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, 2014

[ ] 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. [ ]

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 [ ] Smaller reporting company [ ]
(Do not check if a smaller reporting company)

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

Aggregate market value of the voting and non-voting common stock held by nonaffiliates of the registrant as of June 30, 2014, was $313,638,000 (based upon the last reported sale price of $2.67 per share on June 30, 2014, on the NASDAQ Capital Market).

There were 131,743,365 shares of common stock outstanding as of March 7, 2015.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2015 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

ANTARES PHARMA, INC.
FORM 10-K
TABLE OF CONTENTS

PART I

PART II

PART III

PART IV

PART I

Item 1. BUSINESS

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties. You should not place undue reliance on those statements because they are subject to numerous uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "project," "intend," "should," "plan," "believe," "hope," and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and product development. In particular, these forward-looking statements include, among others, statements about:

- our expectations regarding commercialization of OTREXUP™ (methotrexate) injection for subcutaneous use;
- our expectations regarding product developments with Teva Pharmaceutical Industries, Ltd. ("Teva");
- our expectations regarding product development and potential United States Food and Drug Administration ("FDA") approval of Vibex® QuickShot™ ("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 pen ("epinephrine auto injector");
- our expectations regarding trends in pharmaceutical drug delivery characteristics;
- our anticipated continued reliance on contract manufacturers to manufacture our products;
- our sales and marketing plans;
- product development and commercialization plans regarding our other products and product candidates;
- our future cash flow and our ability to support our operations;
- 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 do not undertake to update or revise the forward-looking statements in this annual report after the date of this annual report, except as required by law. In light of these risks and uncertainties, you should keep in mind that any forward-looking statement in this annual report or elsewhere might not occur.

Overview

Antares Pharma, Inc. ("Antares," "we," "our," "us" or the "Company") is an emerging, specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral

pharmaceutical products and technologies. We have numerous partnerships with pharmaceutical companies as well as multiple internal product development programs.

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 have 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 cartridges. We have entered into multiple licenses for these devices mainly in the United States ("U.S."), Europe and Canada with Teva Pharmaceutical Industries, Ltd. ("Teva").

We developed the Vibex® auto injector for our product OTREXUP™ (methotrexate) injection. In February 2014, we launched OTREXUP™ (methotrexate) injection, which is the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP™ is indicated for adults with severe active rheumatoid arthritis ("RA"), children with active polyarticular juvenile idiopathic arthritis ("pJIA") and adults with severe recalcitrant psoriasis. To date, we have received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP™. We have worldwide marketing rights for OTREXUP™ and commercialize OTREXUP™ on our own in the U.S. for the treatment of RA. We have provided LEO Pharma, Inc. ("LEO Pharma") an exclusive license to commercialize OTREXUP™ in the U.S. for the treatment of psoriasis.

We are currently conducting clinical studies of Vibex® QS T, for testosterone replacement therapy. On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males. We also have initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system ("CNS") indication.

We also are developing VIBEX® Sumatriptan for the acute treatment of migraines which if approved will be sold by Teva. In January 2015, we received a complete response letter from FDA regarding our Abbreviated New Drug Application ("ANDA") for VIBEX® Sumatriptan, providing revisions to labelling and citing minor deficiencies, and we submitted our response to FDA in March 2015.

Our development projects in collaboration with Teva include VIBEX® epinephrine, an exenatide multi-dose pen, and another undisclosed multi-dose pen. In December 2014, Teva submitted the final amendment to the VIBEX® epinephrine pen ANDA, and FDA accepted Teva's filing of an ANDA in October 2014 for exenatide, formerly referred to as Teva "Pen 2".

We also make a reusable, needle-free, spring-action injector device known as the Tjet® and Zomajet®, which is marketed for use with human growth hormone ("hGH"). We have had success in achieving distribution of our device for use with hGH through licenses to pharmaceutical partners, Ferring Pharmaceuticals BV ("Ferring") and JCR Pharmaceuticals Co., Ltd. ("JCR"), and it has resulted in product sales and royalties. Ferring commercializes our needle-free injection system with their 4 mg and 10 mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X worldwide. Ferring purchased the U.S. rights to 5 mg Tev-Tropin from Teva in the fourth quarter of 2014. Tev-Tropin 10 mg is pending FDA approval. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

We also have a portfolio of gel-based products which are commercialized through various partners. We received FDA approval in December 2011 for an oxybutynin gel product, Gelnique 3%™, for the treatment of overactive bladder ("OAB"). We have a licensing agreement with Actavis plc ("Actavis") under which Actavis is currently marketing Gelnique 3%™ in the U.S. Elestrin® (estradiol gel) is currently marketed by Meda Pharmaceuticals, Inc. ("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:

