton South, Suite 300, Ewing, New Jersey 08628. Our telephone number is (609) 359-3020. We have wholly-owned subsidiaries in Switzerland (Antares Pharma AG and Antares Pharma IPL AG) and in the United Kingdom (Antares Pharma UK Limited).

Market Overview

Our focus is specifically on the market for delivery of self-administered injectable drugs, comprised of non-biologic small molecule drugs and biological products. We believe that many injectable products currently offered in vials could be replaced with user friendly injectors promoting better compliance and improvement in dose accuracy. Several manufacturers of injectable products have 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 and products offer further improvements in convenience and comfort for patients self-administering injectable products as well as provide the appropriate technique to the patient to accurately self-inject and that our

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business model of developing our own pharmaceutical products in targeted therapeutic categories using our pressure assisted auto injectors and pen injectors has the potential for further market penetration in the future. Also, partnering with pharmaceutical manufacturers of injectable products that are outside of our therapeutic focus offers us additional potential to profit from our proprietary injector systems.

SELF-ADMINISTRATION OF INJECTABLE DRUGS

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

Condition	Products
Diabetes	Humalog (Lilly), Humulin (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 (Abbvie), Simponi (Centocor Ortho Biotech), Cimzia (UCB)
Multiple Sclerosis	Avonex (Biogen Idec), Betaseron (Bayer), Copaxone (Teva), Rebif (EMD Serono)
Chronic Hepatitis C	Intron-A (Merck), Pegasys (Roche), Peg-Intron (Merck)
Anemia/Neutropenia	Aranesp (Amgen), Neulasta (Amgen)
Migraine	Imitrex (GSK, Par, Sandoz), Sumavel (Zogenix), Alsuma (Pfizer) Sumatriptan Autoinjector (Sun Pharma)
Allergic Emergency	Epipen (Pfizer), Twinject (Amedra), Auvi-Q (Sanofi)

In addition to the drugs listed in the table above and the products we already have in development, we have identified more than 60 additional injectable single and multi-source drug products currently on the market that are appropriate for self-administration and are candidates for our device technologies.

Non-biologic injectable drugs

According to a Merrill Lynch report, non-biologic injectables accounted for roughly 28% of the U.S. pharma market in 2010, making the segment valued at $89 billion. Generic injectables accounted for about $5.4 billion in 2011 according to Merrill Lynch, however, represent a disproportionately large proportion of unit volume due to substantially lower unit cost compared to branded injectable products.

Many non-biologic small molecule drugs are injected rather than taken orally for one or more of several reasons including improved absorption, onset of action, tolerability and safety. Our OTREXUP product is an example of changing the route of administration from oral to injection for better absorption and tolerability. Vibex Sumatriptan and Vibex Epinephrine are examples of using the injection route for faster onset of action. Generic products, like sumatriptan and methotrexate, are the majority of non-biologic injectable product volume in the current market.

Biologic injectable drugs

Given the market success of several injectable 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

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2008. According to IMS Health, the worldwide market for biologic products was estimated to be $157 billion in annual sales in 2011. As biological drugs lose patent and market exclusivity, they become prime targets for follow-on biologics, also known as biosimilars. IMS Health forecasts that the worldwide biosimilar market will grow from $693 million in 2011 to $4.0 to $6.0 billion in 2016. We estimate that self-administered injectable biologics represent well over half the market value of biologic products facing future competition from biosimilars. Since, by design, biosimilar molecules will be nearly identical to the innovator biologic, both the innovator and biosimilars manufacturers will seek other ways to differentiate their products in the market. We believe that manufacturers will look to proprietary self-administration devices, such as those offered by our injection device systems, as a key way to compete as the biosimilar market begins to emerge over the next few years.

THERAPEUTIC MARKET OPPORTUNITIES FOR OUR INJECTOR SYSTEMS

OTREXUP (methotrexate)

OTREXUP is our proprietary, wholly owned, combination product comprised of a pre-filled methotrexate syringe and our Medi-Jet self-injection system designed to enable rheumatoid arthritis patients to self-inject methotrexate reliably, comfortably, and conveniently at home. OTREXUP is in development for the treatment of rheumatoid arthritis. Rheumatoid arthritis is a chronic autoimmune disease in which an affected person s white blood cells (leukocytes) attack the synovial tissues surrounding the joints, resulting in pain, stiffness, swelling, joint damage, and loss of function of the joints. According to a study sponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) the incidence of rheumatoid arthritis is about 0.6 percent of the U.S. population (about 1.5 million people). The disease onset generally occurs between the ages of 25 to 50 years and is about twice as prevalent among women as among men. According to IMS Health, U.S. sales of biologic agents products approved to treat rheumatoid arthritis were approximately $17.6 billion in 2012. Some of these agents are also approved for other indications including plaque psoriasis, Crohn s disease, ulcerative colitis, juvenile idiopathic, ankylosing spondylitis, and psoriatic arthritis, making it difficult to determine the proportion of sales attributable to use in rheumatoid arthritis.

Methotrexate is the most commonly prescribed disease modifying anti-rheumatic drug (DMARD), used in an estimated 70% of rheumatoid arthritis patients. Methotrexate is started at a low dose, generally 7.5mg given orally, once-a-week, and titrated up for greater therapeutic effect, or until the patient incurs side effects. The maximum oral dose given is generally 20mg to 25mg per week (8 to 10, 2.5mg tablets given in one dose). Studies have reported as many as 30% to 60% of patients experience gastrointestinal side effects with oral methotrexate, preventing further dose escalation or requiring discontinuation in some patients. Also, the extent of oral absorption of methotrexate varies considerably between patients and has been shown to decline with increasing doses, which may also contribute to insufficient therapeutic response even after dose escalation. Studies have shown that switching patients from oral to parenteral methotrexate improves absorption and has been associated with improved therapeutic response. Additionally, some studies have shown a lower incidence of gastrointestinal side effects in patients that were switched from oral to parenteral methotrexate.

Other rheumatological conditions for which methotrexate is an approved treatment are polyarticular-course juvenile rheumatoid arthritis (JIA), in children who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs) and in patients with severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy after a definite diagnosis has been established, as by biopsy, for example. The recommended dosing schedule for methotrexate in psoriasis is 10 to 25 mg per week until adequate response is achieved. In JIA the recommended dosing range is 10 mg/m^2 to 30 mg/m^2 given once weekly.

Psoriasis is believed to be an autoimmune disease, characterized by thick patches of inflamed, scaly skin, created by abnormal, rapid, and excessive proliferation of skin cells. The NIAMS states that psoriasis affects 2-2.6% of the U.S population, with a higher incidence in Caucasians; it affects men and women at about the same rate. Children are also affected. Approximately 15% of psoriasis patients may subsequently develop psoriatic arthritis. According to the National Psoriasis Foundation 7.5 million Americans have psoriasis with about 150,000 new cases diagnosed each year.

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JIA is the most common rheumatic disease in childhood with an estimated prevalence between 7 and 400 for every 100,000 children. According to the NIAMS, JIA affects nearly 300,000 children in the U.S. Most forms of JIA are autoimmune disorders that cause pain, swelling, stiffness, and loss of motion in the joints. It can persist over many years and can also lead to disability and dysfunction in adulthood.

We believe that OTREXUP offers physicians and patients an important alternative to oral methotrexate tablets and vials of the injectable form of the drug. Many patients who start on oral methotrexate fail to achieve adequate therapeutic results due in part to poor oral absorption or poor tolerability. Published studies have demonstrated that switching to a parenteral route of administration can improve absorption; however, fewer than 10% of patients on methotrexate are being prescribed the injectable form. Instead, patients who fail to achieve adequate response on oral methotrexate are often prescribed a biologic response modifier (biologic). The biologics have been demonstrated to improve the patient s therapeutic response when added to methotrexate. However, the biologics are expensive, typically costing in excess of $20,000 per year (based on published manufacturers direct prices), have their own limitations including increasing the risk of serious infections and certain malignancies and are not appropriate for all patients. OTREXUP could offer physicians and patients a convenient, practical and cost-effective option for administering parenteral methotrexate as an alternative to proceeding directly from oral methotrexate to biologics. Additionally, OTREXUP is a self-contained injection device which should minimize accidental contact with methotrexate, a hazardous drug agent.

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

Vibex QS T (testosterone)

Vibex QS T is the Company s wholly owned, proprietary combination product that consists of testosterone and our next generation Vibex QS auto injector in development for the treatment of testosterone deficiency or testosterone replacement therapy. The Vibex QS auto injector is designed specifically to provide a fast injection of highly-viscous fluids such as testosterone in oil.

The U.S. testosterone replacement therapy (TRT) market in 2012 was approximately $2.2 billion according to IMS Health, and grew 29% vs. 2011. According to a Global Industry Analysts report, the market is projected to be $5 billion by 2017. There is significant competition with the TRT market between many pharmaceutical companies including Abbvie (formerly Abbott), Lilly, Endo, Pfizer, Actavis, Auxillium, Actient, Sandoz, Mylan, Bedford Labs, and Teva.

An estimated 2 to 4 million men in the U.S. suffer from symptomatic low testosterone (Therapeutics and Clinical Risk Management, 2009:5 427-448) yet only about 12% were treated according to a study published in the May 26, 2008 issue of Archives of Internal Medicine. Symptoms and health risks associated with low testosterone include reduced libido, compromised sexual function, loss of bone density, reduced muscle mass, lethargy, mood disorders, impaired cognition, and cardiovascular disease. Several factors, including low awareness, embarrassment and stigma associated with low testosterone are believed to contribute to the relatively low diagnosis and treatment levels.

Testosterone replacement therapy is given to restore patients testosterone levels to within the normal range, generally defined as 300 to 1100 nanograms per deciliter (ng/dL) of serum. The Association of Clinical Endocrinologists (AACE) guidelines for treatment state that men with testosterone levels less than 200 ng/dL are definite candidates for therapy. AACE states the potential benefits of therapy are restored libido and erectile function, increased energy levels, and improved mood. TRT can also improve body composition by decreasing fat mass, increase lean body mass, potentially increase muscle strength, and stabilize or increase bone mineral density, as well as reduce bone fractures.

Topical gel formulations such as Androgel, Testim, Fortesta and Axiron are the most frequently prescribed versions of TRT, accounting for nearly 70% of prescriptions according to IMS Health. Injectable testosterone formulations account for nearly 30% of prescriptions. The remainder of testosterone prescriptions are for dermal patches, buccal delivery, and implantable pellets.

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Not all men are able to adequately absorb the gel formulations or otherwise find them unacceptable for reasons including risks of transferring the gel to spouses or children or dissatisfaction with the application process. Injectable testosterone is an option for men who prefer to avoid gels or have inadequate response. The injections are usually given deep into the muscle tissue of the buttocks. Injection testosterone is an esterified formulation in oil which is absorbed slowly from the muscle tissue, producing a sustained increase in serum testosterone over time, requiring repeated injections typically administered in the physician s office every two to four weeks. The higher doses given to facilitate less frequent injections are sometimes associated with supra-physiologic levels. Such high levels may lead to polycythemia, a proliferation of red blood cells, which places the patient at increased risk of risk of thrombus or clot formation leading to strokes, heart attacks, pulmonary embolism, and possibly death. Excessive variability between peak testosterone levels occurring shortly after the injection to the lowest levels immediately preceding a dose are also associated with mood swings. For these reasons the Company is developing Vibex QS T as an injectable testosterone product that could be conveniently self-administered at potentially lower dosages given more frequently than is generally practical with repeated visits to the physician s office.

Tjet® / Zomajet® (hGH)

Tjet® / Zomajet® is our needle-free auto injector offered by Teva and Ferring, respectively, to patients who use their brands of hGH. It is designed to deliver hGH treatment to children without the use of a needle.

According to IMS Health, hGH sales in the U.S. were $1.5 billion in 2012. There is significant competition within the hGH market between major pharmaceutical companies such as Lilly, Roche, Pfizer, NovoNordisk, Sandoz, Teva and Merck Serono among others. We believe that 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® continue to increase. This trend supports the notion that devices can increase patient use of a partner s brand of drug due to the benefits of a device. We sell the Tjet® and Zomajet® devices along with disposables to our partners as well as receive a royalty on net sales of the hGH product.

Vibex with Epinephrine

We have a license agreement with Teva for our Vibex system which we have designed for a product containing epinephrine and have scaled up the commercial tooling and molds for this product. We are awaiting FDA approval of the product as a generic substitute of Pfizer s branded product, EpiPen®, which is distributed by Mylan, Inc.

The EpiPen® is the global market leader in the epinephrine auto injector market. In the U.S., according to IMS Health, sales of epinephrine injection products were about $700 million in 2012 with the EpiPen® accounting for 97% of the total. Mylan, Inc. reported that EpiPen® has more than 95% market share in the U.S. and more than 90% market share worldwide. Epinephrine is utilized for the treatment of severe allergic reactions (anaphylaxis) to insect venom, foods, drugs and other allergens as well as anaphylaxis to unknown substances or exercise-induced anaphylaxis.

Vibex with Sumatriptan

We have a license agreement with Teva for our Vibex system which we have designed for a product containing sumatriptan and are in the process of scaling up the commercial tooling and molds for this product. We are awaiting FDA approval of the product as a generic substitute of GlaxoSmithKline s branded product, Imitrex® STATdose Pen®. In the U.S., according to IMS Health, sales of migraine products were about $1.8 billion in 2012. Oral drugs accounted for $1.4 billion of the total. Injectable products accounted for about $250 million.

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According to a survey commissioned by the National Headache Foundation migraines affect nearly 30 million Americans. Migraine headaches are characterized by headache of moderate or severe intensity; nausea (the most characteristic); one-sided and/or pulsating quality; aggravated by routine physical activity; with duration of hours to 2-3 days; and attack frequency anywhere between once a year and once a week. An estimated 60% of migraine sufferers use a triptan medicine, such as GSK s Imitrex (sumatriptan) and Amerge (naratriptan); Pfizer s Relpax (eletriptan), Merck s Maxalt (rizatriptan), Impax Laboratories Zomig (zolmitriptan), Janssen Pharmaceuticals Axert (almotriptan), and Endo Pharmaceuticals Frova (frovatriptan) to relieve acute symptoms of a migraine attack (Medco claims database study).

The majority of patients who use triptans take oral tablets. While the oral triptans have benefited many migraine sufferers, they are most consistently effective when taken at a relatively early stage in the migraine attack. None is as effective and as rapid-acting as injectable sumatriptan in treating a migraine headache that has reached the moderate to severe level of intensity. About 10% of triptan prescriptions are for injectable triptans. Sumatriptan is the only injectable triptan approved for use in the U.S. Several manufacturers offer versions of injectable sumatriptan with a delivery device, including GSK (Imitrex StatDose), Pfizer (Alsuma) Zogenix (Sumavel DosePro), and Sun Pharma (generic sumatriptan autoinjector). Two companies, Par and Sandoz, market authorized generic versions of GSK s Imitrex StatDose. At least three companies, including Bedford Labs, Teva, and Fresenius Kabi have FDA approval to market injection sumatriptan in prefilled syringes, although we are not aware of any that presently market this product configuration. Additionally, several generics manufacturers offer injectable sumatriptan in vials.

Other Injectable Drugs

Other injectable drugs that are presently self-administered and may be suitable for injection with our systems include therapies for the prevention of blood clots and treatments for multiple sclerosis, 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® (Abbvie) 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® (Bristol Myers) for diabetes, Rebif® (EMD Serono) for multiple sclerosis, Copaxone® (Teva) for multiple sclerosis and Gonal-F® (EMD Serono) for fertility treatment.

THERAPEUTIC MARKET OPPORTUNITIES FOR TRANSDERMAL GEL PRODUCTS

Oxybutynin Gel 3%

Our topical oxybutynin gel 3% product for the treatment of OAB was approved by the FDA in December 2011. According to IMS Health, the U.S. OAB market value was about $2 billion, based on over 18 million prescriptions written in 2010. OAB is a condition marked by urinary urgency, which is a sudden need to urinate that can happen at any time whether or not the bladder is full. OAB is typically caused when the smooth muscle of the bladder undergoes involuntary contractions and may result in uncontrolled leakage. OAB is defined as urgency, with or without incontinence and usually includes increased urinary voiding frequency and nocturia (waking up one or more times during the night to urinate). According to published reports it is estimated that more than 30 million Americans have OAB, and while it can happen at any age is more prevalent among older individuals. It is estimated, however, that half of the U.S. adults suffering from OAB either are too embarrassed to discuss the symptoms or are not aware that pharmacological treatment is available. Patient acceptance of older incontinence drugs, such as oral oxybutynin, is hindered by anticholinergic side-effects including moderate to severe dry mouth, constipation and somnolence. A goal of transdermal delivery is to minimize these common anticholinergic side effects.

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In July 2011 we licensed our oxybutynin gel 3% product to Actavis for commercialization in the U.S. and Canada and in January 2012 we licensed this product to Daewoong Pharmaceuticals for commercialization once approved in South Korea. The product was approved by the FDA in December 2011 and in April 2012 we announced, with Actavis, the launch of Gelnique 3% in the U.S.

Actavis is currently marketing Gelnique 3% along with Gelnique 10% with a large sales force focused on urologists. The two products have been growing slightly in total, month over month, but we anticipate the sales will increase once heavy sampling of Gelnique 3% is completed. We receive royalties on net sales of both Gelnique 3% and Gelnique 10%.

Elestrin®

According to IMS Health, the U.S. hormone replacement market, including estrogens, progestogens, and estrogen-progestogen and estrogen-androgen combinations, was $2.3 billion in 2012. 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 $1.8 billion in 2012, of which the transdermal segment, mostly patches, was about $407 million. Elestrin®, which is currently being marketed by Meda as an estrogen replacement gel for the treatment of hot flashes, has been steadily growing month over month but is still a relatively small product in this market at approximately $12 million in sales in 2012. We receive a single digit royalty from Meda on the end sales of Elestrin®.

Nestragel (Contraception)

According to IMS Health, the U.S. contraceptives market in 2012 was $5.5 billion. Oral contraceptives account for the majority of the market with the remainder consisting of hormonal implants and patches, injections and intra-uterine systems. Transdermal contraceptive systems potentially 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 17ß-estradiol (E2), which is chemically identical to the naturally occurring estrogen. This combination was chosen because of its 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.

We have a joint development agreement with the Population Council, to develop a contraceptive formulation product containing Nestorone®, by using the Population Council s patented compound and other proprietary information covering the compound, and our transdermal delivery gel. We are responsible for research and development activities as they relate to the gel 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 to complete the development of this product.

Technology and Product Platforms

We are leveraging our experience in device technologies to enhance the product performance of established drugs as well as new drugs in development. Our current portfolio includes disposable pressure assisted auto injection systems (Vibex); disposable pen injection systems and reusable needle-free injection systems (Vision).

Disposable (Vibex) Injectors

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

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Pressure assisted auto injection is a form of parenteral drug delivery that continues to gain acceptance among the medical and patient 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. We have designed disposable, pressure assisted auto injector devices to address acute medical needs, such as allergic reactions, migraine headaches, acute pain and other daily therapies. Our proprietary Vibex disposable auto injector systems combine a low-energy, spring-based power source with a shielded needle, which delivers up to 0.5ml of the needed drug solution subcutaneously or intramuscularly.

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 or intramuscular injection
Designed around conventional 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. This device is designed around conventional single dose pre-filled syringes, which is a primary drug container, offering ease of transition for potential pharmaceutical partners. We have signed two license agreements with Teva for our Vibex system. One of these agreements is for a product containing epinephrine and the other is for sumatriptan. We are also developing the Medi-Jet auto injector, based on the Vibex system, for delivery of methotrexate (OTREXUP) for treatment of rheumatoid arthritis.

Our latest advancement in our proprietary line of Vibex auto injectors is the Vibex QS auto injector system which offers a dose capacity of 1 mL and greater in a compact design. Vibex QS is designed to enhance performance on the attributes most critical to patient acceptance speed, comfort and discretion. Vibex QS achieves these advancements by incorporating a novel triggering mechanism and space-saving spring configuration. The new design also accommodates fast injection of highly-viscous drug products that stall less-powerful conventional auto injectors. Many self-injectable biological agents currently marketed and in clinical development are formulated to be administered in a 1 mL dose volume and tend to be of higher viscosity than non-biologic injectable products. We are developing Vibex QS T, based on the Vibex QS system, for delivery of testosterone as replacement therapy in men who have testosterone deficiency.

Disposable Pen Injector System

Our multi use, disposable pen injector complements our portfolio of single-use pressure assisted auto injector devices. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. Our disposable pen injector is designed for chronic conditions such as diabetes, which require daily injection of a product. Depending on dose, our pens can hold up to thirty days of drug dosing. 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.

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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.

Our Injection Products

Zomajet® / Tjet® / Vision

The Zomajet®/Tjet®/Vision has been sold for use in more than 30 countries to deliver either hGH or insulin. 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 Zomajet®/Tjet®/Vision administers injectables by using a spring to push the active ingredient in solution or suspension through a micro-fine opening in the needle-free syringe. The opening is approximately half the diameter of a standard 30-gauge needle. A fine liquid stream then penetrates the skin, and the dose is dispersed into the layer of fatty, subcutaneous tissue. The drug is subsequently distributed throughout the body, successfully producing the desired effect.

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

Patient Candidates for Needle-Free Injection

Young adults and children

Patients looking for an alternative to needles

Patients unable to comply with a prescribed needle program

Patients transitioning from oral medication

New patients beginning an injection treatment program

The Zomajet®/Tjet®/Vision 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.

Our Transdermal Products

Our transdermal gels consist of a hydro-alcoholic base including a combination of permeation enhancers. The gels are 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.