Product	*Drug*	*Partners*	*Indication*	*Territory*	*Status*
OTREXUP™	Methotrexate	None	RA; pJIA	U.S.	Approved
OTREXUP™	Methotrexate	LEO Pharma	Psoriasis	U.S.	Approved
Tjet® Needle-free Injector	hGH (4 mg)	Ferring	Growth Retardation	Europe, Asia Pacific	Approved
Zomajet® Needle-free Injector	hGH (10 mg)	Ferring	Growth Retardation	Europe, Asia Pacific	Approved
Tev-Tropin®	hGH (5 mg)	Ferring	Growth Retardation	U.S.	Approved
Tev-Tropin®	hGH(10 mg)	Ferring	Growth Retardation	U.S.	Filed
Twin-Jector® EZ II Needle-free Injector	hGH	JCR	Growth Retardation	Japan	Approved
Elestrin®	Estradiol	Meda	HRT	North America, other countries	Approved
Oxybutynin Gel 3%	Oxybutynin	Actavis	OAB	U.S., Canada	Approved
Vibex® Auto Injector	Epinephrine	Teva	Anaphylaxis	U.S., Canada	Filed
Vibex® Auto Injector	Sumatriptan	Teva	Migraines	U.S., Canada	Filed
Vibex® QS T	Testosterone	None	TRT		Clinical
Vibex® QS M	Undisclosed	None	Undisclosed	Undisclosed	Preclinical
Disposable Pen Injector	Undisclosed Product #1	Teva	Undisclosed		Clinical
Disposable Pen Injector	Exenatide	Teva	Diabetes		Filed
Undisclosed	Undisclosed	Pfizer	Consumer Health	Undisclosed	Clinical
Nestragel™	Nestorone®	Population Council	Contraception	Worldwide	Clinical

Our only reportable segment is drug delivery, which includes the development and commercialization of injection devices and injection-based pharmaceutical products as well as transdermal gel products. See Note 9 to the Consolidated Financial Statements – in Part II, Item 8 - for segment financial information.

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 and pressure-assisted, needle-based technology, and Permatec specialized in delivering drugs across the skin using gel technologies. With both companies focused on drug delivery, but 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.

We are a Delaware corporation with principal executive offices located at 100 Princeton South Corporate Center, Suite 300, Ewing, New Jersey 08628. 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 or biosimilars. We believe that many injectable products currently offered in vials could be replaced with user-friendly auto 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. Additionally, the delivery of pharmaceutical therapies through injection systems often improves the systemic bioavailability of those treatments by overcoming absorption barriers common with oral and, in some cases, transdermal delivery. Improved bioavailability is considered beneficial when considering the role of route of administration on pharmaceutical efficacy. Our 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 used in managing chronic medical conditions presenting a need for repeated injections over time and are also used in management of acute conditions where the rapid onset of an injected drug is desirable.

Cost containment pressure by managed care organizations, 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 chronic care injections and even some acute care injections being administered by a doctor or nurse to self-administration by the patient, 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), 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

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. In the case of many of these compounds, bypassing the gastrointestinal tract by switching a route of administration from oral tablet to subcutaneous injection improves the side effect profile of the drug and does not cause gastrointestinal adverse events. Our OTREXUP™ product is an example of changing the route of administration from oral to injection for better bioavailability, systemic absorption, and tolerability. Vibex® Sumatriptan and Vibex® Epinephrine are examples of using the injection route for faster onset of action that is thought to result in more-rapid symptomatic relief. Generic products, like sumatriptan and methotrexate, represent a large portion of non-biologic injectable product volume in the current market.

THERAPEUTIC PRODUCTS AND PRODUCT MARKET OPPORTUNITIES FOR OUR INJECTOR SYSTEMS

OTREXUP™ (methotrexate) injection

OTREXUP™ is our proprietary combination product comprised of a pre-filled methotrexate syringe and our Vibex® self-injection system designed to enable rheumatoid arthritis and psoriasis patients to self-inject methotrexate reliably, accurately, comfortably and conveniently at home. On October 14, 2013, we announced the FDA had approved OTREXUP™ (methotrexate) injection, the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. Our new drug application ("NDA") approved in October 2013 covered the 10 mg, 15 mg, 20 mg and 25 mg dosage strengths. In July 2014, we submitted a supplemental NDA for the 7.5 mg strength of OTREXUP™, and we received FDA approval in November 2014. We plan to begin marketing for pJIA in 2015.