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The following is a summary of the products on the market or being developed by partners.

Gelnique 3%

In December 2011, the FDA approved Gelnique 3% (oxybutynin gel) for the treatment of OAB. In July 2011, we entered into a licensing agreement with Actavis to commercialize Gelnique 3% in the U.S. and Canada. Actavis launched the product (Gelnique 3%) in the U.S. in April 2012. Under this agreement we received payments for certain manufacturing start-up activities, delivery of launch quantities, milestone payments and upon launch of the product, we began receiving royalties based on net sales of both Gelnique 3% and their oxybutynin gel product Gelnique® 10%. In January 2012, we entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize our oxybutynin gel 3% product in South Korea, once approved. Under this agreement we will receive milestone payments and royalties.

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 BioSante Pharmaceuticals (BioSante) through a license agreement under which we receive milestone payments and royalties. BioSante sublicensed Elestrin® to Azur Pharma International II Limited (Azur), who was subsequently acquired by Jazz Pharmaceuticals (Jazz). In October 2012 Jazz divested its women s health business including Elestrin® to Meda, which is currently marketing the product in the U.S.

Research and Development

We currently perform clinical, regulatory and commercial development work primarily in our Ewing, NJ corporate location for our own portfolio of products. Additionally, we perform parenteral device development work primarily at our Minneapolis, MN facility. We have various products at earlier stages of development as highlighted in our products schedule on page 2 above. Additionally, pharmaceutical partners are developing compounds using our technology (see Collaborative Arrangements and License Agreements).

OTREXUP *(methotrexate and Medi-Jet auto injector).* Historically, parenteral methotrexate use has been limited in clinical practice for several reasons including the inconvenience of weekly injections by a healthcare professional, and/or the challenges associated with teaching patients with impaired hand function, safe and sterile self-injection techniques. To address these issues, we are developing the OTREXUP methotrexate system incorporating the easy-to-use, single-use Medi-Jet auto injector to optimize the clinical benefit of methotrexate by allowing patients to self-administer parenteral methotrexate conveniently at home and potentially reduce overall healthcare costs. In December 2012, we filed a New Drug Application (NDA) for OTREXUP for the treatment of rheumatoid arthritis (RA), poly-articular-course juvenile RA and psoriasis. In February 2013, the NDA was accepted for filing by the FDA with a PDUFA goal date of October 14, 2013.

In November 2012, we announced positive results from an open-label, randomized, crossover study comparing the systemic availability of OTREXUP to oral methotrexate in adult patients with rheumatoid arthritis. This study was designed to compare the relative systemic availability of methotrexate following oral administration to subcutaneous (SC) self-administered methotrexate using the Medi-Jet device. Patients were assigned to one of four dose levels of methotrexate, 10 mg, 15 mg, 20 mg, and 25 mg. Results showed that the systemic availability of methotrexate following oral dosing plateaus above 15 mg. Following administration of methotrexate with Medi-Jet , the systemic availability increased proportionally at every dose, which will extend the range of exposure compared to patients receiving oral therapy.

In September 2012, we announced positive results from an Actual Human Use (AHU) study for OTREXUP . The clinical trial was conducted as a multi-center, open-label, single-arm, in-clinic study to evaluate the actual human use of methotrexate administered via the Medi-Jet auto injector in adult patients with rheumatoid arthritis. The study assessed the safe usability of OTREXUP for self-administration of parenteral methotrexate in adult RA patients after standardized training by site personnel and review of written instructions. Secondary objectives included evaluation of the reliability, ease of use and robustness of the Medi-Jet ; assess the safety and local tolerance of Medi-Jet administered methotrexate and to evaluate the effectiveness of the patient education tools including written instructions for use.

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The AHU study consisted of three visits over nine days and included a screening period, a treatment period and a follow-up visit. In total, 101 patients were enrolled in four study dose groups, 10 mg. (n=20), 15 mg. (n=30), 20 mg. (n=31) and 25 mg. (n=20). The single methotrexate dose was self-administered by the patient from one of the four dose groups using the Medi-Jet auto injector. The results of this study showed that self-administration of methotrexate using Medi-Jet was safe and well tolerated. Following standardized training by site personnel and review of written instructions, all 101 patients performed the self-administration successfully. In addition, the Medi-Jet functioned correctly and as intended for each and every administration thereby demonstrating reliability and robustness. Results of the Ease of Use Questionnaire indicated that 98% of patients found the Medi-Jet easy to use and 100% of patients found the instructions and training to be clear and easy to follow. Patients were also asked to report site administration pain at the end of the treatment period. Administration site pain was measured using a 100 mm Visual Analog Scale (VAS) and showed that patients experienced minimal or no pain with a mean value of 3.6 mm on a scale of 100 mm. Importantly, no patients experienced treatment-emergent serious adverse events related to the drug.

In June 2012, we announced positive results from a human factors usability study for the Medi-Jet auto injector. The purpose of this study was to conduct a cumulative and summative round of simulated usability testing of the Medi-Jet auto injector in accordance with Food and Drug Administration (FDA) draft guidance Applying Human Factors and Usability Engineering to Optimize Medical Device Design, dated June 22, 2011 . The study design was reviewed by the FDA prior to initiation. Fifty individuals representing three user groups participated in this study, including 17 RA patients, 16 lay caregivers and 17 healthcare professionals. All participants in the patient group had been diagnosed with rheumatoid arthritis by a physician. In addition, the patients were screened twice using the Health Assessment 20 Item Disability Scale (HAQ) to determine the extent of hand function impairment of the sort associated with RA patients. Patients with an average HAQ score of 2.0 to 2.5, defined as severe to very severe hand function impairment, were enrolled into the study. The RA patients and lay caregivers (n=33) completed simulated injections on two days spaced one week apart, which is reflective of the intended weekly dosing. The healthcare professionals (n=17) participated in a single session where they used Medi-Jet on a simulated patient. The results of the study showed that the Medi-Jet auto injector is safe and effective for intended users, uses and use environments. The validation testing proved the product is easy to learn and safe to use as demonstrated by correct and successful injections.

In August 2011, we announced the positive results of a pharmacokinetic study evaluating several dose strengths of methotrexate delivered by a healthcare professional to RA patients with the Medi-Jet auto injector versus the currently approved route, intramuscular injection, using a conventional needle and syringe. The primary end points were met with all three methods of administration providing equivalent performance in the patients studied, together with comparable safety.

Gelnique 3% *(Oxybutynin Gel 3%).* In December 2011, the FDA approved our topical oxybutynin gel 3% product, Gelnique 3% , for the treatment of OAB. Our oxybutynin gel 3% is a topical, translucent hydroalcoholic gel containing oxybutynin, an antispasmodic, antimuscarinic agent. Applied once daily to the thigh, abdomen, upper arm or shoulder, an 84 mg (approx. 3 mL) dose delivers a consistent dose of oxybutynin through the skin over a 24-hour period, providing significant efficacy without sacrificing tolerability. The approval of our oxybutynin gel 3% was based on a 12-week, multi-center placebo controlled Phase 3 clinical study. Patients were randomized to either an 84 mg (3 pumps of dispenser) or 56 mg (2 pumps of dispenser) dose application of oxybutynin gel 3% versus placebo. The FDA approved the 84 mg dose application. Patients treated with 84 mg oxybutynin gel daily achieved steady state drug concentrations within three days and experienced a statistically significant decrease in OAB symptoms versus placebo, including the number of urinary incontinence episodes per week. Statistically significant improvements in daily urinary frequency and urinary void volume were also seen with the 84 mg dose.

The product was well tolerated in the study. The most frequently reported treatment-related adverse events (>3%) were dry mouth (12.1% versus 5% in placebo), application site erythema (3.7% versus 1.0% in placebo) and application site rash (3.3% versus 0.5% in placebo).

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In July 2011, we licensed our oxybutynin gel 3% product to Actavis for commercialization in the U.S. and Canada. Under this agreement we received payments for certain manufacturing start-up activities, delivery of launch quantities, and royalties on both our oxybutynin gel 3% product and their oxybutynin gel product Gelnique® 10%, and will potentially receive sales based milestone payments. In January 2012, we entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize our oxybutynin gel 3% product, once approved in South Korea. Under this agreement we will receive milestone payments and royalties.

Vibex QS T *(testosterone).* We are developing Vibex QS T for self-administered weekly injections of testosterone for men who have testosterone deficiency and are on a testosterone replacement therapy program. The Vibex QS T injector is based on our Vibex QS auto injector system which offers a dose capacity of 1 mL and greater in a compact design. Vibex QS is designed to enhance performance on the attributes most critical to patient acceptance speed, comfort and discretion. Vibex QS achieves these advancements by incorporating a novel triggering mechanism and space-saving spring configuration. The new design also accommodates fast injection of highly-viscous drug products, such as testosterone, that stall less-powerful conventional auto injectors. On December 5, 2012, we conducted a pre-IND meeting with the FDA as part of preparing to initiate clinical development of Vibex QS T, establishing an agreed upon clinical path forward. We intend to begin clinical studies in 2013.

Device Development Projects. We, along with our pharmaceutical partner Teva, 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 a product containing epinephrine and for a product containing sumatriptan as well as 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 with Epinephrine

We have designed the Vibex for a product containing epinephrine and have scaled up the commercial tooling and molds for this product. During 2012, 2011 and 2010, we received approximately $850,000, $1,000,000 and $800,000, respectively, from Teva for this tooling as well as other development work for this program. In 2012, we recognized revenue of approximately $2,500,000 for work performed for Teva. From a regulatory standpoint Teva filed this product as an abbreviated new drug application (ANDA), and the FDA accepted the filing as such. Currently, Teva is conducting its own development work on the drug product (epinephrine). 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 Teva and the FDA.

Vibex with Sumatriptan

We had designed the Vibex for a product containing sumatriptan and had completed the majority of the commercial tooling and molds for the product. From a regulatory standpoint Teva filed the product as an ANDA and the FDA rejected the filing as such. The FDA s rejection was based primarily on the opinion that the device was sufficiently different than the innovator s device not to warrant an ANDA. We redesigned the device to address the FDA s concern of device similarity and submitted the new device to the FDA. The FDA reactivated the ANDA file in 2010, and since that time we have been conducting user studies and scaling up commercial tooling and molds for the newly designed device. We plan on submitting this new data in 2013 and then the FDA is expected to complete its review of the ANDA, the timing of which is completely dependent on the FDA.

Disposable pen injector #1

We previously provided clinical supplies for the first pen injector product to Teva. From a regulatory standpoint Teva has conducted a bioequivalence study for the product and determined the appropriate regulatory pathway is a 505(b)(2). The FDA has requested additional clinical work be conducted in support of the filing. Teva decided to redesign the pen injector for this product and we completed the process of making significant design modifications. Teva is developing this product for both Europe and the U.S. with the European clinical/regulatory team leading the development. Drug development and device fabrication for a drug stability program to support a regulatory filing is anticipated to be completed during 2013.

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Disposable pen injector #2

We have designed and produced prototype pen injectors for the second pen injector product. Teva believes the regulatory pathway for this product is an ANDA pathway. Teva has initiated drug stability and completed the device development program and is expecting to file an ANDA in the next 12 months. There is also a concurrent development program which was initiated in 2011 for this product in Europe. If the drug stability and ANDA filing are successful, full commercial development of the device molds, tooling and automation equipment will need to be completed during the regulatory review process.

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 2013, 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 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 for our OTREXUP and Vibex epinephrine products.

We have contracted with Uman Pharma (Montreal, Canada) to supply commercial quantities of methotrexate pre-filled syringes for the U.S and Canadian markets for OTREXUP .

Sales and Marketing

OTREXUP

We retain all U.S. commercialization rights for OTREXUP , have begun to build an internal sales and marketing organization, and are entering into agreements with a contract sales organization and other vendors for commercialization services such as third party contracting and distribution. We anticipate launching OTREXUP , provided it is approved by FDA, with a field force comprised initially of approximately 30 sales representatives, to market the product in the U.S. to key rheumatology specialists. We also plan to explore co-promotion opportunities in the U.S. with companies that have appropriate commercial capabilities to potentially extend our reach to dermatologists, assuming that OTREXUP is also approved for psoriasis, and other appropriate high potential prescribers. We intend to enter into licensing or additional distribution arrangements for commercialization of our products outside the U.S., such as our relationship with Uman Pharma for the commercialization of OTREXUP in Canada. As part of our longer-term strategy, we anticipate we will further develop our product candidates and selectively license or acquire additional products and/or late stage product candidates that are synergistic with our commercial strategy.

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Partnered Products

During 2012, 2011 and 2010, international revenue accounted for approximately 25%, 38% and 48%, respectively, of total revenue. Europe accounted for 88%, 93% and 94% of international revenue in 2012, 2011 and 2010, respectively, with the remainder coming primarily from Asia. Teva accounted for 33%, 50% and 44% of our worldwide revenues in 2012, 2011 and 2010, respectively, Ferring accounted for 22%, 35% and 45% of our worldwide revenues in 2012, 2011 and 2010, respectively, and Actavis accounted for 30% of our worldwide revenues in 2012. Revenue from Teva and Ferring resulted from sales of injection devices and disposable components for their hGH formulations, and related royalties. Revenue from Teva also included development revenue related to license agreements with Teva for our Vibex system and for our pen injector device. Revenue from Actavis in 2012 resulted from Gelnique 3% product sales, manufacturing start-up and other development activities, royalties and a milestone payment deferred at December 31, 2011 that was recognized in 2012.

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 10 to the Consolidated Financial Statements for revenues by geographic area.

Collaborative Arrangements and License Agreements

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

Partner	Drug	Market Segment	Product
Ferring	hGH (Zomacton®)	Growth Retardation	Needle Free
	(4mg formulation)	(U.S., Europe, Asia & Pacific)	Zomajet® 2 Vision
Ferring	hGH (Zomacton®)	Growth Retardation	Needle Free
	(10 mg formulation)	(U.S., Europe, Asia & Pacific)	Zomajet® Vision X
Teva	hGH (Tev-Tropin®) 5mg	Growth Retardation (United States)	Needle Free Tjet®
JCR	hGH	Growth Retardation (Japan)	Needle Free Twin-Jector® EZ II
Teva	Epinephrine	Anaphylaxis (U.S. and Canada)	Vibex Auto Injector
Teva	Sumatriptan	Migraines (U.S. and Canada)	Vibex Auto Injector
Teva	Undisclosed	Undisclosed	Pen Injector
	Product #1	(North America, Europe & others)	
Teva	Undisclosed	Undisclosed	Pen Injector
	Product #2	(North America, Europe & others)	
Actavis	Oxybutynin	U.S. and Canada	Gelnique 3%
Daewoong	Oxybutynin	South Korea	Oxybutynin Gel 3%
Meda	Estradiol	Hormone replacement therapy	Elestrin® Gel
		(North America, other countries)	
Pfizer	Undisclosed	Consumer Health	Undisclosed
Population Council	Nestorone ®/Estradiol	Contraception (Worldwide)	Nestragel
Ferring	Undisclosed	Undisclosed (Worldwide)	Transdermal 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 four of our gel technology products for use in hormone replacement therapy in North America and other countries. BioSante paid us an upfront payment upon execution of the agreement and is also required to make royalty payments once commercial sales of the products have begun. The royalty payments are based on a percentage of sales of the products and must be paid for a period of 10 years following the first commercial sale of the products, or when the last patent for the products expires, whichever is later. The agreement also provides for milestone payments to us upon the occurrence of certain events related to regulatory filings and approvals. In November 2006, BioSante entered into a sublicense and marketing agreement with Bradley Pharmaceuticals, Inc. (Bradley) for Elestrin®. In

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December 2006, the FDA approved Elestrin® for marketing in the United States. Bradley was acquired by Nycomed Inc. in February 2008 and returned Elestrin® to BioSante. In December 2008, Elestrin® was sublicensed to Azur and subsequently relaunched in 2009. In January 2012, Azur was acquired by Jazz. In October 2012, Jazz women s health business, including Elestrin®, was acquired by Meda. We receive royalties on sales of Elestrin® as well as potential sales-based milestone payments. Currently we expect that Elestrin® will be the only product developed under this license agreement.

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 2007, we amended this agreement providing for non-exclusive rights in Asia along with other changes to financial terms of the agreement. We receive a purchase price and a royalty for each device sold to Ferring and a royalty on their hGH sales if we meet certain product quality metrics.

We have an agreement with JCR through 2014 under which they will continue to market our needle free injector in Japan for use with their hGH product Growject®. We receive a negotiated purchase price for each device sold, as well as royalties on JCR s net sales of hGH.

In July 2006, we entered into an exclusive License Development and Supply Agreement with Teva. Pursuant to the agreement; Teva is obligated to purchase all of its delivery device requirements from us for an epinephrine auto injector product to be marketed in the United States and Canada. We received an upfront cash payment, and will receive a negotiated purchase price for each device sold, as well as royalties on sales of their product. This agreement has been amended numerous times and provides for payment of capital equipment and other development work that was outside the scope of the original agreement. The agreement will continue until the later of July 2016 or the expiration of the last to expire patent that is filed no later than 12 months after FDA approval.

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. Under the terms of the joint development agreement, we are responsible for research and development activities as they relate to the gel. 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 to complete the clinical program for this potential product. The term of the agreement is perpetual unless mutually terminated.

In September 2006, we entered into a Supply Agreement with Teva. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from us for hGH marketed in the United States. We received an upfront cash payment and have received milestone fees and royalty payments on Teva s net sales of hGH, as well as a purchase price for each device sold. The original term of this agreement extends through September 2013, and will be automatically renewed for two years and will continue to automatically renew for successive periods of two years each unless terminated by either party six months ahead of the expiring term.

In December 2007, we entered into a license, development and supply agreement with Teva under which we will develop and supply a disposable pen injector for use with two undisclosed patient-administered pharmaceutical products. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by us under certain circumstances. In January 2011, this agreement was amended to provide payments to us for capital equipment and other development work. In 2012 and 2011, statements of work in connection with continued development of these two products were agreed upon, providing additional payments to us. This agreement will continue until the later of December 2017 or the expiration date of the last to expire patent covering the device or product that is filed no later than 12 months after FDA approval, and will be automatically renewed for successive periods of two years each.

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In November 2009 we entered into a license agreement with Ferring under which we licensed certain of our patents and agreed to transfer know-how for our transdermal gel technology for certain pharmaceutical products. Under this agreement, we received an upfront payment, milestone payments and will receive additional milestone payments as certain defined product development milestones are achieved. The agreement is effective until the last to expire patent applicable under the agreement which currently is 2028.

In July 2011, we entered into a licensing agreement with Actavis (formerly Watson) under which Actavis will commercialize our oxybutynin gel 3% product in the U.S. and Canada. Under this agreement we received payments for certain manufacturing start-up activities, delivery of launch quantities, and royalties on both our oxybutynin gel 3% product and their oxybutynin gel product Gelnique® 10%, and will potentially receive sales based milestone payments. The term of the agreement ends on the later of April 2024 or the expiration date of the last to expire patent.

In December 2011, we entered into a licensing agreement with Pfizer Consumer Healthcare (Pfizer) for one of our drug delivery technologies to develop an undisclosed product on an exclusive basis for North America. Pfizer will assume full cost and responsibility for all clinical development, manufacturing, and commercialization of the product in the licensed territory, which also includes certain non-exclusive territories outside of North America. We will receive undisclosed upfront payments, development milestones and sales based milestones, as well as royalties on net sales for three years post launch in the U.S.

In January 2012, we entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize our oxybutynin gel 3% product in South Korea, once approved. The agreement terms include an upfront payment, development and sales-based milestone payments and escalating royalties based on product sales in South Korea. The term of the agreement ends on the later of fifteen years following launch of the product or the expiration date of the last to expire patent.

In November 2012, we entered into a license, supply and distribution agreement with Teva for an auto injector product containing sumatriptan for the treatment of migraines. We will manufacture the device and do final assembly and packaging of the final product, and Teva will manufacture and supply the drug and will distribute the product in the United States. Teva also received an option for rights in other territories. Under the agreement, we received an upfront payment and will receive a milestone payment upon commercial launch. In addition, net profits will be split 50/50 between us and Teva. The term of the agreement is seven years from commercial launch, with automatic one year renewals unless terminated by either party after the initial term.

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 U.S. distribution/supply arrangements under which the distributors/suppliers sell our needle-free injection devices and related disposable components for use with insulin.

Competition

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

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Competition in the U.S. testosterone replacement market includes Abbvie s Androgel® and Androgel® 1.62%, Lilly s Axiron®, Endo Pharmaceuticals Fortesta® and Delatestryl®, Pfizer s Depo®-Testosterone, Actavis Androderm®, Auxillium s Testim®, Actient s Striant® and Testopel® and several generic testosterone in oil products sold by Actavis, Sandoz, Mylan, Bedford Labs, Teva and others. In addition, at least three additional treatments for low testosterone levels are in development. Endo Pharmaceuticals has also filed for U.S. FDA approval of testosterone undecanoate injection, Aveed . Endo licensed testosterone undecanoate injection from Bayer, which markets the product as Nebido® in Europe and elsewhere. Clarus Labs is developing an oral formulation of testosterone undecanoate, CLR-610, announcing positive Phase III clinical study results in September 2012. Trimel Pharmaceuticals is developing an intra-nasal testosterone formulation, CompleoTRT , announcing positive Phase III clinical study results in December 2012.

Competition in the U.S. OAB market includes Pfizer s Detrol® LA (tolterodine extended release capsules), Janssen Pharmaceutical s Ditropan® XL (oxybutynin extended release tablets) and generic forms of oxybutynin tablets, GSK/Astellas Vesicare® (sofenicin tablets) (17%), Warner Chilcott s Enablex® (darifenacin extended release tablets), Pfizer s Toviaz® (fesoteridine tablets), Allergan s Sanctura XR® (tropsium extended release capsules), Astellas Pharma s Myrbetriq® (mirabegron extended release tablets) and Actavis transdermal oxybutynin patch Oxytrol®. Allergan s Botox® (onabotulinumtoxinA) received FDA approval in 2011 for OAB due to neurologic disease.

Competition in the hGH market consists of products from several manufacturers, including Humatrope (Lilly), Norditropin (NovoNordisk), Genotropin (Pfizer), Nutropin (Roche/Genentech), Omnitrope (Sandoz), Serostim (EMD Serono), Saizen (EMD Serono), Zorptive (EMD Serono), and Tev-Tropin (Teva). While all hGH products currently available in the United States are exclusively produced from recombinant technology in the form of somatropin, individual hGH products vary in the indications for which they are approved, the formulations (ready-to-use liquids and lyophyllized powder for reconstitution), strengths, and drug delivery systems (e.g., vials for use with conventional needle and syringe, pre-filled syringes, pens, needle-free auto-injectors) in which they are available. Approved indications include growth hormone deficiency in children, Turner s syndrome, Prader-Willi syndrome, Noonan syndrome, small for gestational age (SGA), growth delay in children with chronic renal failure and SHOX (short stature homeobox-containing gene) gene deletion. Approved indications in adults includes growth hormone deficiency in adults, continuation of therapy from growth hormone deficiency in childhood, treatment of AIDS wasting, and treatment of short bowel syndrome. Different manufacturers hGH products may or may not be approved for one or more of the indicated uses, which, along with differences in formulation, available strengths, drug delivery devices, promotional activities, and price discounts and rebates all combine to form a highly complex and competitive hGH market.

Competition in the hormone replacement market consists of products from several manufacturers, including Premarin tablets (Pfizer), Premarin vaginal cream (Pfizer), Vagifem (NovoNordisk), Estrace (Warner-Chilcott), Vivelle-Dot (Novartis), Estradiol Transdermal System (Mylan), Climara (Bayer). Our gel product Elestrin is competing against oral tablets, vaginal creams and transdermal patches, which together make up nearly 97% of the U.S. market for hormone replacement therapy.

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.

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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 an ability to self-inject products at home. We believe the patient-friendly attributes of our injection technologies meet these market needs.

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 methods such as our injector systems will continue to be accepted by the market.

In addition to the increase in the number of drugs requiring self-injection, recommended changes in the frequency of injections may contribute to an increase in the number of self-injections. In March 2010, Congress passed the Biologics Price Competition and Innovation Act as part of the Patient Protection and Affordable Care Act. This legislation creates a pathway for regulatory approval, authorizing the FDA to establish criteria for review and approval of biosimilar and interchangeable biological products that are similar to the innovator biologic after patent and exclusivity expiration of the innovator product. The approval of biosimilar products is intended to reduce the cost of biological products by increasing competition just as the Hatch-Waxman legislation did by creating an abbreviated pathway for approval of generic drugs. In order to differentiate between different version of similar biologic agents, novel patented delivery systems are becoming more important to extend product proprietary position as well as secure patient preference.

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

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. We expect branded and specialty pharmaceutical companies will continue to seek differentiating device characteristics to defend against generic competition and to optimize convenience to patients. The new device may offer therapeutic advantages, convenience or improved dosing 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.

Recently a trend has emerged where companies are now focusing on branded generics wherein an established drug is coupled with a device technology in order to improve the drug utility to the patient or improve the ease of use of an injectable drug. This concept is the basis of our OTREXUP and Vibex QS T products and potentially provides the pharmaceutical company a high value branded product.

Finally, our device platforms work well in the generic marketplace, the opposite end of the branded strategy. There are a large number of injectable branded products losing patent protection in the near term which will be or have been subject to the Abbreviated New Drug Application (ANDA) pathway. Three of our potential products with our partner Teva (Epinephrine, Sumatriptan and an undisclosed product in our pen technology) are being developed as generic substitutes to the branded products. Unlike branded products which need to be detailed to a physician by a sales force, a generic product with an AB rating is substituted at the pharmacy in lieu of the branded product affording a potentially low cost, high penetration generic product. Our device platform allows for device customization which can provide multiple opportunities in the generic market space.

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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, such as safety stock levels, 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 2028. In addition to issued patents and patent applications, we are also protected by trade secrets in all of our technologies.

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

Third Party Reimbursement and Pricing

In both U.S. and foreign markets, our ability to commercialize OTREXUP successfully depends in significant part on the availability of adequate coverage and reimbursement from third-party payers, including, in the U.S., government payers such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third-party payers are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. This is especially true in markets where generic options exist. Third-party payers may use tiered reimbursement and may adversely affect demand for OTREXUP by placing it in a more expensive tier. We cannot be certain that OTREXUP will successfully be placed on the list of drugs covered by particular health plan formularies. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If OTREXUP is not included on these preferred drug lists, physicians may not be inclined to prescribe it to their Medicaid patients, thereby diminishing the potential market for OTREXUP .

We may need to conduct pharmacoeconomic studies to demonstrate the cost effectiveness of OTREXUP for formulary coverage and reimbursement. Even with studies, OTREXUP may be considered less safe, less effective or less cost-effective than existing products, and third-party payers may not provide coverage and reimbursement for OTREXUP , in whole or in part. Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our future business. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, PPACA establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the donut hole); and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

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In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for OTREXUP or the amounts of reimbursement available for OTREXUP , and could limit the acceptance and availability of OTREXUP . Approval of OTREXUP may be delayed or rejected based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review. Changes in regulatory approval policy, regulations or statutes or the process for regulatory review during products development or approval periods may cause delays in the approval or rejection of an application. The adoption of some or all of these proposals could materially impact numerous aspects of our business.

Our partnered products encounter the same issues with reimbursement stated above. Although we do not control the reimbursement rate or discounts contracted with third party payers by our partners, it ultimately affects our royalty payments on products such as Tev-Tropin® and Gelnique®. We have encountered a widening gap between gross sales and net sales after discounts on both of these products which has negatively affected our royalty revenue.

Government Regulation

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

Drug Approval Process

Pharmaceutical based products or drug delivery technologies 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. Drug delivery based 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 products include the filing of an NDA for new drugs, new indications of approved drugs or new dosage forms of approved drugs. Alternatively, these dosage forms can obtain marketing approval as a generic product by the filing of an ANDA, providing the new generic product is bioequivalent to and has the same labeling as a comparable approved product or as a filing under Section 505(b)(2) of the FD&C Act where there is an acceptable reference product. The combination of the drug, its dosage form and label claims, and FDA requirements will ultimately determine which regulatory approval route will be required.

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

pre-clinical laboratory and animal tests;

submission to the FDA of an IND application, which must be in effect before clinical trials may begin;

adequate and well controlled human clinical trials to establish the safety and efficacy of the drug for its intended indication(s);

FDA compliance inspection and/or clearance of all manufacturers;

submission to the FDA of an NDA; and

FDA review of the NDA or product license application in order to determine, among other things, whether the drug is safe and effective for its intended uses.

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

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

Clinical trials are typically conducted in three sequential Phases, which may overlap. During Phase I, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, distribution, metabolism and excretion. Phase I studies are often conducted with healthy volunteers depending on the drug being tested. Phase II involves studies in a limited patient population, typically patients with the conditions needing treatment, to evaluate preliminarily the efficacy of the product for specific, targeted indications; determine dosage tolerance and optimal dosage; and identify possible adverse effects and safety risks.

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

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

An sNDA is a submission to an existing NDA that provides for changes to the NDA and therefore requires FDA approval. Changes to the NDA that require FDA approval are the subject of either the active ingredients, the drug product and/or the labeling. A supplement is required to fully describe the change.

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.

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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 marketed products such as Gelnique 3% (oxybutynin gel 3%) and Elestrin®, as well as our products being developed by our partners such as Nestragel and the undisclosed Pfizer product are subject to the above regulations. Device combination products developed by us, such as OTREXUP or Vibex QS T, and being developed by our partner Teva are subject to the sNDA, ANDA and 505(b)(2) regulations cited above, as well as the device approval process below.

Device Approval Process

Drug delivery systems such as our injectors can also be evaluated as part of the drug approval process such as an NDA, sNDA, ANDA, 505(b)(2) or a Product License Application (PLA). Combination drug/device products raise unique scientific, technical and regulatory issues. The FDA has established an Office of Combination Products (OCP) to address the challenges associated with the review and regulation of combination products. The OCP assists in determining strategies for the approval of drug/delivery combinations and assuring agreement within the FDA on review responsibilities. Device regulatory filings could take the form of a device master file (MAF). In most cases, the device specific information may need to be filed as part of the drug approval submission, and in those cases we will seek agreement from the Agency for review of the device portion of the submission by the Center for Devices and Radiological Health (CDRH) under the medical device provisions of the law.

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

Development of a device with a previously unapproved new drug likely will be handled as part of the NDA for the new drug itself. Under these circumstances, the device component will be handled as a drug accessory and will be approved, if ever, only when the NDA itself is approved. Our injectors may be required to be approved as a combination drug/device product under an sNDA for use with previously approved drugs. Under these circumstances, our device could be used with the drug only if and when the supplemental NDA is approved for this purpose. It is possible that, for some or even all drugs, the FDA may take the position that a drug-specific approval must be obtained through a full NDA or supplemental NDA before the device may be packaged and sold in combination with a particular drug. Teva launched the Tjet® device in August of 2009 for use in delivery of Teva s form of hGH, Tev-Tropin®, following the approval of the hGH sNDA in June 2009.

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To the extent that our injectors are packaged with the drug, as part of a drug delivery system, the entire package will 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.

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We have ISO 13485: 2003 certification, the medical device industry standard for our quality systems. This certification shows that our device 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. Regular surveillance audits by our notified body, British Standards Institute, are required to demonstrate continued compliance.

Employees

We believe that our success is largely dependent upon our ability to attract and retain qualified personnel in the research, development, manufacturing, business development and commercialization fields. As of March 4, 2013, we had 42 full-time employees. Of the 42 employees, 29 are primarily involved in research, development and manufacturing activities, three 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, particularly in the sales and marketing areas with the potential approval of OTREXUP in 2013.

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.

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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 $11,427,450 and $4,387,920 in the fiscal years ended 2012 and 2011, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2012 of $152,789,165. The costs for research and product development of our product candidates and 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 October 2012, we sold 12,500,000 shares of common stock at a price of $4.00 per share in a public offering, and in November 2012 we sold 1,759,868 shares of common stock at $4.00 per share as a result of the partial exercise of the underwriters over-allotment option. The sales of common stock resulted in net proceeds of $53,328,188 after deducting offering expenses of $3,711,284. In May 2011, we sold a total of 14,375,000 shares of common stock at a price of $1.60 per share in a public offering, which resulted in net proceeds of $21,280,718 after deducting offering expenses of $1,719,282. In addition, we received proceeds from warrant and stock option exercises of $11,579,413 and $6,020,436 in 2012 and 2011, respectively. If in the future we do not turn profitable or generate cash from operations and additional capital is needed to support operations, economic and market conditions may make it difficult to raise additional funds through debt or equity financings.

At December 31, 2012 we had cash and investments of $85,225,593. The combination of our current cash and investments balance and projected product sales, product development, license revenues, milestone payments and royalties should provide us with sufficient funds to support operations. However, if funds are not sufficient to support operations, we may need to pursue a financing or reduce expenditures to meet our cash requirements. If we do obtain such financing, we cannot assure that the amount or the terms of such financing will be as attractive as we may desire. If we are unable to obtain such financing when needed, or if the amount of such financing is not sufficient, it may be necessary for us to take significant cost saving measures or generate funding in ways that may negatively affect our business in the future. To reduce expenses, we may be forced to make personnel reductions or curtail or discontinue development programs. To generate funds, it may be necessary to monetize future royalty streams, sell intellectual property, divest of technology platforms or liquidate assets. However, there is no assurance that, if required, we will be able to generate sufficient funds or reduce spending to provide the required liquidity.

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

- our ability to successfully develop our own product candidates such as OTREXUP and Vibex QS T;
- our ability to successfully launch and sell our products if we choose not to partner the product;
- our ability to manufacture products efficiently, at the appropriate commercial scale, and with the required quality;
- timing of our partners development, regulatory and commercialization plans;

the demand for our technologies from current and future pharmaceutical partners;

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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 obtain reimbursement for our products from third party payers;

our ability to develop additional commercial applications for our products;

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.

We are currently preparing for the FDA approval and commercial launch of OTREXUP and as a company we have limited marketing and no sales capabilities.

We currently are in the process of building a commercial organization for the sales and marketing and distribution of pharmaceutical products, and as a company, we have limited experience commercializing pharmaceutical products on our own. In order to commercialize OTREXUP , we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. The establishment and development of our own commercial organization to market OTREXUP and any additional products we may develop will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We will also have to compete with other pharmaceutical companies to recruit, hire, train and retain sales and marketing personnel. To the extent we rely on additional third parties to commercialize OTREXUP , such as pharmaceutical partners or third party contract sales organizations, we may receive less revenues or incur more expenses than if we commercialized OTREXUP ourselves. In addition, we may have limited control over the sales efforts of any third parties involved in our commercialization efforts. In the event we are unable to fully develop our own commercial organization or collaborate with a third-party sales and marketing organization or enter into co-promotion agreements, we may not be able to commercialize OTREXUP and execute on our business plan. If we are unable to successfully implement our commercial plans and drive adoption by patients and physicians of OTREXUP through our sales, marketing and commercialization efforts, or if our partners fail to successfully commercialize OTREXUP , then we may not be able to generate sustainable revenues from product sales which will have a material adverse effect on our business and future product opportunities. Similarly, we may not be successful in establishing the necessary commercial infrastructure, including managed care, medical affairs and pharmacovigilance teams. If we do not rapidly expand our internal sales and marketing capabilities and establish the necessary infrastructure or if our efforts to do so take more time and expense than anticipated, our ability to market and sell OTREXUP may be adversely affected.

Commercialization of OTREXUP will require significant resources and if we do not receive FDA approval or achieve the sales expected we may lose the substantial investment made in OTREXUP .

We have made and are continuing to make substantial expenditures in advance of commercializing OTREXUP and our other product candidates. We are devoting substantial resources to building our manufacturing and assembly equipment for OTREXUP as well as building commercial

supply inventories of OTREXUP to support potential commercialization. We have and expect to continue to devote substantial resources to establish and maintain a marketing capability for OTREXUP . These costs have increased as we near the potential launch of OTREXUP . If OTREXUP or other products we develop are not approved for commercial sale, we may be unable to recover the large investment we have made in research, development, manufacturing and marketing efforts, and our business and financial condition could be materially adversely affected.

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

Pharmaceutical company partners such as Teva help us develop, obtain regulatory approvals for, manufacture and sell our products. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of the products as planned, our revenues and profits may not reach expectations or may decline. We may not be able to control the timing and other aspects of the development of products because pharmaceutical company partners may have priorities that differ from ours. Therefore, commercialization of products under development may be delayed unexpectedly. The success of the marketing organizations of our pharmaceutical company partners, as well as the level of priority assigned to the marketing of the products by these entities, which may differ from our priorities, will determine the success of the products incorporating our technologies. Competition in this market could also force us to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability.

We are currently working with Teva on four products (Vibex with epinephrine, Vibex with sumatriptan and 2 undisclosed pen products) for which we are anticipating approval and launch in the 2014 to 2016 timeframe. Additionally, we are working with Pfizer on an undisclosed product for which we are anticipating approval and launch in 2016. There is no assurance that development of these products will continue or that they will receive FDA approval or if FDA approved they will be a significant revenue source for us.

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, 2012, we derived approximately 33% of our revenue from Teva, 30% from Actavis and 22% from Ferring. For the year ended December 31, 2011, we derived approximately 50% of our revenue from Teva and 35% from Ferring. The revenue from Teva was product sales, royalties and license and development revenue. The revenue from Actavis was product sales, manufacturing start-up and other development activities, royalties and a milestone payment deferred at December 31, 2011 that was recognized in 2012. Although significant in 2012, Actavis product sales and development revenue is expected to be minimal in 2013, as Actavis is assuming manufacturing responsibilities in early 2013. The revenue from Ferring was primarily product sales and royalties.

The loss of any of these significant 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 Teva s 5mg Tev-Tropin® brand 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, milestone and development 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.

We have a license agreement with Ferring, under which Ferring commercialized our needle-free injection system with their 4mg and 10mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. We receive a purchase price and a royalty for each device sold to Ferring and a royalty on their hGH sales if we meet certain product quality metrics. Although these products have been on the market for many years, there can be no assurance that Ferring will continue to use our device or that approval of new devices developed by us will occur.

In July 2011, we entered into an exclusive licensing agreement with Actavis (formerly Watson) for Actavis to commercialize, in the U.S. and Canada, our topical oxybutynin gel 3% product, which was subsequently approved by the FDA in December 2011. Under terms of the agreement, Actavis has made payments for certain manufacturing start-up activities and milestone payments based on the achievement of regulatory approval. Additionally, milestone payments will be made upon the achievement of certain sales levels. Upon launch of the

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product, we began receiving royalties based on product sales in the U.S. and Canada for both our oxybutynin gel 3% product and their oxybutynin gel product Gelnique® 10%. In 2013, Actavis will assume all responsibility for manufacture and supply of the product. Although milestone payments and royalties have been received from Actavis, there is no assurance that future sales based milestones or significant royalties will be received under this agreement.

In December 2011, we announced that we licensed one of our drug delivery technologies to Pfizer Inc. s Consumer Healthcare Business Unit to develop an undisclosed product on an exclusive basis for North America. Pfizer will assume full cost and responsibility for all clinical development, manufacturing, and commercialization of the product in the licensed territory, which also includes certain non-exclusive territories outside of North America. We received an upfront payment, and will receive development milestones and sales based milestones, as well as royalties on net sales for three years post launch in the U.S. Although an upfront payment has been received, there can be no assurance that there ever will be commercial sales or future milestone payments or royalties under this agreement.

We have recently become more commercially oriented by further developing our own products and less dependent on our pharmaceutical partners, 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 bringing such products to market; therefore, we may experience difficulties in execution of development of internal product candidates. We are currently developing OTREXUP with a view to potentially market this product ourselves. There is no guarantee that the development will be successful or if successful that we will market the product effectively.

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

We do not possess the facilities to manufacture commercial quantities of our Vibex MTX product, OTREXUP , or any other of our future drug candidates. We must contract with manufacturers to produce products 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 entered into multiple commercial supply agreements with third-party manufacturers, including:

- the production of the methotrexate drug substance in pre-filled syringes;
- the final assembly and packaging of OTREXUP in Medi-Jet auto injectors;
- the supply of the methotrexate drug substance;
- the manufacture and partial assembly of Medi-Jet auto injectors; and
- the manufacture of prefillable syringes.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including:

reliance on the third party for regulatory compliance, quality assurance and adequate training in management of manufacturing staff;

the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and

the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

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We depend on these third party manufacturers to comply with Current Good Manufacturing Practice regulations (cGMPs) enforced by the FDA and other regulatory requirements and to deliver materials on a timely basis. In addition, because regulatory approval to manufacture a drug is generally site-specific, the FDA and other regulatory authorities will repeatedly inspect our current and future third-party manufacturers facilities for compliance with cGMPs. If we or our third-party manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may issue warning letters or suspend or withdraw our regulatory approval for approved or in-market products, among other things. Any of these actions could delay our development of products, delay the submission of these products for regulatory approval or result in insufficient product quantity to support commercial demand. As a result, our business, financial condition and results of operations could be seriously harmed. See additional risk factors associated with manufacturing in the section Risks Related to Regulatory Matters.

We had contracted with a commercial supplier of pharmaceutical chemicals to supply us with the active pharmaceutical ingredient of oxybutynin for commercial quantities of Gelnique 3% in a manner that meets FDA requirements via reference of their DMF for oxybutynin. Additionally, we had contracted with Patheon, a manufacturing development company, to supply commercial quantities of Gelnique 3% in a manner that meets FDA requirements. In 2013, all manufacturing responsibility related to Gelnique 3% will be transferred to Actavis.

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 continue 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, used in such products as our epinephrine auto injector for Teva and our proprietary OTREXUP methotrexate system, 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 internal quality and regulatory group or pharmaceutical partner would have a negative impact on our future revenue expectations.

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

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

If transdermal gels do not achieve greater market acceptance, we may not realize significant revenue from these products.

Because transdermal gels are not a widely understood method of drug delivery, our partners and consumers may have little experience with such products. Our assumption of value may not be shared by the partner and consumer. To date, transdermal gels have gained successful entry into only a limited number of markets such as the testosterone replacement market and the pain 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. In January 2012 Azur was acquired by Jazz. Elestrin® is currently being marketed in the U.S. by Meda, who recently acquired the product from Jazz. The multiple licenses of Elestrin® and shifting marketing responsibilities has had a negative impact on the marketing efforts of Elestrin® and to date, the market penetration of Elestrin® has been low.

Gelnique 3%, our transdermal oxybutynin product, competes in a large market dominated by oral products. To date, transdermal products such as gels and patches have not had overwhelming success in gaining market share. Gelnique 3% was launched in April 2012 by our partner Actavis. We are aware that Actavis has been sampling the product heavily to physicians like most new product launches, but at this early stage of the product launch we cannot determine what effect, if any, the sampling program has had or will have on general market acceptance or future growth of the product.