OTREXUP™ is indicated for use in adults with severe, active RA or children with pJIA, and adults with severe recalcitrant psoriasis. RA is a chronic autoimmune disease, resulting in pain, stiffness, swelling, joint damage, and loss of function of the joints. According to a 2008 study sponsored by the Arthritis Foundation, RA affects approximately 1.5 million Americans, which is almost 0.5% of the U.S. population. The disease onset generally occurs between the ages of 40 to 70 years and is about three times as prevalent among women as among men. According to Symphony Health Solutions, a healthcare data and analytics company, U.S. sales of biologic agents products approved to treat rheumatoid arthritis were approximately $17.3 billion in 2014. 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. A November 2012 analysis utilizing United Healthcare data and conducted by Optum found that methotrexate is usually started at 7.5 mg, 10 mg or 15 mg 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 20 mg to 25 mg per week (8 to 10, 2.5 mg 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. In a study performed by Schiff et al published in *The Annals of Rheumatic Diseases* in 2014, researchers showed that the bioavailability of methotrexate delivered via subcutaneous injection was dose proportional and continued to increase compared with oral drug, which plateaued at 15 mg. According to studies by Dr. Wegrzyn published in *The Annals of Rheumatic Diseases* in 2004, Dr. Mainman published in *Clinical Rheumatology* in 2010, Dr. Bakker published in *The Annals of Rheumatic Diseases* in 2010, and Dr. Braun published in *Arthritis and Rheumatism* in 2008, RA patients switching from oral to parenteral methotrexate may improve clinical response or lower the incidence of gastrointestinal side effects..

Other rheumatological conditions for which methotrexate is an approved treatment are pJIA 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 indicated in the OTREXUP™ prescribing information, the recommended dosing schedule for methotrexate in psoriasis is 10 to 25 mg per week until adequate response is achieved. In pJIA the recommended starting dose is is 10 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 National Psoriasis Foundation, a non-profit health agency dedicated to curing psoriatic disease, stated in 2015 that psoriasis is the most prevalent autoimmune disease in the U.S. According to current studies, as many as 7.5 million Americans, or approximately 2.2% of the population suffer from psoriasis, with a higher incidence in Caucasians. And, according to information published by the World Psoriasis Day consortium in 2015, 125 million people worldwide, or 2% to 3% of the total population have psoriasis.

pJIA is the most common rheumatic disease in childhood with an estimated prevalence between 7 and 400 for every 100,000 children. According to the Arthritis Foundation, pJIA affects nearly 300,000 children in the U.S. Most forms of pJIA 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 administered with a needle and syringe. According to a studies by Dr. Wegrzyn published in *The Annals of Rheumatic Diseases* in 2004, Dr. Mainman published in *Clinical Rheumatology* in 2010, Dr. Bakker published in *The Annals of Rheumatic Diseases* in 2010, and Dr. Braun published in *Arthritis and Rheumatism* in 2008, many patients who start on oral methotrexate may have an inadequate clinical response due in part to a lack of efficacy or poor tolerability.Although published studies have demonstrated switching to a parenteral route of administration can improve absorption, a 2012 report by Source Healthcare Analytics found that fewer than 5% 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"). Biologic therapies have been demonstrated to improve the patient's therapeutic response when added to methotrexate. However, according to Source Healthcare Analytics data published in 2013, the average retail price for biologics was in excess of $32,000 annually, excluding administrative and other fees that could be incurred. A number of peer-reviewed articles by key thought leaders in the rheumatology community have called on clinicians to optimize methotrexate therapy for rheumatoid arthritis and ensure that the drug is given adequate time to achieve the desired results before biologic therapies are initiated. Biologics have shown to have their own limitations including increasing the risk of serious infections and certain malignancies and are not appropriate for all patients.

In a phase 2 clinical study by Freundlich, et al, in 2014, OTREXUP™ was well tolerated with almost no administration site pain and minimal erythema. Limitations in functional status did not affect ability to self-administer. Improving the delivery of subcutaneous methotrexate may increase patient tolerance of self-injection thereby improving adherence in patients with RA.

OTREXUP™ may 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 designed to minimize accidental contact with methotrexate, a hazardous drug agent.