As health insurance companies and other third-party payers 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 payers. Currently, insurance companies and other third-party payers reimburse the cost of certain products on a case-by-case basis and may refuse reimbursement if they do not perceive benefits to a product s use in a particular case. Third-party payers are increasingly challenging the pricing of medical products and devices, and there can be no assurance that such third-party payers will not in the future increasingly reject claims for coverage of the cost of certain of our products. Additionally, even if the product is covered, third party payers are continually seeking larger rebates from the manufacturers of the products for product coverage resulting in less net sales of the product. Insurance and third-party payer 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.

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

Gelnique 3%, for which we receive royalties from our partner based on net sales, was launched in April 2012. It is too early at this point to determine if third party reimbursement has had an impact on product acceptance.

Our Tjet® device was launched by Teva in the U.S. in 2009 for use with Teva s hGH, Tev-Tropin®. Although Teva currently provides the device and disposables at no cost to the patient, the amount of health insurance reimbursement of Tev-Tropin® has a direct impact on the device product sales and royalty due from Teva to us. Additionally, Teva has provided significant rebates to third party payers, which reduces net sales of Tev-Tropin® thus reducing the royalty payable to us.

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

One of our business strategies to reduce development risk is to enter into license agreements with pharmaceutical companies covering the development, manufacture, use and marketing of our drug delivery devices with specific drug therapies. Under these arrangements, the partners typically assist us in the development of the product and sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery device with the licensed drug therapy. Our licensees may also be responsible for distribution and marketing of the product or technologies for these 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 or products. 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, Actavis and Pfizer 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 effect 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 methotrexate, 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 injector based technologies include Ypsomed, Owen Mumford, Elcam, SHL, Bioject Medical Technologies, Inc., Haselmeier, Bespak-Consort Medical, West

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Pharmaceuticals and Becton Dickinson, 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.

The rheumatoid arthritis market, which is the main focus of our efforts for OTREXUP , is intensely competitive. We face competition with respect to OTREXUP from major pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than OTREXUP . Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for OTREXUP .

In the rheumatoid arthritis market we face competition from several branded and generic products, many from larger companies that have more experience and greater resources than does our Company. Competition in the rheumatoid arthritis market includes tablets and parenteral forms of methotrexate that are currently marketed in the U.S. by several generic manufacturers, including Teva, Mylan, Roxane, Bedford Labs, APP Pharmaceuticals and Hospira. In several European countries, Canada, and South Korea, Medac International or its licensees market methotrexate in prefilled syringes (Metoject®). Other commonly used pharmaceutical treatments for rheumatoid arthritis include analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, so-called disease modifying anti-rheumatic drugs (DMARDs) and biologic response modifiers. In addition to methotrexate, the DMARDs include azathioprine (Imuran®), cyclosporine (Neoral®), hydroxychloroquine (Plaquenil®), auranofin (Ridura®), leflunomide (Arava®) and sulfasalazine (Azulfidine®). The biologic response modifiers include blockbuster products etanercept (Enbrel®), adalimumab (Humira®), golimumab (Simponi®), tocilizumab (Actemra®), certolizumab (Cimzia®), infliximab (Remicaid®), abatacept (Orencia®), and rituximab (Rituxan®). They are often prescribed in combination with DMARDs such as methotrexate.

The Biologics Price Competition and Innovation Act permits the FDA to approve biosimilar versions of biological products like Humira®, Enbrel®, Simponi®, Cimzia®, Orencia®, Actemra®, Rituxan® and Remicaid® through an abbreviated approval pathway. This regulatory pathway could result in earlier entry of lower-cost biosimilars which could lower our value proposition of OTREXUP relative to that of costlier branded biologics. The approval of lower-cost biosimilar products could decrease the revenue we receive for Otrexup.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing and distributing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in acquiring products, product candidates and technologies complementary to our programs or advantageous to our business.

Although not currently approved for subcutaneous administration, we may face competition from generic versions of injectable methotrexate offered at substantially lower cost. Manufacturers may seek approval to market low cost generic products without the cost and benefit of an auto injector which could appeal to third party payers and reduce the market penetration of OTREXUP .

Additionally, injection technologies are mostly used with drugs for which oral drug delivery methods are not possible. 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 or effectively developing an oral product that was once thought not possible. The successful development and commercial introduction of such non-injection techniques could have an adverse effect on our business.

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 and device 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.

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We currently hold numerous patents and have numerous patent applications pending in the U.S. and other countries. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain their own patents that may have an adverse effect on our ability to conduct business, or are able to otherwise circumvent our patents. Additionally, our products and 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 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 these are not resolved favorably, 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 or unenforceable, 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. 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. Ultimately, we may be unable to commercialize some of our product candidates as a result of patent infringement claims, which could potentially harm our business.

In November 2008, Meridian Medical Technologies (Meridian) received U.S. Patent 7,449,012 (the 012 patent) relating to a specific type of auto injector for use with epinephrine. The 012 patent is set to expire in September 2025. The 012 patent was listed in FDA s Orange Book in July 2009 under the EpiPen® NDA. On July 21, 2009, Meridian and King Pharmaceuticals, Inc. (King) received a copy of Paragraph IV certification from Teva giving notice that Teva had filed an ANDA to commercialize an epinephrine injectable product and referring to our auto injector device and challenging the validity and alleging non-infringement of the 012 patent. On August 28, 2009, King and Meridian filed suit against Teva in the U.S. District Court for the District of Delaware asserting its 012 patent. On October 21, 2009, Teva filed its answer asserting non-infringement and invalidity of the 012 patent. On November 3, 2011, Meridian and King requested to dismiss their claims against Teva involving the 012 patent, and the Court entered the dismissal on November 7, 2011, removing the 012 patent from the litigation.

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

In November 2010, Meridian and King received a copy of Paragraph IV certification from Teva challenging the validity and alleging non-infringement of the 432 patent. King and Meridian filed an amended complaint, in the same litigation as the 012 patent, adding the 432 patent. In October 2010, Pfizer announced it was acquiring King, and the acquisition was completed on or about March 1, 2011. On January 28, 2011, Teva filed its answer asserting non-infringement and invalidity of the 432 patent.

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On February 16, 2012, the case proceeded to trial in the U.S District Court for the District of Delaware. One day of the bench trial was held on that day. The Court scheduled the remaining days of trial for March 7-9, 2012.

On April 26, 2012 the Company announced that Meridian Medical Technologies, a Pfizer subsidiary, entered into a settlement agreement with Teva that would resolve pending patent litigation related to its abbreviated new drug application (ANDA) for a generic epinephrine auto injector. According to the terms of the settlement, Teva may launch a generic epinephrine auto-injector covered by its ANDA on June 22, 2015 or earlier under certain circumstances, subject to receipt of approval from the U.S. Food and Drug Administration.

Under a separate agreement, Teva has agreed to provide the Company with device orders of an undisclosed amount in the years 2013 and 2014, to make a milestone payment to the Company upon FDA approval of epinephrine auto-injector, and to assume all litigation costs related to the patent litigation between Teva and Meridian Medical.

Although the litigation has been settled, there can be no assurance that the epinephrine auto injector product will be approved by the FDA or that we will receive a milestone payment or royalties in the future under our agreement with Teva.

Additionally, we are developing other products for Teva under the ANDA pathway and there can be no assurance that those products do not follow the same type of litigation process of the epinephrine case which could delay or prohibit the launch of those potential products.

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 we are subject to a product liability claim, our product liability insurance may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses that may have been suffered. A successful product liability claim against us, if not covered by, or if in excess of our product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations. Adverse claim experience for our products or licensed technologies or medical device, pharmaceutical or insurance industry trends may make it difficult for us to obtain product liability insurance or we may be forced to pay very high premiums, and there can be no assurance that insurance coverage will continue to be available on commercially reasonable terms or at all. Additionally, if the coverage limits of the product liability insurance are not adequate, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

If we 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.

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.

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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 NDA 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 developing our own combination products such as OTREXUP and Vibex QS T (testosterone) as well as injection devices for use with our partner s drugs. The regulatory path for approval of such combination products may be subject to review by several centers within the FDA and although precedent and guidance exists for the requirements for such combination products, there is no assurance that the FDA will not change what it requires or how it reviews such submissions. Human clinical testing may be required by the FDA in order to commercialize these products and 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 product or device cost prohibitive for ourselves or our partners. Such delay or failure to launch these products or devices could adversely affect our revenues and future profitability.

In December 2012, we filed a New Drug Application for OTREXUP for the treatment of rheumatoid arthritis (RA), poly-articular-course juvenile RA and psoriasis. On February 26, 2013, the NDA was accepted for filing by the FDA. We cannot offer any assurances or predict with any certainty as to when or if the FDA will approve OTREXUP for marketing. FDA approval, if obtained, may be limited to specific indications, patient types in which the drug may be used, or otherwise require specific warning or labeling language, any of which might reduce the commercial potential of OTREXUP . Furthermore, previously unknown issues involving safety or efficacy could emerge or the Company may fail to comply with post-approval regulatory requirements, including requirements with respect to manufacturing practices, reporting of adverse effects, advertising, promotion and marketing, which may result in restrictions on the marketing of OTREXUP or the withdrawal of OTREXUP from the market.

In December 2008, one of our device partners, Teva, filed an ANDA for their epinephrine product. The ANDA submission was accepted by the FDA. Teva is in the process of completing the work required for the submission. The submission of the ANDA does not ensure that the FDA will approve the filing and without FDA approval we cannot market or sell our injector for use with this drug product in the U.S.

In 2007, our partner Teva filed a second injector device with sumatriptan as an ANDA and the FDA rejected such filing. The FDA s rejection was based primarily on the opinion that the device was sufficiently different than the innovator s device not to warrant an ANDA. We redesigned the device to address the FDA s concern of device similarity and submitted the new device to the FDA. The FDA reactivated the ANDA file in 2010, and since that time we have successfully completed user studies and are scaling up commercial tooling and molds for the newly designed device. Teva is completing some required manufacturing work related to the drug and we expect to submit the results later in 2013, then the FDA is expected to complete its review of the ANDA, the timing of which is completely dependent on the FDA. The reactivation of the ANDA does not ensure that the FDA will approve the filing and without FDA approval we cannot market or sell our injector for use with sumatriptan in the U.S.

As part of our device regulatory strategy, we have filed three 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.

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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.

In 2012, our partner Daewoong filed with the regulatory agency in South Korea for approval of our oxybutynin gel 3% product. We cannot offer any assurances or predict with any certainty as to when or if our oxybutynin gel 3% product will be approved for marketing in South Korea. If approval is delayed or is not received, we may not realize any further revenues under this agreement.

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.

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

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

- should a more appropriate reference product(s) be approved by the FDA at any time before or during the review of our NDA, we would be required to submit a new application referencing the more appropriate product;

- the FDA cannot disclose whether such predicate product(s) is under development or has been submitted at any time during another company s review cycle.

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

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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). Additionally, the instructions for use (IFU) for a device in a drug/device combination product is also reviewed for accuracy, ease of use and educational requirements. 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.

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

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

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

warning letters;

fines;

product seizures or recalls;

injunctions;

refusals to permit products to be imported into or exported out of the applicable regulatory jurisdiction;

total or partial suspension of production;

withdrawals of previously approved marketing applications; or

criminal prosecutions.

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

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

Risks Related to our Common Stock

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

As of March 4, 2013, we have warrants outstanding that are exercisable, at prices ranging from $1.00 per share to $3.78 per share, for an aggregate of approximately 2,963,000 shares of our common stock. We also have options outstanding that are exercisable, at exercise prices ranging from $0.37 to $4.26 per share, for an aggregate of approximately 7,734,000 shares of our common stock. Purchasers of our common stock could therefore experience dilution of their investment upon exercise of the above warrants or options.

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

As of March 4, 2013, our officers and directors beneficially owned an aggregate of approximately 17,900,000 shares (or approximately 13.7%) of our outstanding common stock, including stock options exercisable within 60 days. If our officers and directors, or other stockholders, sell a substantial amount of our common stock, it could cause the market price of our common stock to decrease.

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS.
None.

Item 2. PROPERTIES.
We lease approximately 8,000 square feet of office space in Ewing, New Jersey for our corporate headquarters facility. This lease will terminate in October 2019. In January 2013, we signed an amendment to this lease to expand our total square footage to approximately 11,000 square feet. We believe the facility will be sufficient to meet our requirements at this time.

We lease approximately 9,300 square feet of office, laboratory and manufacturing space in Plymouth, a suburb of Minneapolis, Minnesota. The lease will terminate in August 2016. We believe we may need additional space before the end of the lease term and will begin exploring options in 2013.

We also lease a small amount of office space in Muttenz, Switzerland. The lease is month-to-month and requires a three month notice prior to termination. We believe the facilities will be sufficient to meet our requirements through the lease period at this location.

Item 3. LEGAL PROCEEDINGS.
None.

Item 4. MINE SAFETY DISCLOSURES.
Not applicable.

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PART II

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

Market Information

Our common stock began trading on the NASDAQ Capital Market on June 15, 2012 under the symbol ATRS . Prior to that time, our common stock traded on the NYSE Amex under the symbol AIS . The following table sets forth the per share high and low closing sales prices of our common stock for each quarterly period during the two most recent fiscal years.

	High	Low
2012:		
First Quarter	$ 3.32	$ 2.05
Second Quarter	$ 3.71	$ 2.72
Third Quarter	$ 5.32	$ 3.67
Fourth Quarter	$ 4.40	$ 3.59
2011:		
First Quarter	$ 1.80	$ 1.51
Second Quarter	$ 2.21	$ 1.58
Third Quarter	$ 2.57	$ 1.80
Fourth Quarter	$ 2.82	$ 1.67

Common Shareholders

As of February 28, 2013, we had 89 shareholders of record of our common stock as well as approximately 18,660 shareholders in street name.

Dividends

We have not paid or declared any cash dividends on our common stock during the past ten years. We have no intention of paying cash dividends in the foreseeable future on our common stock.

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Performance Graph

The graph below provides an indication of cumulative total stockholder returns (Total Return) for the Company as compared with the NASDAQ Composite Index, the NASDAQ Biotechnology Stock Index, the Amex Composite Index, and the Amex Biotechnology Stock Index weighted by market value at each measurement point. Our common stock began trading on the NASDAQ Capital Market on June 15, 2012 and prior to that time was traded on NYSE Amex. For this reason, we are comparing Total Returns for the Company to indexes from both NASDAQ and NYSE Amex. The graph covers the period beginning December 31, 2007, through December 31, 2012. The graph assumes $100 was invested in each of our common stock, the NASDAQ Composite Index, the NASDAQ Biotechnology Stock Index, the Amex Composite Index, and the Amex Biotechnology Stock Index on December 31, 2007 (based upon the closing price of each). Total Return assumes reinvestment of dividends.

	December 31,					
	2007	2008	2009	2010	2011	2012
Antares Pharma, Inc.	$ 100.00	$ 37.76	$ 116.33	$ 173.47	$ 224.49	$ 388.78
NASDAQ Composite Index	100.00	59.46	85.55	100.02	98.22	113.85
NASDAQ Biotechnology Stock Index	100.00	87.37	101.03	116.19	129.91	171.36
Amex Composite Index	100.00	58.00	75.74	91.65	94.55	97.76
Amex Biotechnology Stock Index	100.00	82.28	119.79	164.99	138.77	196.70

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Item 6. SELECTED FINANCIAL DATA

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

	At December 31,				
	2012	2011	2010	2009	2008
Balance Sheet Data:					
Cash and cash equivalents	$ 52,097	$ 19,358	$ 9,848	$ 13,559	$ 13,096
Investments	33,129	15,038			
Working capital	69,721	26,257	5,804	8,307	7,537
Total assets	95,527	41,963	15,141	19,143	19,911
Long-term liabilities, less current maturities	1,038	810	1,843	2,051	5,297
Accumulated deficit	(152,789)	(141,362)	(136,974)	(130,883)	(120,592)
Total stockholders equity	86,551	31,144	6,627	8,851	7,243

	Year Ended December 31,				
	2012	2011	2010	2009	2008
Statement of Operations Data:					
Product sales	$ 9,138	$ 7,630	$ 5,774	$ 3,506	$ 3,350
Development revenue	7,422	4,462	2,127	2,607	541
Licensing fees	2,141	1,221	2,856	1,595	1,238
Royalties	3,874	3,145	2,062	603	532
Revenues	22,575	16,458	12,819	8,311	5,661
Cost of revenues	9,520	6,797	4,273	4,140	2,020
Research and development	14,921	6,699	8,803	7,903	7,866
Sales, marketing and business development	2,383	1,553	1,035	1,051	1,625
General and administrative	7,202	5,846	4,734	4,911	6,348
Operating expenses	24,506	14,098	14,572	13,865	15,839
Operating loss	(11,451)	(4,437)	(6,026)	(9,694)	(12,198)
Net other income (expense)	24	49	(65)	(597)	(492)
Net loss applicable to common shares	$ (11,427)	$ (4,388)	$ (6,091)	$ (10,291)	$ (12,690)
Net loss per common share (1) (2)	$ (0.10)	$ (0.05)	$ (0.07)	$ (0.14)	$ (0.19)
Weighted average number of common shares	110,185	96,995	83,170	73,489	67,233

(1) Basic and diluted loss per share amounts are identical as the effect of potential common shares is anti-dilutive.
(2) We have not paid any dividends on our common stock since inception.

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

You should read the following discussion in conjunction with Item 1A. (Risk Factors) and our audited consolidated financial statements included elsewhere in this annual report. Some of the statements in the following discussion are forward-looking statements. See the discussion about forward-looking statements in Item 1. (Business) and Forward-Looking Statements in Management s Discussion and Analysis.

Forward-Looking Statements in Management s Discussion and Analysis

Management s discussion and analysis of the significant changes in the consolidated results of operations, financial condition and cash flows of the Company is set forth below. Certain statements in this report may be considered to be forward-looking statements as that term is defined in the U.S. Private Securities Litigation Reform Act of 1995, such as statements that include the words expect, estimate, project, anticipate, shou intend, probability, risk, target, objective and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and product development. In particular, these forward-looking statements include, among others, statements about:

- our expectations regarding product development of OTREXUP (Vibex MTX);
- our expectations regarding commercialization of our oxybutynin gel 3% product (Gelnique 3%) by Actavis;
- our expectations regarding product development of Vibex QS T;
- our expectations regarding continued product development with Teva;
- our plans regarding potential manufacturing and marketing partners;
- our future cash flow;
- the impact of new accounting pronouncements; and
- our expectations regarding the year ending December 31, 2013.

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

- delays in product introduction and marketing or interruptions in supply;
- a decrease in business from our major customers and partners;

our inability to compete successfully against new and existing competitors or to leverage our research and development capabilities and our marketing capabilities;

our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers;

our inability to attract and retain key personnel;

adverse economic and political conditions; and

our inability to obtain additional financing, reduce expenses or generate funds when necessary.

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

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

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

Overview

Antares Pharma, Inc. is an emerging specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies and topical gel-based products. We have numerous partnerships with pharmaceutical companies as well as multiple internal product development programs.

We have developed both subcutaneous and intramuscular injection technology systems which include Vibex disposable pressure-assisted auto injectors, Vision reusable needle-free injectors, and disposable multi-use pen injectors. We have licensed our reusable needle-free injection device for use with human growth hormone (hGH) to Teva Pharmaceutical Industries, Ltd. (Teva), Ferring Pharmaceuticals BV (Ferring) and JCR Pharmaceuticals Co., Ltd. (JCR), with Teva and Ferring being two of our primary customers. Our needle-free injection device is marketed by Teva as the Tjet® injector system to administer their 5mg Tev-Tropin® brand hGH marketed in the U.S. Our needle-free injection device is marketed by Ferring with their 4mg and 10mg hGH formulations as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. We have also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and are engaged in product development activities for Teva utilizing these devices.

In addition to development of products with partners, we are developing our own drug/device combination products. Our lead product candidate, OTREXUP , is a proprietary combination product comprised of a pre-filled methotrexate syringe and our Medi-Jet self-injection system for the treatment of moderate to severe rheumatoid arthritis (RA). On December 17, 2012 we announced submission of a New Drug Application (NDA) for OTREXUP and then on February 27, 2013 announced the FDA acceptance of that filing for review. The Prescription Drug User Fee Act (PDUFA) goal date for FDA approval is October 14, 2013. We have worldwide marketing rights for OTREXUP and have provided Uman an exclusive license to commercialize the product in Canada. Our strategy is to potentially commercialize OTREXUP in the U.S. on our own and to enter into licensing or distribution agreements for commercialization outside the U.S. We are also developing Vibex QS T for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and have conducted a pre-IND meeting with the FDA as part of preparing to initiate clinical development for this product.

In the gel-based product area, we announced with Actavis (formerly Watson Pharmaceuticals) on April 26, 2012, the launch of Gelnique 3% , our topical oxybutynin gel product for the treatment of overactive bladder (OAB), which was approved by the FDA in December 2011. We have a licensing agreement with Actavis under which Actavis is currently marketing Gelnique 3% in the U.S. In January 2012, we entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize this product, once approved in South Korea. Our gel portfolio also includes Elestrin® (estradiol gel) currently marketed by Meda Pharma in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

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We have two facilities in the U.S. The Parenteral Products Group located in Minneapolis, Minnesota directs the manufacturing and marketing of our reusable needle-free injection devices and related disposables, and develops our disposable pressure-assisted auto injector and pen injector systems. Our corporate head office and Product Development Group are located in Ewing, New Jersey, where our gel based products were developed and where the Product Development Group directs the clinical, regulatory and commercial development of our internal drug/device combination products.

Critical Accounting Policies and Use of Estimates

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

Revenue Recognition

A significant portion of our revenue relates to product sales for which revenue is recognized upon shipment, with limited judgment required related to product returns. Product sales are shipped FOB shipping point. We also enter into license arrangements that are often complex as they may involve license, development and manufacturing components. Licensing and development revenue recognition requires significant management judgment to evaluate the effective terms of agreements, our performance commitments and determination of fair value of the various deliverables under the arrangement. Current applicable accounting standards require a vendor to allocate revenue to each unit of accounting in arrangements involving multiple deliverables. To separate deliverables into individual units of accounting, there must be evidence of standalone selling price for each deliverable. The evidence preferred includes either vendor specific objective evidence or third party evidence, but a vendor is allowed to make its best estimate of the standalone selling price when neither of these is available.

We have deferred revenue amounts of $3,194,811 at December 31, 2012, where non-refundable cash payments have been received, but the revenue is not immediately recognized due to the nature of the respective agreements. Subsequent factors affecting the initial estimate of the effective terms of agreements could either increase or decrease the period over which the deferred revenue is recognized.

Due to the requirement to defer significant amounts of revenue and the extended period over which the revenue will be recognized, along with the requirement to recognize certain deferred development costs over an extended period of time, revenue recognized and cost of revenue may be materially different from cash flows.

On an overall basis, our reported revenues can differ significantly from billings and/or accrued billings based on terms in agreements with customers. The table below is presented to help explain the impact of the deferral of revenue on reported revenues, and is not meant to be a substitute for accounting or presentation requirements under U.S. generally accepted accounting principles.

	2012	2011	2010
Product sales	$ 9,137,573	$ 7,630,402	$ 5,773,734
Development fees	4,054,993	3,986,564	1,496,161
Licensing fees and milestone payments	2,215,716	3,200,000	974,925
Royalties	3,874,284	3,144,980	2,061,703
Billings received and/or accrued per contract terms	19,282,566	17,961,946	10,306,523
Deferred billings received and/or accrued	(3,075,758)	(5,138,081)	(1,240,089)
Deferred revenue recognized	6,368,770	3,634,627	3,752,264
Total revenue as reported	$ 22,575,578	$ 16,458,492	$ 12,818,698

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Valuation of Long-Lived and Intangible Assets and Goodwill

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

Each year we review patent costs for impairment and identify patents related to products for which there are no signed distribution or license agreements or for which no revenues or cash flows are anticipated. No impairment charges were recognized in 2012, 2011 or 2010. The gross carrying amount and accumulated amortization of patents, which are our only intangible assets subject to amortization, were $2,244,086 and $1,120,434, respectively, at December 31, 2012 and were $1,979,502 and $1,027,116, respectively, at December 31, 2011. The Company s estimated aggregate patent amortization expense for the next five years is $107,000, $120,000, $127,000, $127,000 and $127,000 in 2013, 2014, 2015, 2016 and 2017, respectively.

We have $1,095,355 of goodwill recorded as of December 31, 2012 that relates to our Minnesota operations. We evaluate the carrying amount of goodwill on December 31 of each year and between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying amount. Such circumstances could include, but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, (3) an adverse action or assessment by a regulator, or (4) a sustained significant drop in our stock price. When evaluating whether goodwill is impaired, we compare the fair value of the Minnesota reporting unit to the carrying amount, including goodwill. If the carrying amount of the Minnesota reporting unit exceeds its fair value, then the amount of the impairment loss must be measured. The impairment loss would be calculated by comparing the implied fair value of goodwill to its carrying amount. In calculating the implied fair value of goodwill, the fair value of the Minnesota reporting unit would be allocated to all of its other assets and liabilities based on their fair values. The excess of the fair value of the Minnesota reporting unit over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. An impairment loss would be recognized when the carrying amount of goodwill exceeds its implied fair value.

In evaluating whether the fair value of the Minnesota reporting unit was below its carrying amount, we used the market capitalization of the Company at December 31, 2012, which was approximately $480 million, to calculate an estimate of fair value of the Minnesota reporting unit. We determined that the percentage of the total market capitalization of the Company at December 31, 2012 attributable to the Minnesota reporting unit would have to be unreasonably low before the fair value of the Minnesota reporting unit would be less than its carrying amount. In making this determination, we evaluated the activity at the Minnesota reporting unit compared to the total Company activity, and considered the source and potential value of agreements currently in place, the source of recent product sales and development revenue growth, the source of total Company revenue and the source of cash generating activities. After performing the market capitalization analysis and concluding that the fair value of the Minnesota reporting unit was not below its carrying amount, we determined that no further detailed determination of fair value was required.

Our evaluation of goodwill completed during 2012, 2011 and 2010 resulted in no impairment losses.

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Results of Operations

Years Ended December 31, 2012, 2011 and 2010

Revenues

Total revenue was $22,575,578, $16,458,492 and $12,818,698 for the years ended December 31, 2012, 2011 and 2010, respectively.

Product sales were $9,137,573, $7,630,402 and $5,773,734 for the years ended December 31, 2012, 2011 and 2010, respectively. Prior to 2012, our product sales primarily included sales of reusable needle-free injector devices and disposable components. In 2012, product sales also included the sale of our topical oxybutynin gel 3% product to Actavis in connection with their launch of Gelnique 3% in April 2012, which was the primary reason for the increase in product sales compared to the prior year, and included sales of pre-commercial auto injector and pen injector devices to Teva. Product sales to Actavis will not continue after the first quarter of 2013, as Actavis will assume all manufacturing of Gelnique 3% in 2013 as contracted. Our sales of injector related products are generated primarily from sales to Ferring and Teva. Ferring uses our needle-free injector with their 4mg and 10mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. Teva uses our Tjet® needle-free device with their 5mg hGH Tev-Tropin® marketed in the U.S. In 2012, 2011 and 2010, revenue from sales of needle-free injector devices totaled $1,285,042, $2,054,315 and $1,613,988, respectively. Sales of disposable components in 2012, 2011 and 2010 totaled $4,047,895, $5,457,621 and $4,052,206, respectively. The 2012 decreases in sales of devices and disposable components were due to decreases in sales to both Ferring and Teva. Sales of the hGH drug product for both Ferring and Teva continue to grow, but we do not control our partners inventory levels of our hGH injectors or disposable components and this can cause significant fluctuations in product sales. The 2011 increase in device sales was due to an increase in sales to Ferring. The 2011 increase in sales of disposable components was due to nearly equal increases in sales to Teva and Ferring.

Development revenue was $7,422,412, $4,462,287 and $2,127,033 for the years ended December 31, 2012, 2011 and 2010, respectively. The revenue in 2012 included $2,787,157 and $840,000 related to the Teva auto injector and pen injector programs, respectively, $2,764,234 recognized under our license agreement with Actavis, $750,000 earned when Pfizer achieved a development milestone related to its undisclosed Consumer Healthcare product, and amounts earned under various other agreements. The revenue in 2011 included $2,083,977 and $1,314,069 related to the Teva auto injector and pen injector programs, respectively. The development revenue related to the pen injector program in 2011 included the recognition of $304,600 of previously deferred development revenue in connection with an amendment, in the first quarter of 2011, to a license, development and supply agreement with Teva originally entered into in December of 2007. In addition, the 2011 development revenue included $1,024,240 earned under the Actavis license agreement. Approximately $1,400,000 of the development revenue recognized in 2010 was related to auto injector development work under a License, Development and Supply agreement with Teva originally signed in July 2006. In 2010, approximately $250,000 of revenue was recognized in connection with a pen injector development program with Teva. The balance of the revenue in 2010 was attributable primarily to projects related to our gel technology.

Licensing revenue was $2,141,309, $1,220,823 and $2,856,228 for the years ended December 31, 2012, 2011 and 2010, respectively. The licensing revenue in 2012 was primarily due to an upfront license fee received in connection with our licensing agreement with Daewoong signed in January of this year and license revenue recognized in connection with our license agreement with Actavis, as well as additional payments from our partners under various license agreements. The licensing revenue in 2011 was primarily due to an upfront payment from Pfizer associated with a license agreement entered into in December 2011, and included revenue recognized that was previously deferred in connection with license agreements with Teva, Ferring and BioSante, including $337,776 of revenue previously deferred that was recognized as a result of the amended license, development and supply agreement with Teva for a disposable pen injector, as discussed in Note 9 to the consolidated financial statements. The 2010 licensing revenue was primarily due to recognition of revenue deferred in 2009 under an Exclusive License Agreement with Ferring, along with a sales based milestone payment from Teva and milestone payments received from BioSante. The remaining licensing revenue in each year is primarily due to recognizing portions of previously deferred amounts related to upfront license fees or milestone payments received under various agreements.

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Royalty revenue was $3,874,284, $3,144,980 and $2,061,703 for the years ended December 31, 2012, 2011 and 2010, respectively. We receive royalties from Teva and Ferring related to needle-free injector device sales and/or hGH sales, and we receive royalties on sales of Elestrin® marketed by Meda Pharma. In addition, in 2012 we received our first royalty payments from Actavis on sales of Gelnique 3%, which was the primary reason for the increase in royalties in 2012 compared to 2011. The increase in 2011 was primarily due to increases in royalties from Teva and Ferring. Both companies experienced growth in their hGH business in 2011. The royalties in 2010 were impacted by first year royalties of $1,404,053 received from Teva in connection with sales of their hGH Tev-Tropin®. Nearly all remaining royalty revenue in 2010 was generated under the license agreement with Ferring described in more detail in Note 8 to the consolidated financial statements. Royalties from Ferring are earned on device sales and under a provision in the Ferring agreement in which royalties on their hGH sales are triggered by the achievement of certain quality standards. Royalty revenue in each year also included royalties from JCR on sales of hGH and royalties from Azur/Jazz on sales of Elestrin®.

Cost of Revenues and Gross Margins

The cost of product sales includes product acquisition costs from third party manufacturers and internal manufacturing overhead expenses. Cost of product sales were $6,116,726, $3,623,186 and $2,799,253 for the years ended December 31, 2012, 2011 and 2010, respectively, representing gross margins of 33%, 53% and 52%, respectively. The gross margin decrease in 2012 was due primarily due to sales of our topical oxybutynin gel 3% product to Actavis at a lower gross profit than is realized on injector related product sales. The gross margin increases in 2011 were due primarily to internal manufacturing overhead expenses that decreased as a percent of product sales compared to the prior year as a result of increased sales volumes.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. Cost of development revenue was $3,403,746, $3,174,006 and $1,473,957 for the years ended December 31, 2012, 2011 and 2010, respectively. Approximately $2,300,000, $1,453,000 and $1,000,000 of development costs were recognized in 2012, 2011 and 2010, respectively, in connection with revenue recognized related to auto injector development programs with Teva. In 2012 and 2011, development costs of approximately $460,000 and $675,000, respectively, were recognized in connection with our disposable pen injector programs with Teva. Of the amount recognized in 2011, $408,250 had been previously deferred and was recognized as a result of the amended license, development and supply agreement with Teva, as discussed in Note 9 to the consolidated financial statements. In 2012 and 2011, development costs of approximately $589,000 and $1,024,000, respectively, were related to certain manufacturing readiness activities under the Actavis license agreement. Development costs in 2010 also included costs recognized in connection with revenue recognized under a pen injector development program with Teva and projects related to our gel technology.

Research and Development

Research and development expenses consist of external costs for studies and analysis activities, design work and prototype development, and salaries and overhead costs. Research and development expenses were $14,921,552, $6,699,325 and $8,802,502 for the years ended December 31, 2012, 2011 and 2010, respectively. The increase in 2012 was primarily due to expenses related to development of OTREXUP (Vibex MTX auto injector) for delivery of methotrexate for the treatment of rheumatoid arthritis, including a fee of approximately $2,000,000 paid in connection with the New Drug Application submitted to the FDA in December 2012. External expenses in connection with the OTREXUP program totaled approximately $7,600,000, $2,000,000 and $370,000 in 2012, 2011 and 2010, respectively. The increase in 2012 research and development was also impacted by expenses of approximately $900,000 related to Vibex QS T for testosterone replacement therapy and an increase in personnel costs due mainly to employee additions of approximately $1,500,000. The decrease in 2011 compared to the prior year was due primarily to a decrease in expenses following completion of the Phase III study of our oxybutynin gel 3% product and filing of our NDA in the fourth quarter of 2010. Expenses related to our transdermal gel products, primarily our oxybutynin gel 3% product, decreased to approximately 20% of our total research and development expenses in 2011 from approximately 75% in 2010. Expenses for development work to prepare for commercialization and expenses associated with the Phase III study were approximately $700,000 and $4,900,000 in the years ended December 31, 2011 and 2010, respectively. Partially offsetting the decrease in expenses related to our oxybutynin gel 3% product was an increase in external expenses of approximately $1,600,000 related to development of OTREXUP , along with an increase in personnel costs due to employee additions. The 2010 expenses were partially offset by the receipt of approximately $430,000 from the qualifying therapeutic discovery grant program under section 48D of the internal revenue code.

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Sales, Marketing and Business Development

Sales, marketing and business development expenses were $2,382,625, $1,553,174 and $1,035,017 for the years ended December 31, 2012, 2011 and 2010, respectively. The increase in 2012 was primarily due to expenses of approximately $600,000 related to OTREXUP market research, and an increase of approximately $400,000 in employee related expenses due to added sales and marketing personnel, partially offset by a reduction in other professional fees related primarily to services outsourced in 2011 that were moved in-house in 2012. The increase in 2011 compared to 2010 was primarily due to increases in legal costs in connection with executed and potential partner agreements and professional fees related to market research, along with increases in payroll related expenses, which included noncash stock compensation expense.

General and Administrative

General and administrative expenses were $7,202,428, $5,845,588 and $4,734,427 for the years ended December 31, 2012, 2011 and 2010, respectively. The increase in 2012 was primarily due to increases in employee and director compensation expenses, including noncash stock compensation expense, of approximately $840,000 and increases in professional fees of approximately $200,000 as well as increases in patent related expenses of approximately $276,000 associated primarily with pen and auto injector technologies and products. The increase in 2011 was primarily due to increases in payroll related expenses, primarily noncash stock compensation expense, patent related expenses and professional fees.

Liquidity and Capital Resources

We have reported net losses of $11,427,450, $4,387,920 and $6,091,198 in the fiscal years ended 2012, 2011 and 2010, respectively. We have accumulated aggregate net losses from the inception of business through December 31, 2012 of $152,789,165. We have not historically generated, and do not currently generate, enough revenue to provide the cash needed to support our operations, and have continued to operate primarily by raising capital.

In October 2012, we sold 12,500,000 shares of common stock at a price of $4.00 per share in a public offering, and in November 2012 we sold 1,759,868 shares of common stock at $4.00 per share as a result of the partial exercise of the underwriters over-allotment option. The sales of common stock resulted in net proceeds of $53,328,188 after deducting offering expenses of $3,711,284. Proceeds from this offering are being used for further development of OTREXUP (our proprietary MTX Medi-Jet injection system for the treatment of rheumatoid arthritis), development of the Company s proprietary VIBEX QS T product for male testosterone deficiency and general corporate purposes.

In 2012, we received proceeds of $11,579,413 from the exercise of warrants and stock options, which resulted in the issuance of 8,021,672 shares of our common stock.

In May 2011, we received net proceeds of $21,280,718 from the sale of 14,375,000 shares of common stock at a price of $1.60 per share in a public offering. Proceeds from this offering were used for development of the Company s proprietary Vibex MTX methotrexate injection system for the treatment of rheumatoid arthritis and for general corporate purposes.

In 2011, we received proceeds of $6,020,436 in connection with exercises of options and warrants to purchase shares of our common stock, which resulted in the issuance of 4,475,335 shares of our common stock.

At December 31, 2012 we had cash and investments of $85,225,593. All investments are U.S. Treasury bills or U.S. Treasury notes which we intend to hold to maturity. We believe that the combination of our current cash and investments balances and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations. We do not currently have any bank credit lines. If in the future we do not turn profitable or generate cash from operations as anticipated and additional capital is needed to support operations, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

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Net Cash Used in Operating Activities

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, general and administrative costs, research and development projects including clinical studies, and sales, marketing and business development activities. Net cash used in operating activities was $10,472,988, $1,926,007 and $6,079,370 for the years ended December 31, 2012, 2011 and 2010, respectively. Net operating cash outflows were primarily the result of net losses of $11,427,450, $4,387,920 and $6,091,198 in 2012, 2011 and 2010, respectively, adjusted by noncash expenses and changes in operating assets and liabilities.

In 2012, the net loss increased by $7,039,530 to $11,427,450 from $4,387,920 in 2011 primarily due to an increase in spending associated with OTREXUP (Vibex MTX) of approximately $5,600,000, including a $2,000,000 NDA filing fee, and an increase in personnel costs of approximately $3,500,000 associated mainly with employee additions related to increased research and development activities. The increase in the net loss due to the increase in expenses was partially reduced by an increase in gross profit of approximately $3,300,000.

In 2011, the net loss decreased by $1,703,278 to $4,387,920 from $6,091,198 in 2010 primarily as a result of an increase in gross profit of $1,115,812 along with a decrease in operating expenses of $473,859. The gross profit increase was primarily due to an increase in gross profit related to product sales and to an increase in royalties which have no associated direct cost. These increases were partially offset by a decrease in gross profit from development activities and a decrease in licensing revenue.

Noncash expenses totaled $2,375,989, $2,010,945 and $1,556,824 in 2012, 2011 and 2010, respectively. The increase in 2012 was primarily due to an increase in stock-based compensation expense of $152,760 and due to the loss on disposal of equipment, molds, furniture and fixtures of $119,429 related mainly to the write off of a tool replacement. The increase in 2011 was primarily due to an increase in stock-based compensation expense of $561,595 compared to 2010. This increase was mainly due to discretionary stock awards granted in 2011 that were both higher in number and higher in grant date fair value compared to similar grants in prior years.

In 2012, the change in operating assets and liabilities used cash of $1,421,527. This use of cash was mainly due to a decrease in deferred revenue of $3,340,951, partially offset by an increase in accrued expenses and other current liabilities of $687,297 and an increase in accounts payable of $724,802. Deferred revenue decreased primarily due to recognition of amounts received and deferred in 2011 under our license agreement with Actavis and amounts recognized under pen and auto injector development programs with Teva. The increases in accrued expenses and other current liabilities and accounts payable were affected by overall company growth which included personnel additions and increases in operating activities, particularly research and development activities.

In 2011, the change in operating assets and liabilities generated cash of $450,968. The primary reasons for this were an increase in deferred revenue of $1,543,840, which was due mainly to a payment received from Actavis and payments from Teva that together exceeded amounts recognized as revenue during 2011 that had been deferred in prior years, and increases in accounts payable and accrued expenses and other current liabilities that totaled $772,346, partially offset by an increase in accounts receivable of $1,300,995 and an increase in inventories of $629,510. The receivable increase was due to billings to Ferring and Teva in December for product shipments and development work, nearly all of which was collected in January 2012. The inventory increase was due to timing of production of devices and disposable components for order fulfillment in early 2012, along with raw material inventory purchased for production of Gelnique 3% launch quantities.

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

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Net Cash Used in Investing Activities

In 2012, cash used in investing activities was $21,667,632, consisting of purchases of investments of $30,166,239, purchases of equipment, molds, furniture and fixtures of $3,256,632, additions to patent rights of $244,761, and proceeds from maturities of investments of $12,000,000. The purchases of equipment, molds, furniture and fixtures were primarily for OTREXUP (Vibex MTX) auto injector device molds and assembly equipment. In 2011, cash used in investing activities was $15,605,780, consisting of purchases of investments of $15,053,981, additions to patent rights of $231,260, purchases of equipment, molds, furniture and fixtures of $350,539, and net proceeds from sales of equipment, molds, furniture and fixtures of $30,000. The investment purchases in 2012 and 2011 were U.S. Treasury bills or U.S. Treasury notes that matured in six to twenty-two months of purchase and were classified as held-to-maturity because we had the positive intent and ability to hold the securities to maturity. In 2010, cash used in investing activities was $182,916, consisting of additions to patent rights of $122,720, purchases of equipment, molds, furniture and fixtures of $89,293, and net of proceeds from sales of equipment, molds, furniture and fixtures of $29,097.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled $64,878,685, $27,067,863 and $2,463,419 for the years ended December 31, 2012, 2011 and 2010. In 2012, we received net proceeds of $53,328,188 from the sale of common stock and $11,579,413 from the exercise of warrants and stock options. In 2011, we received net proceeds of $21,280,718 from the sale of common stock and $6,020,436 from the exercise of warrants and stock options, and we made payments of $233,291 for employee withholding taxes on net share settlement of equity awards. A portion of shares held by employees that vested in 2012 and 2011 were net-share settled such that the Company withheld shares with value equivalent to the employees minimum statutory obligation for the applicable income and other employment taxes, and remitted the cash to the appropriate taxing authorities. The total shares withheld were 11,165 and 121,182 in 2012 and 2011, respectively, and were based on the value of the shares on their vesting date as determined by the Company s closing stock price. In 2010, we received proceeds from exercise of warrants and stock options of $2,463,419.

Our contractual cash obligations at December 31, 2012 are associated with operating leases and are summarized in the following table:

		Payment Due by Period			
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Total contractual cash obligations	$ 2,011,050	$ 310,439	$ 903,520	$ 473,147	$ 323,944

In January 2013, we signed an amendment to our lease agreement for our office space in Ewing, NJ, which ends in October 2019, to expand our total square footage. This amendment will increase our future cash obligations.

Off Balance Sheet Arrangements

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

Research and Development Programs

During 2012, our research and development activities were primarily related to OTREXUP (Vibex MTX), Vibex QS T and device development projects.