Since its launch in February 2014, OTREXUP™ has been adopted by clinical rheumatologists. Marketing data reveal that some physicians regularly use OTREXUP™ in RA patients who have experienced an inadequate response to oral methotrexate therapy for reasons of tolerability and/or efficacy. We have worldwide marketing rights for OTREXUP™ and independently market OTREXUP™ on our own in the U.S. for the treatment of RA. LEO Pharma has the exclusive right to market OTREXUP™ in the U.S. for the treatment of psoriasis. Commercial sales of OTREXUP™ commenced in early 2014, with good initial clinical adoption/utilization, and reimbursement

status among payer organizations that is consistent with newly launched products. On July 14, 2014, Medac Pharma Inc. ("Medac Pharma"), a privately held pharmaceutical company, announced FDA approval of an NDA for their product candidate, Rasuvo™, a subcutaneous injectable methotrexate in a ready-to-use injection device indicated for the treatment of management of adults with severe, active RA or children with active pJIA who are intolerant of or had an inadequate response to first-line therapy, including full dose non-steroidal anti-inflammatory agents. Medac Pharma launched Rasuvo™ on October 6, 2014. The product is available in 10 dosage strengths, ranging from 7.5 mg to 30 mg in 2.5 mg increments.

Vibex® QS T (testosterone)

Vibex® QuickShot® Testosterone ("QS T") is our proprietary combination product that consists of testosterone and our next generation Vibex® QuickShot® ("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 2014 was approximately $2.8 billion according to a Symphony Health Solutions report, and declined approximately 9% compared to 2013. There is significant competition within the TRT market among many pharmaceutical companies including Abbvie, Inc. (formerly Abbott), Eli Lilly and Company ("Lilly"), Endo Pharmaceuticals, Inc ("Endo"), Pfizer, Inc. ("Pfizer"), Actavis PLC ("Actavis"), Sandoz, Inc. ("Sandoz"), Mylan, Inc. ("Mylan"), Bedford Laboratories ("Bedford"), and Teva.

According to the Urology Care Foundation in June 2014, low serum testosterone, also known as hypogonadism or andropause, affects roughly 39% of men over the age of 45. The prevalence of low testosterone increases with age. Researchers have found that the incidence of low testosterone increases from approximately 20% of men over 60, to 30% of men over 70 and 50% of men over 80 years of age. In May 2014, Forbes.com estimated 13 million men in the U.S. suffer from lower than average testosterone. 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, The potential benefits of therapy include 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 formulations, such as Androgel, Testim, Fortesta, Axiron, dermal patches and buccal delivery are the most frequently prescribed versions of TRT. An NDA for an oral formulation of TRT indicated in hypogonadism secondary to obesity was submitted to the FDA by Repros Therapeutics, Inc. in February 2015.

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, dissatisfaction with the application process, or suboptimal clinical results due to variability in exposure and compliance. Injectable testosterone is an option for men with an inadequate response to transdermal therapies.

Currently, injectable testosterone is available and represents a significant percentage of all TRT prescriptions. These injections, prescribed as a combination of a vial, needle, and syringe, are usually given deep into the muscle tissue of the buttocks with large bore needles (typically 19 gauge needles). Injection testosterone is an esterified formulation in oil that 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 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, we are developing Vibex® QS T, a once-weekly subcutaneous 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. The Vibex® QS T utilizes a small gauge needle for patient comfort. On February 25, 2014, we released positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's ongoing, multi-center, phase III clinical study (QST-13-003) evaluating the efficacy and safety of QS T administered once-weekly in testosterone deficient adult males. Participants in the study will remain on QS T and will be followed for an additional 40 weeks, and the collection of safety data is ongoing.

Tjet® / Zomajet® (hGH)

Tjet® / Zomajet® is our needle-free auto injector offered by Ferring to patients who use its brand of hGH. It is designed to deliver hGH treatment to children without the use of a needle.

According to Symphony Health Solutions, hGH sales in the U.S. were $1.6 billion in 2014. There is significant competition within the hGH market between major pharmaceutical companies such as F. Hoffmann-La Roche AG, Pfizer, Novo Nordisk, Inc, Sandoz, Teva and EMD Serono, Inc. 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.

The Zomajet®/Tjet® device can administer 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**
- **Patients with metal allergies**

The Zomajet®/Tjet® device 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.

The Zomajet®/Tjet® device has been sold for use in more than 30 countries to deliver hGH. The product is reusable, with each device designed to last for approximately 3,000 injections (or approximately two years) while the needle-free syringe is disposable after approximately one week when used by a patient for injecting from multi-dose vials. Our pharmaceutical partner, JCR, markets hGH in Japan as the Twin-Jector® EZ II Needle-free Injector. Our pharmaceutical partner, Ferring, has an established branded product 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. Since Teva launched the Tjet® needle-free device in late 2009, gross sales of hGH Tev-Tropin® increased year over year until Teva initiated a recall of the drug product, Tev-Tropin® (not the device which we supply), in April 2014 having halted sales of the drug earlier in 2014. We do not know when sales of Tev-Tropin® will resume. In December 2014, Ferring acquired the U.S. rights to Tev-Tropin® from Teva and assumed Teva's obligations under the Supply Agreement. 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 Specialty, a division of Mylan, Inc.

The EpiPen® is the global market leader in the epinephrine auto injector market. In the U.S., according to Symphony Health Solutions, sales of epinephrine injection products were approximately $1.8 billion in 2014 with the EpiPen® accounting for 87% of the total. Mylan, Inc. reported that EpiPen® has a 90% world market share in the U.S. and 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 that we have designed for a product containing sumatriptan. We are in the process of preparing for commercialization, including engaging a third party to prepare commercial tooling and molds, and await FDA approval of the product as a generic substitute of GlaxoSmithKline plc ("GSK") branded product, Imitrex® STATdose Pen®. According to Catamaran, Inc., a pharmacy management company, the total U.S. anti-migraine market is expected to be valued at $3.2 billion in 2015. In the U.S., according to Symphony Health Solutions, sales of migraine products were about $2.7 billion in 2014. Oral drugs accounted for $2.2 billion of the total. Injectable and nasal products combined accounted for about $465 million of the total value.

There are currently seven triptans marketed in the U.S. indicated for treatment of migraine. Five are available as generics and two retain patent exclusivity. According to Catamaran, patent protection for Eletriptan (Relpax, Pfizer) will expire in December 2016, while patent protection for Almotriptan (Axert, Janssen) ends in June 2017.

According to a survey commissioned by the National Headache Foundation, migraine affects nearly 37 million Americans. Migraine headaches are often characterized by a headache of moderate or severe intensity, nausea (the most common characteristic), one-sided and/or pulsating quality, aggravated by routine physical activity, duration of hours to 2-3 days; and an attack frequency anywhere between once a year and once a week. Healthcare professionals frequently prescribe triptans to stop migraine attacks , such as GSK's Imitrex (sumatriptan) and Amerge (naratriptan); Pfizer's Relpax (eletriptan), Merck & Co., Inc.'s ("Merck") 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 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 9% of triptan prescriptions are currently for injectable triptans. Sumatriptan is the only injectable triptan approved for use in the U.S. Sumatriptan is currently available in an oral formation, a nasal spray (Imitrex, GSK and generic), a needless injector (Sumavel, Astellas/Zogenix), and a transdermal patch (Zecuity, Teva).

Several manufacturers offer versions of injectable sumatriptan with a delivery device, including GSK (Imitrex StatDose), Pfizer (Alsuma) Zogenix, Inc. (Sumavel DosePro), and Sun Pharma (generic sumatriptan autoinjector) and recently Dr. Reddy's Laboratories (generic sumatriptan autoinjector). Two companies, Par Pharmaceutical Companies, Inc. 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.

Disposable Pen Injector with Exenatide

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. We are planning to scale up tooling and molds for commercial scale production. 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 products: "Pen 1" which is undisclosed and under development in Europe and "Pen 2", an exenatide pen which has an ANDA under active review at the FDA.

Exenatide, marketed as Byetta, is used along with diet and exercise to treat type 2 diabetes, a condition in which the body does not use insulin normally and therefore cannot control the amount of sugar in the blood. Exenatide works by stimulating the pancreas to secrete insulin when blood sugar levels are high. Insulin helps move sugar from the blood into other body tissues where it is used for energy. Exenatide also slows the emptying of the stomach and causes a decrease in appetite. Exenatide is not used to treat type 1diabetes, a condition in which the body does not produce insulin and therefore cannot control the amount of sugar in the blood. Exenatide is not used instead of insulin to treat people with diabetes who need insulin. Total U.S. sales of Exenatide/Byetta by Astrazeneca AB ("Astrazeneca") and Amylin Pharmaceuticals, LLC ("Amylin") in 2014 were approximately $350 million according to Symphony Health Solutions.

Other Injectable Drugs

Other injectable drugs that are presently self-administered and may be suitable for injection with our systems include therapies for the treatment of gout, epileptic seizure, Alzheimer's Disease, blood clots, 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 PRODUCTS AND PRODUCT MARKET OPPORTUNITIES FOR TRANSDERMAL GEL 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.