OTREXUP (Vibex MTX). In December 2012, we submitted a New Drug Application to the FDA for OTREXUP , a combination product for the delivery of methotrexate (MTX) using Medi-Jet technology, which NDA was accepted for filing on February 26, 2013. OTREXUP is being developed for subcutaneous administration of MTX to enhance the treatment of rheumatoid arthritis (RA), poly-articular-course juvenile RA and psoriasis.

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In November 2012, we announced positive results from an open-label, randomized, crossover study comparing the systemic availability of OTREXUP to oral methotrexate in adult patients with rheumatoid arthritis. This study was designed to compare the relative systemic availability of methotrexate following oral administration to subcutaneous (SC) self-administered methotrexate using the Medi-Jet device. Patients were assigned to one of four dose levels of methotrexate, 10 mg, 15 mg, 20 mg, and 25 mg. Results showed that the systemic availability of methotrexate following oral dosing plateaus above 15 mg. Following administration of methotrexate with Medi-Jet , the systemic availability increased proportionally at every dose, which will extend the range of exposure compared to patients receiving oral therapy.

In September 2012, we announced positive results from an actual human use study in 101 RA patients. The results of this study showed that self-administration of MTX using the Vibex MTX (Medi-Jet) is safe and well tolerated. Following standardized training by site personnel and review of written instructions, all 101 patients performed the self-administration successfully. In addition, the Medi-Jet device functioned correctly and as intended for each and every administration thereby demonstrating reliability and robustness. Results of the Ease of Use Questionnaire indicated that 98% of patients found the Medi-Jet device easy to use and 100% of patients found the instructions and training to be clear and easy to follow.

In June 2012, we announced positive results from a human factors usability study for our Medi-Jet methotrexate injection system. Fifty individuals representing three user groups participated in this study, including 17 RA patients, 16 lay caregivers and 17 healthcare professionals.

In August 2011, we announced positive results from a clinical PK study initiated in the first quarter of 2011 evaluating OTREXUP (Vibex MTX). The clinical study evaluated several dose strengths of methotrexate delivered with our Medi-Jet versus conventional needle and syringe administration by a healthcare professional.

In 2010, we entered into an agreement with Uman Pharma under which both companies will invest jointly to develop and commercialize OTREXUP (Vibex MTX). We will lead the clinical development program and FDA regulatory submissions, and will retain rights to commercialize the Vibex MTX product outside of Canada. Uman Pharma will perform formulation development and manufacturing activities to support the registration of Vibex MTX and supply methotrexate in prefilled syringes to us for the U.S. market. Uman Pharma received an exclusive license to commercialize the Vibex MTX product in Canada.

As of December 31, 2012, we have incurred external costs of approximately $10,100,000 in connection with our Vibex MTX development program, of which approximately $7,600,000 was incurred in 2012 including approximately $2,000,000 paid in connection with the New Drug Application submitted to the FDA in December 2012. We also incurred approximately $2,600,000 of equipment costs in 2012 that have been capitalized and included in equipment, molds, furniture and fixtures at December 31, 2012. We anticipate total spending on this program for development and capital equipment could approach an additional $7,000,000 in 2013 as well as sales and marketing expense in 2013 of approximately $6,000,000.

Vibex QS T. We have initiated development of Vibex QS T for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and recognized expense of approximately $937,000 in 2012 in connection with this program. We anticipate spending on this program for development will increase in 2013 to approximately $3,000,000.

Device Development Projects. We are also 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 use with epinephrine and sumatriptan and for our pen injector device for two undisclosed products. Our pressure-assisted auto injectors are designed to deliver drugs by injection from single-dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the stage of development where devices are being evaluated in user studies and stability programs. Our development programs consist of the determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly.

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As of December 31, 2012, we have incurred total external costs of approximately $12,600,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately $4,300,000 was incurred in 2012. As of December 31, 2012, approximately $9,200,000 of the total costs of $12,600,000 was initially deferred, of which approximately $8,500,000 has been recognized as cost of sales and $700,000 remains deferred. This remaining deferred balance will be recognized as cost of sales over the same period as the related deferred revenue will be recognized.

The development timelines of the auto and pen injectors related to the Teva products are controlled by Teva. We expect development related to the Teva products to continue in 2013, but the timing and extent of near-term future development will be dependent on certain decisions made by Teva. Although development work payments and certain upfront and milestone payments have been received from Teva, there have been no commercial sales from the auto injector or pen injector programs, timelines have been extended and there can be no assurance that there ever will be commercial sales or future milestone payments under these agreements.

Other research and development costs. In addition to the Vibex MTX project, Vibex QS T project and the Teva related device development projects, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include salaries, administrative and other overhead costs of managing our research and development projects. Total other research and development costs were approximately $5,900,000 for the year ended December 31, 2012.

Recently Issued Accounting Pronouncements

In October 2012, the FASB made certain technical corrections and conforming fair value amendments to the FASB Accounting Standards Codification. The amendments affect various codification topics and apply to all reporting entities within the scope of those topics. The provisions of the amendments are effective upon issuance, except for amendments that are subject to transition guidance, which will be effective for fiscal periods beginning after December 15, 2012. We do not believe the adoption of the amendment provisions will have a material impact on our consolidated financial statements.

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

Our primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with a licensing agreement with Ferring, under which certain products sold to Ferring and royalties are denominated in Euros. Most of our product sales, including a portion of our product sales to Ferring, and our development and licensing fees and royalties are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. We do not currently use derivative financial instruments to hedge against exchange rate risk. The effect of foreign exchange rate fluctuations on our financial results for the years ended December 31, 2012, 2011 and 2010 was not material.

We also have limited exposure to market risk due to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. To minimize market risk, we have in the past and, to the extent possible, will continue in the future, to hold debt securities to maturity at which time the debt security will be redeemed at its stated or face value. Due to the nature of our marketable securities, we believe that we are not exposed to any material market interest rate risk related to our investment portfolio.

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Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

ANTARES PHARMA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Antares Pharma, Inc.:

We have audited the accompanying consolidated balance sheets of Antares Pharma, Inc. (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2012. We also have audited the Company s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company s internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Antares Pharma, Inc. as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also in our opinion, Antares Pharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ KPMG LLP

Minneapolis, Minnesota

March 13, 2013

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ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2012	December 31, 2011
Assets		
Current Assets:		
Cash and cash equivalents	$ 52,097,064	$ 19,357,932
Short term investments	21,112,623	12,011,388
Accounts receivable	2,228,650	2,535,230
Inventories	1,002,703	891,765
Deferred costs	755,159	1,111,842
Prepaid expenses and other current assets	463,033	357,202
Total current assets	77,659,232	36,265,359
Equipment, molds, furniture and fixtures, net	3,583,104	591,669
Patent rights, net	1,123,652	952,386
Goodwill	1,095,355	1,095,355
Long term investments	12,015,906	3,026,957
Other assets	49,361	31,231
Total Assets	$ 95,526,610	$ 41,962,957
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 2,864,507	$ 2,139,130
Accrued expenses and other liabilities	2,916,700	2,225,311
Deferred revenue	2,157,016	5,644,278
Total current liabilities	7,938,223	10,008,719
Deferred revenue long term	1,037,795	810,393
Total liabilities	8,976,018	10,819,112
Stockholders Equity:		
Preferred Stock: $0.01 par; authorized 3,000,000 shares, none outstanding		
Common Stock: $0.01 par; authorized 150,000,000 shares; 125,949,024 and 103,545,637 issued and outstanding at December 31, 2012 and 2011, respectively	1,259,490	1,035,456
Additional paid-in capital	238,745,612	172,065,429
Accumulated deficit	(152,789,165)	(141,361,715)
Accumulated other comprehensive loss	(665,345)	(595,325)
	86,550,592	31,143,845
Total Liabilities and Stockholders Equity	$ 95,526,610	$ 41,962,957

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2012	2011	2010
Revenue:			
Product sales	$ 9,137,573	$ 7,630,402	$ 5,773,734
Development revenue	7,422,412	4,462,287	2,127,033
Licensing revenue	2,141,309	1,220,823	2,856,228
Royalties	3,874,284	3,144,980	2,061,703
Total revenue	22,575,578	16,458,492	12,818,698
Cost of revenue:			
Cost of product sales	6,116,726	3,623,186	2,799,253
Cost of development revenue	3,403,746	3,174,006	1,473,957
Total cost of revenue	9,520,472	6,797,192	4,273,210
Gross profit	13,055,106	9,661,300	8,545,488
Operating expenses:			
Research and development	14,921,552	6,699,325	8,802,502
Sales, marketing and business development	2,382,625	1,553,174	1,035,017
General and administrative	7,202,428	5,845,588	4,734,427
Total operating expenses	24,506,605	14,098,087	14,571,946
Operating loss	(11,451,499)	(4,436,787)	(6,026,458)
Other income (expense):			
Interest income	63,195	55,592	30,675
Foreign exchange gain (loss)	14,414	(19,784)	(31,525)
Other, net	(53,560)	13,059	(63,890)
Total other income (expense)	24,049	48,867	(64,740)
Net loss	$ (11,427,450)	$ (4,387,920)	$ (6,091,198)
Basic and diluted net loss per common share	$ (0.10)	$ (0.05)	$ (0.07)
Basic and diluted weighted average common shares outstanding	110,185,077	96,994,779	83,170,297

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,		
	2012	2011	2010
Net loss	$ (11,427,450)	$ (4,387,920)	$ (6,091,198)
Foreign currency translation adjustment	(70,020)	(35,488)	53,496
Dissolution of foreign subsidiary			85,994
Comprehensive loss	$ (11,497,470)	$ (4,423,408)	$ (5,951,708)

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

Years Ended December 31, 2010, 2011 and 2012

	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
December 31, 2009	**81,799,541**	**$ 817,995**	**$ 139,614,459**	**$ (130,882,597)**	**$ (699,327)**	**$ 8,850,530**
Exercise of warrants and options	2,176,785	21,769	2,441,650			2,463,419
Stock-based compensation	181,539	1,815	1,262,562			1,264,377
Net loss				(6,091,198)		(6,091,198)
Other comprehensive income					139,490	139,490
December 31, 2010	**84,157,865**	**841,579**	**143,318,671**	**(136,973,795)**	**(559,837)**	**6,626,618**
Issuance of common stock	14,375,000	143,750	21,136,968			21,280,718
Exercise of warrants and options	4,475,335	44,753	5,975,683			6,020,436
Stock-based compensation	537,437	5,374	1,634,107			1,639,481
Net loss				(4,387,920)		(4,387,920)
Other comprehensive loss					(35,488)	(35,488)
December 31, 2011	**103,545,637**	**1,035,456**	**172,065,429**	**(141,361,715)**	**(595,325)**	**31,143,845**
Issuance of common stock	14,259,868	142,599	53,185,589			53,328,188
Exercise of warrants and options	8,021,672	80,217	11,499,196			11,579,413
Stock-based compensation	121,847	1,218	1,995,398			1,996,616
Net loss				(11,427,450)		(11,427,450)
Other comprehensive loss					(70,020)	(70,020)
December 31, 2012	**125,949,024**	**$ 1,259,490**	**$ 238,745,612**	**$ (152,789,165)**	**$ (665,345)**	**$ 86,550,592**

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2012	2011	2010
Cash flows from operating activities:			
Net loss	$ (11,427,450)	$ (4,387,920)	$ (6,091,198)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on dissolution of foreign subsidiary			85,994
Depreciation and amortization	231,028	168,173	188,750
Loss (gain) on disposal of equipment, molds, furniture and fixtures	119,429	(30,000)	(29,097)
Stock-based compensation expense	2,025,532	1,872,772	1,311,177
Changes in operating assets and liabilities:			
Accounts receivable	310,813	(1,300,995)	214,279
Inventories	(118,365)	(629,510)	57,090
Prepaid expenses and other current assets	(111,390)	(146,810)	(40,338)
Deferred costs	444,279	212,097	47,364
Other assets	(18,012)		(9)
Accounts payable	724,802	365,522	(100,809)
Accrued expenses and other current liabilities	687,297	406,824	716,160
Deferred revenue	(3,340,951)	1,543,840	(2,438,733)
Net cash used in operating activities	(10,472,988)	(1,926,007)	(6,079,370)
Cash flows from investing activities:			
Purchase of investments	(30,166,239)	(15,053,981)	
Proceeds from maturities of investments	12,000,000		
Proceeds from sales of equipment, molds, furniture and fixtures		30,000	29,097
Additions to patent rights	(244,761)	(231,260)	(122,720)
Purchases of equipment, molds, furniture and fixtures	(3,256,632)	(350,539)	(89,293)
Net cash used in investing activities	(21,667,632)	(15,605,780)	(182,916)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	53,328,188	21,280,718	
Proceeds from exercise of warrants and stock options	11,579,413	6,020,436	2,463,419
Taxes paid from net share settlement of equity awards	(28,916)	(233,291)	
Net cash provided by financing activities	64,878,685	27,067,863	2,463,419
Effect of exchange rate changes on cash and cash equivalents	1,067	(25,957)	87,592
Net increase (decrease) in cash and cash equivalents	32,739,132	9,510,119	(3,711,275)
Cash and cash equivalents:			
Beginning of year	19,357,932	9,847,813	13,559,088
End of year	$ 52,097,064	$ 19,357,932	$ 9,847,813

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Antares Pharma, Inc. (the Company or Antares) is an emerging specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies and topical gel-based products. The Company has numerous partnerships with pharmaceutical companies as well as multiple internal product development programs.

The Company has developed both subcutaneous and intramuscular injection technology systems which include Vibex disposable pressure-assisted auto injectors, Vision reusable needle-free injectors, and disposable multi-use pen injectors. The Company has licensed its reusable needle-free injection device for use with human growth hormone (hGH) to Teva Pharmaceutical Industries, Ltd. (Teva), Ferring Pharmaceuticals BV (Ferring) and JCR Pharmaceuticals Co., Ltd. (JCR), with Teva and Ferring being two of the Company s primary customers. The Company s needle-free injection device is marketed by Teva as the Tjet® injector system to administer their 5mg Tev-Tropin® brand hGH marketed in the U.S. The Company s needle-free injection device is marketed by Ferring with their 4mg and 10mg hGH formulations as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. The Company has also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and is engaged in product development activities for Teva utilizing these devices.

In addition to development of products with partners, the Company is developing its own drug/device combination products. The Company s lead product candidate, OTREXUP , is a proprietary combination product comprised of a pre-filled methotrexate syringe and the Company s Medi-Jet self-injection system for the treatment of moderate to severe rheumatoid arthritis (RA). On December 17, 2012 the Company announced submission of a New Drug Application (NDA) for OTREXUP and then on February 27, 2013 announced the FDA acceptance of that filing for review. The Prescription Drug User Fee Act (PDUFA) goal date for FDA approval is October 14, 2013. The Company has worldwide marketing rights for OTREXUP and has provided Uman an exclusive license to commercialize the product in Canada. The Company s strategy is to potentially commercialize OTREXUP in the U.S. on its own and to enter into licensing or distribution agreements for commercialization outside the U.S. The Company is also developing Vibex QS T for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and has conducted a pre-IND meeting with the FDA as part of preparing to initiate clinical development for this product.

In the gel-based product area, the Company announced with Actavis (formerly Watson Pharmaceuticals) on April 26, 2012, the launch of Gelnique 3% , the Company s topical oxybutynin gel product for the treatment of overactive bladder (OAB), which was approved by the FDA in December 2011. The Company has a licensing agreement with Actavis under which Actavis is currently marketing Gelnique 3% in the U.S. In January 2012, the Company entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize this product, once approved in South Korea. The Company s gel portfolio also includes Elestrin® (estradiol gel) currently marketed by Meda Pharma in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

The Company has two facilities in the U.S. The Parenteral Products Group located in Minneapolis, Minnesota directs the manufacturing and marketing of the Company s reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. The Company s corporate head office and Product Development Group are located in Ewing, New Jersey, where the Company s gel based products were developed and where the Product Development Group directs the clinical, regulatory and commercial development of the Company s internal drug/device combination products.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

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Use of Estimates

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

Foreign Currency Translation

The majority of the foreign subsidiaries revenues are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the U.S. parent. Nearly all operating expenses of the foreign subsidiaries, including labor, materials, leasing arrangements and other operating costs, are denominated in Swiss Francs. Additionally, bank accounts held by foreign subsidiaries are denominated in Swiss Francs, there is a low volume of intercompany transactions and there is not an extensive interrelationship between the operations of the subsidiaries and the parent company. As such, the Company has determined that the Swiss Franc is the functional currency for its foreign subsidiaries. The reporting currency for the Company is the United States Dollar (USD). The financial statements of the Company s foreign subsidiaries are translated into USD for consolidation purposes. All assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a separate component of stockholders equity, comprising all of the accumulated other comprehensive income (loss). In December 2010, the Company dissolved one of its foreign subsidiaries and recognized approximately $86,000 of expense in connection with removing the applicable cumulative translation adjustment from other comprehensive income. Sales to certain customers by the U.S. parent are in currencies other than the U.S. dollar and are subject to foreign currency exchange rate fluctuations. Foreign currency transaction gains and losses are included in the statements of operations.

Cash Equivalents

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

Allowance for Doubtful Accounts

Trade accounts receivable are stated at the amount the Company expects to collect. The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. The Company considers the following factors when determining the collectability of specific customer accounts: customer credit-worthiness, past transaction history with the customer, current economic industry trends, and changes in customer payment terms. The Company s accounts receivable balance is typically due from its large pharmaceutical customers such as Teva, Ferring and Actavis, and at December 31, 2012, over 95% of the accounts receivable balance was due from these organizations. These companies have historically paid timely and have been financially stable organizations. Due to the nature of the accounts receivable balance, the Company believes the risk of doubtful accounts is minimal. If the financial condition of the Company s customers were to deteriorate, adversely affecting their ability to make payments, additional allowances would be required. The Company provides for estimated uncollectible amounts through a charge to earnings and a credit to a valuation allowance. Balances that remain outstanding after the Company has used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. The Company recorded no bad debt expense in each of the last three years. The allowance for doubtful accounts balance was $10,000 at December 31, 2012 and 2011.

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Inventories

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

Equipment, Molds, Furniture, and Fixtures

Equipment, molds, furniture, and fixtures are stated at cost and are depreciated using the straight-line method over their estimated useful lives ranging from three to ten years. Depreciation expense was $145,775, $86,636 and $79,908 for the years ended December 31, 2012, 2011 and 2010, respectively.

Goodwill

The Company has $1,095,355 of goodwill recorded as of December 31, 2012 that relates to the Minnesota reporting unit. The Company evaluates the carrying amount of goodwill on December 31 of each year and between annual evaluations if events occur or circumstances change that would more likely than not reduce the fair value of the Minnesota reporting unit below its carrying amount. Such circumstances could include, but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, (3) an adverse action or assessment by a regulator, or (4) a sustained significant drop in the Company s stock price. When evaluating whether goodwill is impaired, the Company compares the fair value of the Minnesota reporting unit to the carrying amount, including goodwill. If the carrying amount of the Minnesota reporting unit exceeded its fair value, then the amount of the impairment loss would be measured. The impairment loss would be calculated by comparing the implied fair value of goodwill to its carrying amount. In calculating the implied fair value of goodwill, the fair value of the Minnesota reporting unit would be allocated to all of its other assets and liabilities based on their fair values. The excess of the fair value of the Minnesota reporting unit over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. An impairment loss would be recognized when the carrying amount of goodwill exceeds its implied fair value.

In evaluating whether the fair value of the Minnesota reporting unit was below its carrying amount, the Company used the market capitalization of the Company at December 31, 2012, which was approximately $480 million, to calculate an estimate of fair value of the Minnesota reporting unit. The Company determined that the percentage of the total market capitalization of the Company at December 31, 2012 attributable to the Minnesota reporting unit would have to be unreasonably low before the fair value of the Minnesota reporting unit would be less than its carrying amount. In making this determination, the Company evaluated the activity at the Minnesota reporting unit compared to the total Company activity, and considered the source and potential value of agreements currently in place, the source of recent product sales and development revenue growth, the source of total Company revenue and the source of cash generating activities. After performing the market capitalization analysis and concluding that the fair value of the Minnesota reporting unit was not below its carrying amount, the Company determined that no further detailed determination of fair value was required.

The Company s evaluation of goodwill resulted in no impairment losses in 2012, 2011 and 2010.

Patent Rights

The Company capitalizes the cost of obtaining patent rights when there are projected future cash flows for marketed or partnered products associated with the patent. These capitalized costs are being amortized on a straight-line basis over periods ranging from five to fifteen years beginning on the earlier of the date the patent is issued or the first commercial sale of product utilizing such patent rights. Amortization expense for the years ended December 31, 2012, 2011 and 2010 was $85,253, $81,535 and $108,842, respectively.

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

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

Each year the Company reviews patent costs for impairment and identifies patents related to products for which there are no signed distribution or license agreements or for which no revenues or cash flows are anticipated. No impairment charges were recognized in 2012, 2011 or 2010. The gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, were $2,244,086 and $1,120,434, respectively, at December 31, 2012 and were $1,979,502 and $1,027,116, respectively, at December 31, 2011. The Company s estimated aggregate patent amortization expense for the next five years is approximately $107,000, $120,000, $127,000, $127,000 and $127,000 in 2013, 2014, 2015, 2016 and 2017, respectively.

Fair Value of Financial Instruments

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

All short-term and long-term investments are U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. The fair value of all securities is determined by quoted market prices. All long-term investments mature in less than two years. At December 31, 2012 the short-term investments had a fair value of $21,116,952 and a carrying value of $21,112,623 and the long-term investments had a fair value of $12,016,530 and a carrying value of $12,015,906. At December 31, 2011 the short-term investments had a fair value of $12,012,618 and a carrying value of $12,011,388 and the long-term investments had a fair value of $3,020,859 and a carrying value of $3,026,957.

Revenue Recognition

The Company recognizes revenue from the sale of products and from license fees, milestones and royalties. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

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

Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the deliverable has stand-alone value to the customer, the customer has a general right of return relative to the delivered item and delivery or performance of the undelivered item is probable and substantially within the vendor s control. Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price. The selling price for each deliverable is determined using: (i) vendor-specific objective evidence of selling price (VSOE), if it exists, (ii) third-party evidence of selling price (TPE) if VSOE does not exist, and (iii) the Company s best estimate of the selling price if neither VSOE nor TPE exists. For transactions entered into prior to January 1, 2011, revenue is recognized for each deliverable based upon the applicable revenue recognition criteria discussed above and upon acceptance of goods or performance of service. Effective January 1, 2011, for new or significantly modified transactions, the Company allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables.

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Royalty revenues are recognized in the quarter earned when the Company has information available to determine the royalty amount, however, the majority of the Company s royalty revenues are recognized one quarter in arrears as information is typically not available to determine quarterly royalty earnings until royalty statements are received from partners.

At December 31, 2012, $3,194,811 of non-refundable cash payments received have been recorded as deferred revenue in cases where the revenue is not immediately recognized due to the earnings process not yet having been completed.

Shipping and Handling Costs

The Company records shipping and handling costs in cost of product sales.

Stock-Based Compensation

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

The Company uses the Black-Scholes option valuation model to determine the fair value of stock options. The fair value model includes various assumptions, including the expected volatility and expected life of the awards.

Product Warranty

The Company provides a warranty on its reusable needle-free injector devices. Warranty terms for devices sold to end-users by dealers and distributors are included in the device instruction manual included with each device sold. Warranty terms for devices sold to pharmaceutical partners who provide their own warranty terms to end-users are included in the contracts with the pharmaceutical partners. The Company is obligated to repair or replace, at the Company s option, a device found to be defective due to use of defective materials or faulty workmanship. The warranty does not apply to any product that has been used in violation of instructions as to the use of the product or to any product that has been neglected, altered, abused or used for a purpose other than the one for which it was manufactured. The warranty also does not apply to any damage or defect caused by unauthorized repair or the use of unauthorized parts. The warranty period on a device is typically 24 months from either the date of retail sale of the device by a dealer or distributor or the date of shipment to a customer if specified by contract. The Company recognizes the estimated cost of warranty obligations at the time the products are shipped based on historical claims incurred by the Company. The Company increased the warranty liability in 2011 due to an increase in product sales. Actual warranty claim costs could differ from these estimates. Warranty liability activity is as follows:

	Balance at Beginning of Year	Provisions	Claims	Balance at End of Year
2012	$ 100,000	$ 72,893	$ (72,893)	$ 100,000
2011	$ 20,000	$ 95,766	$ (15,766)	$ 100,000
2010	$ 20,000	$ 3,210	$ (3,210)	$ 20,000

Research and Development

Research and development costs are expensed as incurred.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to historical net losses of the Company, a valuation allowance is established to offset the net deferred tax asset balance for all years presented.

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Net Loss Per Share

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

Potentially dilutive securities at December 31, 2012, 2011 and 2010, excluded from dilutive loss per share as their effect is anti-dilutive, are as follows:

	2012	2011	2010
Stock options and warrants	10,830,530	17,860,956	25,342,935

New Accounting Pronouncements

In May 2011, the FASB issued updated accounting guidance related to fair value measurements and disclosures that result in common fair value measurements and disclosures between Generally Accepted Accounting Principles and International Financial Reporting Standards. This guidance includes amendments that clarify the intent about the application of existing fair value measurements and disclosures, while other amendments change a principle or requirement for fair value measurements or disclosures. This guidance was effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have an impact on our consolidated financial statements.

In June 2011, the FASB issued updated accounting guidance related to presentation of comprehensive income. The guidance gives entities the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. This updated guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity. It does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. In December 2011, the FASB deferred the effective date of the portion of the accounting standards update requiring separate presentation of reclassifications out of accumulated other comprehensive income. This standard was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2011. The implementation of this accounting guidance resulted in the addition of the Consolidated Statement of Comprehensive Loss.

In September 2011, the FASB amended its guidance for goodwill impairment testing. The amendment allows entities to first assess qualitative factors in determining whether or not the fair value of a reporting unit exceeds its carrying value. If an entity concludes from this qualitative assessment that it is more likely than not that the fair value of a reporting unit exceeds its carrying value, then performing a two-step impairment test is unnecessary. This standard was effective for fiscal years beginning after December 15, 2011, and did not have an impact on our consolidated financial statements.

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3. Composition of Certain Financial Statement Captions

	December 31, 2012	December 31, 2011
Inventories:		
Raw material	$ 609,016	$ 415,731
Finished goods	393,687	476,034
	$ 1,002,703	$ 891,765
Equipment, molds, furniture and fixtures:		
Furniture, fixtures and office equipment	$ 1,133,925	$ 860,122
Production molds and equipment	1,503,615	1,311,897
Molds and tooling in process	2,948,249	307,221
Less accumulated depreciation	(2,002,685)	(1,887,571)
	$ 3,583,104	$ 591,669
Patent rights:		
Patent rights	$ 2,244,086	$ 1,979,502
Less accumulated amortization	(1,120,434)	(1,027,116)
	$ 1,123,652	$ 952,386
Accrued expenses and other liabilities:		
Accrued employee compensation and benefits	$ 1,896,832	$ 1,251,498
Other liabilities	1,019,868	973,813
	$ 2,916,700	$ 2,225,311

4. Leases

The Company has non-cancelable operating leases for its corporate headquarters facility in Ewing, New Jersey, and its office, research and development facility in Minneapolis, MN. The leases require payment of all executory costs such as maintenance and property taxes. The Company also leases certain equipment under various operating leases. Rent expense, net, incurred for the years ended December 31, 2012, 2011 and 2010 was $325,971, $261,171 and $228,087, respectively. Future minimum lease payments under operating leases as of December 31, 2012 were as follows:

	Amount
2013	$ 301,242
2014	305,319
2015	310,740
2016	287,461
2017	234,557
Thereafter	562,534
Total future minimum lease payments	$ 2,001,853

5. Income Taxes

The Company was subject to taxes in both the U.S. and Switzerland in each of the years in the three-year period ended December 31, 2012. In the U.S., the Company incurred losses for both book and tax purposes for the year ended December 31, 2012, and, accordingly, no income taxes were provided. In Switzerland, net operating loss carryforwards were used to fully offset taxable income of approximately $5,500,000 in the year ended December 31, 2012, and no income taxes were provided.

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Income (loss) before income taxes was derived from the following sources:

	2012	2011	2010
U.S.	$ (16,477,710)	$ (3,977,263)	$ (6,367,855)
Switzerland	5,050,260	(410,657)	276,657
	$ (11,427,450)	$ (4,387,920)	$ (6,091,198)

Effective tax rates differ from statutory income tax rates in the years ended December 31, 2012, 2011 and 2010 as follows:

	2012	2011	2010
Statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes	(3.6)	(1.6)	(2.1)
Valuation allowance increase (decrease)	29.8	(4.3)	18.3
Effect of foreign operations	(8.5)	1.9	(0.9)
Expiration of unused net operating loss and credit carryforwards	14.0	35.5	21.2
Nondeductible items	0.6	1.8	(0.7)
Other	1.7	0.7	(1.8)
	0.0%	0.0%	0.0%

Deferred tax assets as of December 31, 2012 and 2011 consist of the following:

	2012	2011
Net operating loss carryforward U.S.	$ 22,411,000	$ 17,758,000
Net operating loss carryforward Switzerland	5,551,000	6,473,000
Research and development tax credit carryforward	1,292,000	1,405,000
Deferred revenue	398,000	645,000
Depreciation and amortization	115,000	58,000
Stock-based compensation	1,573,000	1,445,000
Other	1,150,000	1,127,000
	32,490,000	28,911,000
Less valuation allowance	(32,490,000)	(28,911,000)
	$	$

The valuation allowance for deferred tax assets as of December 31, 2012 and 2011 was $32,490,000 and $28,911,000, respectively. The total valuation allowance increased $3,579,000 for the year ended December 31, 2012 and decreased $186,000 for the year ended December 31, 2011. Prior to 2012, management determined that it was more likely than not that the deferred tax assets associated with the NOL carryforwards in Switzerland would not be realized and provided a valuation allowance for the full amount of the deferred tax assets. In 2012, the Company realized the benefit of the deferred tax assets associated with approximately $5,500,000 of NOL carryforwards in Switzerland for which a valuation allowance had been recorded. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences become deductible or in which net operating loss or tax credit carryforwards can be utilized. Both positive and negative evidence is considered in assessing the realizability of deferred tax assets and determining whether or not to record a valuation allowance. After considering the evidence, management determined it is more likely than not that the deferred tax assets will not be realized and has recorded a valuation allowance against all U.S. and Switzerland deferred tax assets.

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The Company has a U.S. federal net operating loss carryforward at December 31, 2012, of approximately $62,770,000, which, subject to limitations of Internal Revenue Code (IRC) Section 382, is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2018 through 2032. Included in the federal net operating loss is approximately $1,850,000 of loss generated by deductions related to equity-based compensation, the tax effect of which will be recorded to additional paid in capital when utilized. Additionally, the Company has a research credit carryforward of approximately $1,292,000. These credits expire in years 2018 through 2031.

Utilization of U.S. net operating losses and tax credits of the Company may be subject to annual limitations under IRC Sections 382 and 383, respectively. The annual limitations, if any, have not yet been determined. When a review is performed and if any annual limitations are determined, then the gross deferred tax assets for the net operating losses and tax credits would be reduced with a reduction in the valuation allowance of a like amount.

The Company also has a Swiss net operating loss carryforward at December 31, 2012, of approximately $41,100,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2013 through 2019, with approximately $29,200,000 expiring over the next three years.

As of December 31, 2012 and 2011, there were no unrecognized tax benefits. Accordingly, a tabular reconciliation from beginning to ending periods is not provided. The Company will classify any future interest and penalties as a component of income tax expense if incurred. To date, there have been no interest or penalties charged or accrued in relation to unrecognized tax benefits.

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

The Company is subject to federal and state examinations for the years 2008 and thereafter. There are no tax examinations currently in progress.

6. Stockholders Equity

Common Stock

In October 2012, the Company sold 12,500,000 shares of common stock at a price of $4.00 per share in a public offering, and in November 2012 the Company sold 1,759,868 shares of the Company s common stock at $4.00 per share as a result of the partial exercise of the underwriters over-allotment option. The Common Stock sales resulted in net proceeds of $53,328,188 after deducting offering expenses of $3,711,284.

In May 2011, the Company sold a total of 14,375,000 shares of common stock at a price of $1.60 per share in a public offering, which resulted in net proceeds of $21,280,718 after deducting offering expenses of $1,719,282.

Stock Options

The Company s 2008 Equity Compensation Plan (the Plan) allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, dividend equivalents and other stock-based awards. All of the Company s officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. Under the Plan, the maximum number of shares authorized for issuance is 13,500,000 and the maximum number of shares of stock that may be granted to any one participant during a calendar year is 1,000,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair market value on the dates of grant. The term of the options range from 10 to 11 years and they vest in varying periods. As of December 31, 2012, the Plan had 67,407 shares available for grant. The number of shares available for grant does not take into consideration potential stock awards that could result in the issuance of shares of common stock if certain performance conditions are met, discussed under Stock Awards below. Stock option exercises are satisfied through the issuance of new shares.

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A summary of stock option activity under the Plan as of December 31, 2012 and the changes during the three years then ended is as follows:

	Number of Shares	Weighted Average Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($)
Outstanding at December 31, 2009	8,339,684	1.13		
Granted/Issued	1,277,487	1.51		
Exercised	(1,566,435)	0.99		772,006
Cancelled/Forfeited	(392,860)	2.00		
Outstanding at December 31, 2010	7,657,876	1.18		
Granted/Issued	972,409	1.75		
Exercised	(750,063)	1.37		488,724
Cancelled/Forfeited	(94,550)	3.21		
Outstanding at December 31, 2011	7,785,672	1.21		
Granted/Issued	1,334,731	3.18		
Exercised	(1,164,636)	1.20		2,620,360
Cancelled/Forfeited	(141,206)	4.06		
Outstanding at December 31, 2012	7,814,561	1.49	6.7	18,129,781
Exercisable at December 31, 2012	6,250,658	1.18	6.1	16,439,231

As of December 31, 2012, there was approximately $1,864,795 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.0 years.

Stock option expense recognized in 2012, 2011 and 2010 was approximately $1,164,000, $1,055,000 and $952,000, respectively. In 2011 and 2010, expense included approximately $20,000 and $62,000, respectively, recognized due to modifications of option terms for employees whose employment with the Company ended in those years. The per share weighted average fair value of options granted during 2012, 2011 and 2010 was estimated as $1.64, $0.89, $0.78, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company s stock. The weighted average expected life is based on both historical and anticipated employee behavior.

	December 31,		
	2012	2011	2010
Risk-free interest rate	0.7%	1.7%	1.7%
Annualized volatility	61.0%	59.0%	60.0%
Weighted average expected life, in years	5.0	5.0	5.0
Expected dividend yield	0.0%	0.0%	0.0%

Option exercises during 2012, 2011 and 2010 resulted in proceeds of $792,203, $1,025,985 and $1,547,894, respectively, and in the issuance of 965,597, 750,063 and 1,566,435 shares of common stock, respectively. In 2012, 583,344 options were exercised under a cashless provision resulting in the issuance of 384,305 shares of common stock and no cash proceeds to the Company.

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Warrants

Warrant activity is summarized as follows:

	Number of Shares	Weighted Average Price ($)
Outstanding at December 31, 2009	18,295,409	1.56
Exercised	(610,350)	1.50
Cancelled		
Outstanding at December 31, 2010	17,685,059	1.56
Exercised	(4,107,759)	1.37
Cancelled	(3,502,016)	1.50
Outstanding at December 31, 2011	10,075,284	1.66
Exercised	(7,056,075)	1.53
Cancelled	(3,240)	2.00
Outstanding at December 31, 2012	3,015,969	1.98

Warrant exercises during 2012, 2011 and 2010 resulted in proceeds of $10,787,210, $4,994,451 and $915,525, respectively, and in the issuance of 7,056,075, 3,725,272 and 610,350 shares of common stock, respectively.

Stock Awards

The employment agreements with certain members of executive management include stock-based incentives under which the executives could be awarded shares of common stock upon the occurrence of various triggering events. As of December 31, 2012, potential future performance awards under these agreements totaled approximately 65,000 shares of common stock. There were 35,000, 145,454 and 57,954 shares awarded under these agreements in 2012, 2011, and 2010, respectively.

At times, the Company makes discretionary grants of its common stock to members of management and other employees in lieu of cash bonus awards or in recognition of special achievements. Discretionary grants of common stock totaled 60,000, 368,267 and 213,268 shares in 2012, 2011, and 2010, respectively.

Expense is recognized on a straight line basis over the vesting period and is based on the fair value of the stock on the grant date. The fair value of each stock award is determined based on the number of shares granted and the market price of the Company s common stock on the date of grant. Expense recognized in connection with performance and discretionary stock awards was $301,017, $771,491 and $320,325 in 2012, 2011 and 2010, respectively.

A portion of the discretionary shares vested in 2012 and 2011 were net-share settled such that the Company withheld shares with value equivalent to the employees minimum statutory obligation for the applicable income and other employment taxes, and remitted the cash to the appropriate taxing authorities. The total shares withheld were 11,165 and 121,182 in 2012 and 2011, respectively, and were based on the value of the shares on their vesting date as determined by the Company s closing stock price. Total payments for the employees tax obligations to the taxing authorities were $28,916 and $233,291 in 2012 and 2011, respectively, and are reflected as a financing activity within the Consolidated Statements of Cash Flows. These net-share settlements had the effect of share repurchases by the Company as they reduced the number of shares that would have otherwise been issued as a result of the vesting and did not represent an expense to the Company.

In addition to the shares granted to members of management and employees, at times directors receive a portion of their annual compensation in shares of Company common stock. Expense is recognized on a straight line basis over the one year period that the compensation is earned. Expense recognized in connection with shares granted to directors was $560,000, $46,500 and $39,250 in 2012, 2011 and 2010, respectively.

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As of December 31, 2012, a total of 120,768 shares previously granted as discretionary awards were unvested and 248,711 shares granted to directors were unvested. As of December 31, 2012, there was approximately $191,500 of total unrecognized compensation cost related to nonvested stock awards that is expected to be recognized over a weighted average period of approximately 3 months. The weighted average fair value of the shares granted in 2012 and 2011, excluding shares granted under the LTIP program, was $2.84 and $1.85 per share, respectively.

Long Term Incentive Program

The Board of Directors of the Company has approved a long term incentive program for the benefit of its executive officers. Pursuant to the long term incentive program, the Company s executive officers have been awarded stock options and performance stock units with a value targeted at the median level of the Company s peer group. Two thirds of that value for each officer is delivered in the form of stock options and one third of that value is delivered in the form of performance stock units. The stock options have a ten-year term, have an exercise price equal to the closing price of the Company s common stock on the date of grant, vest in quarterly installments over three years, and were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan. The performance stock unit awards made to the executive officers will be vested and convert into actual shares of the Company s common stock based on the Company s attainment of certain performance goals over a performance period of three years. No expense has been recognized in connection with the performance stock unit awards as the defined performance goals are not yet considered probable of achievement. The performance stock unit awards and stock options granted under the long term incentive program are summarized in the following table:

	Performance Stock Units		Stock Options	
Grant Date	Number of Shares	Fair Value on Grant Date	Number of Options	Exercise Price
May 17, 2011	182,000	$ 1.66	317,000	$ 1.66
May 17, 2012			470,000	$ 2.94
July 6, 2012	137,715	$ 4.26		

7. Employee 401(k) Savings Plan

The Company sponsors a 401(k) defined contribution retirement savings plan that covers all U.S. employees who have met minimum age and service requirements. Under the plan, eligible employees may contribute up to 50% of their annual compensation into the plan up to the IRS annual limits. At the discretion of the Board of Directors, the Company may contribute elective amounts to the plan, allocated in proportion to employee contributions to the plan, employee s salary, or both. For the years ended December 31, 2012, 2011 and 2010, the total number of employees enrolled in the plan has increased and the Company elected to make contributions to the plan totaling $173,164, $108,825 and $92,153, respectively.

8. License Agreements

Teva License Development and Supply Agreements

In November 2012, the Company entered into a license, supply and distribution agreement with Teva for an auto injector product containing sumatriptan for the treatment of migraines. Teva will manufacture and supply sumatriptan in a prefilled syringe. The Company will manufacture the device, assemble the device and prefilled syringe and supply the final product to Teva for distribution. Teva will distribute the product in the United States. Teva also received an option for rights in other territories. Under the agreement, the Company received an upfront payment and will receive a milestone payment upon commercial launch. In addition, net profits will be split 50/50 between the Company and Teva. The term of the agreement is seven years from commercial launch, with automatic one year renewals.

In December 2007, the Company entered into a license, development and supply agreement with Teva under which the Company will develop and supply a disposable pen injector for use with two undisclosed patient-administered pharmaceutical products. Under the agreement, an upfront payment, development milestones, and

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royalties on Teva s product sales, as well as a purchase price for each device sold are to be received by the Company under certain circumstances. Based on an analysis under accounting literature applicable at the time of the agreement, the entire arrangement was considered a single unit of accounting. Therefore, payments received and development costs incurred were deferred and were to be recognized from the start of manufacturing through the end of the initial contract period. In January 2011, this license, development and supply agreement was amended wherein Teva pays for all development work and tooling associated with device development. Additionally, we are now developing two different disposable pens, one for each product. As further explained in Note 9 to the consolidated financial statements, the Company determined that the changes to the agreement as a result of the amendment are a material modification to the agreement and the accounting for the revenue and costs under this agreement was changed. This agreement will continue until the later of December 2017 or the expiration date of the last to expire patent covering the device or product that is filed no later than 12 months after FDA approval, and will be automatically renewed for successive periods of two years each.

In September 2006, the Company entered into a Supply Agreement with Teva. Pursuant to the agreement, Teva is obligated to purchase all of its needle-free delivery device requirements from Antares for hGH to be marketed in the United States. Antares was entitled to an upfront cash payment, milestone fees and royalty payments on Teva s net sales, as well as a purchase price for each device sold. The upfront payment was recognized as revenue over the development period. The milestone fees and royalties will be recognized as revenue when earned. In 2009, Teva launched the Company s Tjet needle-free device with their hGH Tev-Tropin®. In 2010, the Company received a milestone payment from Teva in connection with this agreement. The original term of this agreement extended through September 2013, but has been automatically renewed for two years and will continue to automatically renew for successive periods of two years each unless terminated by either party.

In July 2006, the Company entered into an exclusive License Development and Supply Agreement with Teva. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from Antares for an auto injector product containing epinephrine to be marketed in the United States and Canada. Antares was entitled to an upfront cash payment, milestone fees, a negotiated purchase price for each device sold, as well as royalties on sales of their product. This agreement will continue until the later of July 2016 or the expiration date of the last to expire patent covering the device or product that is filed no later than 12 months after FDA approval, and will be automatically renewed for successive periods of two years each.

On April 26, 2012, the Company announced that Meridian Medical Technologies, a Pfizer subsidiary, entered into a settlement agreement with Teva that will resolve pending patent litigation related to its abbreviated new drug application (ANDA) for a generic epinephrine auto-injector. According to the terms of the settlement, Teva may launch a generic epinephrine auto-injector covered by its ANDA on June 22, 2015 or earlier under certain circumstances, subject to receipt of approval from the U.S. Food and Drug Administration. Additional terms of the agreement are confidential.

Under a separate agreement, Teva has agreed to provide the Company with device orders of an undisclosed amount in the years 2013 and 2014, to make a milestone payment to the Company upon FDA approval of epinephrine auto-injector, and to assume all litigation costs related to the patent litigation between Teva and Meridian Medical.

Ferring Agreements

On November 6, 2009, the Company entered into an Exclusive License Agreement with Ferring, under which the Company licensed certain of its patents and agreed to transfer know-how for its transdermal gel technology for certain pharmaceutical products. This agreement had no impact on the Company s existing licenses, the transdermal clinical pipeline, or marketed products, including Gelnique 3% , Nestragel (Nestorone®), and Elestrin®. Also on November 6, 2009, in tandem with the execution of the Exclusive License Agreement, the Company entered into an Asset Purchase Agreement (the Purchase Agreement) with Ferring. Pursuant to the terms and conditions of the Purchase Agreement, Ferring purchased from the Company all of the assets, including equipment, fixtures, fittings and inventory, located at the Company s research and development facility located in Allschwil, Switzerland (the Facility). Further pursuant to the terms and conditions of the Purchase Agreement, Ferring assumed the contractual obligations related to the Facility, including the real property lease for the Facility, and continued to employ the employees working at the Facility. The Company also entered into a Consultancy Services Agreement

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with Ferring for a period of 12 months, under which the Company provided services in connection with development of certain pharmaceutical products under the Exclusive License Agreement. Under these agreements the Company received upfront license fees, payments for assets and payments for services rendered under the consultancy agreement. In addition, the Company will receive milestone payments as certain defined milestones are achieved. The agreement is effective until the last to expire patent applicable under the agreement which currently is 2028.

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

The Company entered into a License Agreement, dated January 22, 2003, with Ferring, under which the Company licensed certain of its intellectual property and extended the territories available to Ferring for use of certain of the Company s reusable needle-free injector devices. Specifically, the Company granted to Ferring an exclusive, perpetual, irrevocable, royalty-bearing license, within a prescribed manufacturing territory, to manufacture certain of the Company s reusable needle-free injector devices for the field of human growth hormone. The Company granted to Ferring similar non-exclusive rights outside of the prescribed manufacturing territory. In addition, the Company granted to Ferring a non-exclusive right to make and have made the equipment required to manufacture the licensed products, and an exclusive, perpetual, royalty-free license in a prescribed territory to use and sell the licensed products in the event the Company does not fulfill its supply obligations to Ferring.

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

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

Actavis License and Commercialization Agreement

In July 2011, the Company entered into an exclusive licensing agreement with Actavis to commercialize, in the U.S. and Canada, the Company s topical oxybutynin gel 3% product, which was subsequently approved by the FDA in December 2011.

Under this agreement the Company received payments for certain manufacturing start-up activities and delivery of launch quantities, and has received and is entitled to receive future royalties on both the Company s oxybutynin gel 3% product and Actavis oxybutynin gel product Gelnique® 10%, and will potentially receive sales based milestone payments. The milestone payment based on the achievement of regulatory approval was subject to reimbursement to Actavis if launch quantities were not delivered within a certain defined time period. Actavis will assume all responsibility for manufacture and supply of the product in 2013. The term of the agreement ends on the later of April 2024 or the expiration date of the last to expire patent.

Arrangement consideration has been allocated to the separate units of accounting based on the relative selling prices. Selling prices are determined using vendor specific objective evidence (VSOE), when available, third-party evidence (TPE), when available, or an estimate of selling price when neither of the first two options is available for a given unit of accounting. Selling prices in this arrangement were determined using estimated selling prices because VSOE and TPE were not available. The primary factors considered in determining selling price estimates in this arrangement were estimated costs, reasonable margin estimates and historical experience.

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The Company determined that the license and development activities, which include the manufacturing start-up activities, do not have value to the customer on a stand-alone basis as proprietary knowledge about the product and technology is required to complete the development activities. As a result, these deliverables do not qualify for treatment as separate units of accounting. Accordingly, the license and development activities have been accounted for as a single unit of accounting and arrangement consideration allocated to these deliverables was recognized as revenue over the development period, which ended upon manufacture of launch quantities. The sales based milestone payments will be recognized as revenue when earned, revenue for launch quantities was recognized when product was delivered to Actavis and royalties will be recognized as revenue when earned. The Company received a milestone payment from Actavis in December 2011 upon FDA approval, which was recorded as deferred revenue. This milestone payment was recognized as revenue in March of 2012, as launch quantities were delivered within the defined time period and the potential reimbursement liability was eliminated. In the year ended December 31, 2012, the Company recognized revenue of $6,770,635 in connection with product sales, manufacturing start-up activities, the milestone payment and royalties.

Pfizer License Agreement

In December 2011, the Company announced that it licensed to Pfizer Inc. s Consumer Healthcare Business Unit one of its drug delivery technologies to develop an undisclosed product on an exclusive basis for North America. Pfizer will assume full cost and responsibility for all clinical development, manufacturing, and commercialization of the product in the licensed territory, which also includes certain non-exclusive territories outside of North America. Antares received an upfront payment, and will receive development milestones and sales based milestones, as well as royalties on net sales for three years post launch in the U.S. Because the Company has no development responsibilities, the upfront and each milestone payment will be recognized as revenue when received. Royalties will be recognized as revenue when earned.

Daewoong Development and License Agreement

In January 2012, the Company entered into a licensing agreement with Daewoong Pharmaceuticals (Daewoong) under which Daewoong will commercialize the Company s oxybutynin gel 3% product, once approved in South Korea. The agreement terms include an upfront payment, development and sales-based milestone payments and escalating royalties based on product sales in South Korea. Because the Company has no development responsibilities, the upfront and each milestone payment will be recognized as revenue when received. Royalties will be recognized as revenue when earned. The Company recognized revenue of $442,859 in 2012 in connection with upfront and milestone payments. The term of the agreement ends on the later of fifteen years following launch of the product or the expiration date of the last to expire patent.

BioSante License Agreement

In June 2000, the Company entered into an exclusive agreement to license four applications of its drug-delivery technology to BioSante in the United States, Canada, China, Australia, New Zealand, South Africa, Israel, Mexico, Malaysia and Indonesia (collectively, the BioSante Territories). The Company is required to transfer technology know-how to BioSante until each country s regulatory authorities approve the licensed product. BioSante will use the licensed technology for the development of hormone replacement therapy products. At the signing of the contract, BioSante made an upfront payment to the Company, a portion of which, per the terms of the contract, was used to partially offset a later payment made to the Company as a result of an upfront payment received by BioSante under a sublicense agreement. The initial upfront payment received by the Company was for the delivery of intellectual property to BioSante. The term of the agreement ends on the later of the tenth anniversary of the first commercial sale of a product or the expiration date of the last to expire patent.

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

In December 2009, BioSante entered into a license agreement with Azur Pharma International II Limited (Azur), for Elestrin®. BioSante has received payments from Azur which triggered sublicense payments to the Company. Because final regulatory approval for this product was obtained by BioSante and Antares had no further

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obligations in connection with this product, the sublicense payments were recognized as revenue when received. Elestrin® is being marketed in the U.S. by Meda Pharma, who recently acquired the women s health business from Jazz Pharmaceuticals (Jazz), who had previously acquired Azur. The Company has received royalties on sales of Elestrin®, which have been recognized as revenue when received.

9. Revenue Recognition

In January of 2011, the Company amended the license, development and supply agreement with Teva originally entered into in December of 2007 under which the Company will develop and supply a disposable pen injector for use with two undisclosed patient-administered pharmaceutical products. Under the original agreement, an upfront payment, development milestones, and royalties on Teva s product sales, as well as a purchase price for each device sold were to be received by the Company under certain circumstances. Based on an analysis under accounting literature applicable at the time of the agreement, the entire arrangement was considered a single unit of accounting. Therefore, payments received and development costs incurred were deferred and were to be recognized from the start of manufacturing through the end of the initial contract period. Changes to the original agreement as a result of the amendment included the following: (i) Teva will pay for future device development activities, (ii) Teva will pay for and own all commercial tooling developed and produced under the agreement, and (iii) certain potential milestone payments were eliminated. The Company has determined that the changes to the agreement as a result of the amendment are a material modification to the agreement. Because the agreement was materially modified, the accounting was re-evaluated under the applicable current revenue recognition accounting standards. The re-evaluation resulted in the agreement being separated into multiple units of accounting and resulted in changes to both the method of revenue recognition and the period over which revenue will be recognized. The provisions of the current standards are to be applied as if they were applicable from inception of the agreement. Under the new accounting, the original license fee received will be recognized as revenue over the development period, the development milestone payments previously received were recognized as revenue immediately and revenue during the manufacturing period will be recognized as devices are sold and royalties are earned. For the year ended December 31, 2012, the accounting change resulting from the material modification resulted in recognition of licensing revenue previously deferred of $62,225, and for the year ended December 31, 2011, the accounting change resulting from the material modification resulted in recognition of development and licensing revenue previously deferred of $304,600 and $337,776, respectively, and recognition of costs previously deferred of $408,250.

10. Segment Information and Significant Customers

The Company has one operating segment, drug delivery, which includes the development of injection devices and injection based pharmaceutical products as well as transdermal gel products.

Revenues by customer location are summarized as follows:

	For the Years Ended December 31,		
	2012	2011	2010
United States of America	$ 16,964,635	$ 10,236,304	$ 6,627,689
Europe	4,936,981	5,765,909	5,797,385
Other	673,962	456,279	393,624
	$ 22,575,578	$ 16,458,492	$ 12,818,698

Revenues by product type:

	For the Years Ended December 31,		
	2012	2011	2010
Injection devices and supplies	$ 12,642,537	$ 14,360,078	$ 10,052,603
Transdermal gel products	9,933,041	2,098,414	2,766,095
	$ 22,575,578	$ 16,458,492	$ 12,818,698

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

	2012	2011	2010
Teva	$ 7,495,978	$ 8,175,990	$ 5,693,853
Actavis	6,770,635	1,024,240	
Ferring	4,933,369	5,764,208	5,758,290

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

	2012	2011
Teva	$ 1,033,203	$ 1,371,288
Actavis	522,807	106,391
Ferring	622,885	1,001,073

11. Quarterly Financial Data (unaudited)

	First	Second	Third	Fourth
2012:				
Total revenues	$ 6,864,542	$ 4,523,942	$ 5,685,917	$ 5,501,177
Gross profit	4,873,711	1,992,831	2,389,428	3,799,136
Net loss	(74,394)	(2,807,072)	(3,534,239)	(5,011,745)
Net loss per common share (1)	(0.00)	(0.03)	(0.03)	(0.04)
Weighted average shares	103,658,571	104,551,742	108,961,792	123,436,025
2011:				
Total revenues	$ 3,569,547	$ 3,542,873	$ 3,919,037	$ 5,427,035
Gross profit	2,116,706	2,149,584	2,111,987	3,283,023
Net loss	(1,380,633)	(1,554,097)	(1,299,259)	(153,931)
Net loss per common share (1)	(0.02)	(0.02)	(0.01)	(0.00)
Weighted average shares	85,719,683	95,157,098	103,311,772	103,525,485

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

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Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.
None.

Item 9A. CONTROLS AND PROCEDURES.
Evaluation of disclosure controls and procedures.

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

Management s annual report on internal control over financial reporting.

The Company s management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company s management has assessed the effectiveness of internal control over financial reporting as of December 31, 2012. This assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework.

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

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of the Company s assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that the Company s receipts and expenditures are being made only in accordance with authorizations of the Company s management and board of directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on the Company s assessment using the COSO criteria, management has concluded that its internal control over financial reporting was effective as of December 31, 2012 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. The Company s independent registered public accounting firm, KPMG LLP, has issued an audit report on the Company s internal control over financial reporting. The report on the audit of internal control over financial reporting appears on page 56 of this Form 10-K.

Changes in internal control over financial reporting.

There was no change in the Company s internal control over financial reporting that occurred during the quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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Item 9B. OTHER INFORMATION.

On March 13, 2013, the Company issued a press release announcing the Company s financial results for its fourth fiscal quarter ended December 31, 2012. A copy of the press release is furnished as Exhibit 99.1 to this Form 10-K.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item concerning our directors will be set forth under the caption Election of Directors in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

Information required by this item concerning our executive officers will be set forth under the caption Executive Officers of the Company in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption Section 16(a) Beneficial Ownership Reporting Compliance in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

Information required by this item concerning the audit committee of the Company, the audit committee financial expert of the Company and any material changes to the way in which security holders may recommend nominees to the Company s Board of Directors will be set forth under the caption Corporate Governance in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

The Board of Directors adopted a Code of Business Conduct and Ethics, which is posted on our website at www.antarespharma.com that is applicable to all employees and directors. We will provide copies of our Code of Business Conduct and Ethics without charge upon request. To obtain a copy, please visit our website or send your written request to Antares Pharma, Inc., 100 Princeton South, Suite 300, Ewing, NJ 08628, Attn: Corporate Secretary. With respect to any amendments or waivers of this Code of Business Conduct and Ethics (to the extent applicable to the Company s chief executive officer, principal accounting officer or controller, or persons performing similar functions) the Company intends to either post such amendments or waivers on its website or disclose such amendments or waivers pursuant to a Current Report on Form 8-K.

Item 11. EXECUTIVE COMPENSATION.

Information required by this item will be set forth under the caption Executive Compensation in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

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

Information required by this item concerning ownership will be set forth under the caption Security Ownership of Certain Beneficial Owners and Security Ownership of Directors and Executive Officers in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

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The following table provides information for our equity compensation plans as of December 31, 2012:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding shares reflected in the first column)
Equity compensation plans approved by security holders	7,814,561	$ 1.49	67,407

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

Information required by this item will be set forth under the captions Certain Relationships and Related Transactions and Corporate Governance in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Information required by this item will be set forth under the caption Ratification of Selection of Independent Registered Public Accountants in our definitive proxy statement for our 2013 annual meeting, and is incorporated herein by reference.

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PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

(1) Financial Statements see Part II

(2) Financial Statement Schedules

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

(3) Item 601 Exhibits see list of Exhibits below

(b) Exhibits

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

Exhibit No.	Description
3.1	Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 4.1 to Form S-3 on April 12, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 19, 2008 and incorporated herein by reference.)
3.3	Amended and Restated By-laws of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 15, 2007 and incorporated herein by reference.)
4.1	Form of Certificate for Common Stock (Filed as an exhibit to Form S-1/A on August 15, 1996 and incorporated herein by reference.)
4.2	Registration Rights Agreement with Permatec Holding AG dated January 31, 2001 (Filed as Exhibit 10.2 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
4.3	Warrant Agreement with Eli Lilly and Company dated September 12, 2003 (Filed as exhibit 10.60 to Form 8-K on September 18, 2003 and incorporated herein by reference.)
4.4	Registration Rights Agreement with Eli Lilly and Company dated September 12, 2003 (Filed as exhibit 10.61 to Form 8-K on September 18, 2003 and incorporated herein by reference.)
4.5	Stock Purchase Agreement with Sicor Pharmaceuticals, Inc., dated November 23, 2005 (Filed as exhibit 10.55 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
4.6	Form of Warrant to Purchase Common Stock (Filed as Exhibit 4.1 to Form 8-K on July 24, 2009 and incorporated herein by reference).
4.7	Form of Warrant to Purchase Common Stock (Filed as Exhibit 4.1 to Form 8-K on September 18, 2009 and incorporated herein by reference).
4.8	Form of Subscription Agreement, by and between Antares Pharma, Inc. and the investor party thereto (Filed as Exhibit 10.2 to Form 8-K filed on July 24, 2009 and incorporated herein by reference).
4.9	Form of Subscription Agreement, by and between Antares Pharma, Inc. and the investor party thereto (Filed as Exhibit 10.1 to Form 8-K filed on September 18, 2009 and incorporated herein by reference).

4.10+	Antares Pharma, Inc. 2008 Equity Compensation Plan, as amended (Filed as exhibit 4.1 to Form S-8 on June 11, 2010 and incorporated herein by reference.)
10.0	Stock Purchase Agreement with Permatec Holding AG, Permatec Pharma AG, Permatec Technologie AG and Permatec NV with First and Second Amendments dated July 14, 2000 (Filed as an exhibit to Schedule 14A on December 28, 2000 and incorporated herein by reference.)

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10.1	Third Amendment to Stock Purchase Agreement, dated January 31, 2001 (Filed as exhibit 10.1 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
10.2*	License Agreement with BioSante Pharmaceuticals, Inc., dated June 13, 2000 (Filed as exhibit 10.34 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.3*	Amendment No. 1 to License Agreement with BioSante Pharmaceuticals, Inc., dated May 20, 2001 (Filed as exhibit 10.35 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.4*	Amendment No. 2 to License Agreement with BioSante Pharmaceuticals, Inc., dated July 5, 2001 (Filed as exhibit 10.36 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.5*	Amendment No. 3 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 28, 2001 (Filed as exhibit 10.37 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.6*	Amendment No. 4 to License Agreement with BioSante Pharmaceuticals, Inc., dated August 8, 2002 (Filed as exhibit 10.38 to Form 10-K/A for the year ended December 31, 2001 and incorporated herein by reference.)
10.7*	License Agreement between Antares Pharma, Inc. and Ferring, dated January 21, 2003 (Filed as exhibit 10.47 to Form 8-K on February 20, 2003 and incorporated herein by reference.)
10.8	Office lease with The Trustees Under the Will and of the Estate of James Campbell, Deceased, dated February 19, 2004 (Filed as exhibit 10.65 to Form 10-K for the year ended December 31, 2003 and incorporated herein by reference.)
10.9	First Amendment to Lease Agreement between James Campbell Company LLC and Antares Pharma, Inc., dated November 2, 2010. (Filed as exhibit 10.20 to Form 10-K for the year ended December 31, 2010 and incorporated herein by reference.)
10.10	Form of Indemnification Agreement, dated February 11, 2008, between Antares Pharma, Inc. and each of its directors and executive officers (Filed as exhibit 10.1 to Form 8-K on February 13, 2008 and incorporated herein by reference.)
10.11+	Senior Management Agreement by and between Antares Pharma, Inc. and Robert F. Apple, dated February 9, 2006 (Filed as exhibit 10.1 to Form 8-K on February 14, 2006 and incorporated herein by reference.)
10.12+	Amendment to Senior Management Agreement with Robert F. Apple, dated November 12, 2008. (Filed as Exhibit 10.1 to Form 10-Q for the Quarter Ended September 30, 2008 and incorporated herein by reference.)
10.13+	Amendment 2012-1 to Senior Management Agreement with Robert F. Apple, dated December 14, 2012.#
10.14+	Employment Agreement, dated July 7, 2008 by and between Antares Pharma, Inc. and Dr. Paul K. Wotton (Filed as Exhibit 10.1 to Form 8-K on July 7, 2008 and incorporated herein by reference.)
10.15+	Amended and Restated Employment Agreement, dated November 12, 2008, by and between Antares Pharma, Inc. and Dr. Paul K. Wotton (Filed as Exhibit 10.1 to Form 10-Q on May 9, 2011 and incorporated herein by reference.)
10.16+	Amendment 2012-1 to Amended and Restated Employment Agreement, dated December 14, 2012, by and between Antares Pharma, Inc. and Dr. Paul K. Wotton #
10.17+	Employment agreement with Kaushik Dave, dated March 3, 2008 (Filed as exhibit 10.18 to Form 10-K for the year ended December 31, 2011 and incorporated herein by reference.)
10.18+	Amendment 2012-1 to Employment agreement with Kaushik Dave, dated December 14, 2012 #
10.19+	Form of Performance Stock Unit Grant (Filed as Exhibit 10.1 to Form 8-K on May 23, 2011 and incorporated herein by reference.)
10.20+	Form of Performance Stock Unit Grant (Filed as Exhibit 10.1 to Form 8-K on July 12, 2012 and incorporated herein by reference.)
10.21	Lease Agreement between Princeton South Investors, LLC and Antares Pharma, Inc., dated February 3, 2012 (Filed as exhibit 10.21 to Form 10-K for the year ended December 31, 2011 and incorporated herein by reference.)

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10.22	First Amendment to Lease between Princeton South Investors, LLC and Antares Pharma, Inc., dated January 28, 2013.#
21.1	Subsidiaries of the Registrant #
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm #
31.1	Certification of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.#
31.2	Certification of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.#
32.1	Certification of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.##
32.2	Certification of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.##
99.1	Press Release, dated March 13, 2013 ##
101.INS	XBRL Instance Document ##
101.SCH	XBRL Taxonomy Extension Schema ##
101.CAL	XBRL Taxonomy Extension Calculation Linkbase ##
101.LAB	XBRL Taxonomy Extension Label Linkbase ##
101.PRE	XBRL Taxonomy Extension Presentation Linkbase ##
101.DEF	XBRL Taxonomy Extension Definition Linkbase ##

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report to be signed on its behalf by the undersigned thereunto duly authorized, in the City of Ewing, State of New Jersey, on March 13, 2013.

ANTARES PHARMA, INC.

/s/ Paul K. Wotton
Dr. Paul K. Wotton

President and Chief Executive Officer

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this annual report has been signed by the following persons on behalf of the registrant in the capacities indicated on March 13, 2013.

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