Oxybutynin Gel 3%

Our topical oxybutynin gel 3% product for the treatment of OAB was approved by the FDA in December 2011. According to Symphony Health Solutions, the U.S. OAB market value was about $3.2 billion in 2014. In July 2011, we licensed our oxybutynin gel 3% product to Actavis for commercialization in the U.S.. 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. Gelnique has not experienced the patient acceptance originally anticipated and is a small product in this field. We receive royalties on net sales of both Gelnique 3% and Gelnique 10%.

Elestrin®

Elestrin® is a transdermal estradiol gel for the treatment of moderate-to-severe vasomotor symptoms associated with menopause. According to Symphony Health Solutions, the U.S. hormone replacement market, including estrogens, progestogens, and estrogen-progestogen and estrogen-androgen combinations, was $3.2 billion in 2014. According to industry estimates, approximately six million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone therapy. 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. We receive a single digit royalty from Meda on the net end sales of Elestrin®.

Nestragel™ (Contraception)

According to IMS Health, a healthcare information, services and technology company, the U.S. contraceptives market in 2014 was $5.8 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 has a development agreement 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 17β-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 effective at stopping ovulation at a low dose. It is not active when taken orally and is therefore especially appropriate for topical application.

We have a joint development agreement with the Population Council to develop a contraceptive formulation product containing Nestorone® 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. Together, we are looking for a 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.

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.

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 and chronic medical needs, such as rheumatoid arthritis and psoriasis, allergic reactions, migraine headaches, acute pain and other undisclosed therapies. Our proprietary Vibex® disposable auto injector systems combine a spring-based power source with a shielded needle, which delivers up to 0.5 ml 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 also developed the Medi-Jet™ auto injector, based on the Vibex® system, for delivery of methotrexate (OTREXUP™) for treatment of RA, pJIA and psoriasis.

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 and Vibex® QS M with an undisclosed drug for treatment of a CNS indication.

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. We are planning to scale up tooling and molds for commercial scale production. 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 products: “Pen 1” which is undisclosed and under development in Europe and “Pen 2”, an exenatide pen which has an ANDA under active review at the FDA.

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. However, needle-free devices may be commercially limited due to the high cost of the product and the need for consumable disposables.

Research and Development

We currently perform clinical, regulatory, parenteral device development and commercial development work. We have various products at earlier stages of development as highlighted in our products schedule on page 2 above, as well as OTREXUP™, which we have already launched. Additionally, see Collaborative Arrangements and License Agreements in this Item 1 for a discussion of pharmaceutical partners that are developing compounds using our technology.

Vibex® QS and QS T (testosterone). We are developing Vibex® QS T for self-administered weekly injections of testosterone enanthate in a preservative free formulation for clinically hypogonadal men requiring testosterone replacement.

On December 5, 2012, we conducted a pre-IND (Investigational New Drug application) meeting with the FDA as part of preparing to initiate clinical development of Vibex® QS T, establishing an agreed upon clinical path forward. In September 2013, we announced that the first patients were dosed in a clinical study evaluating the PK profile of testosterone enanthate administered weekly by subcutaneous injection at doses of 50 mg and 100 mg via the VIBEX® QS T auto injector device in hypogonadal adult males. The study enrolled 39 patients at nine investigative sites in the U.S. We announced our top line results of this study in a press release on February 20, 2014. We believe that the results are positive in that Vibex® QS T treatment resulted in most patients achieving average levels of testosterone within the normal range from the first dose onward. Vibex® QS T was also safe and well tolerated by all dosed patients.

On November 3, 2014, we announced that the last patient has been enrolled in a double-blind, multiple-dose, phase III study (QST-13-003) to evaluate the efficacy and safety of Vibex® QS T administered subcutaneously once each week to testosterone-deficient adult males. Patients enrolled in this study had a documented diagnosis of hypogonadism or testosterone deficiency defined as having testosterone levels below 300 ng/dL. The study includes a screening phase, a treatment titration and efficacy phase and an extended treatment phase. One hundred fifty patients are enrolled in this study. Patients meeting all eligibility criteria were assigned to receive a starting dose of Vibex® QS T once weekly for six weeks. Adjustments to dose could be made at week seven based upon the week six pre-dose blood level. The efficacy of Vibex® QS T and dose adjustment to regulate testosterone levels will be evaluated after 12 weeks of treatment.

On January 13, 2015, we announced that we received written recommendations from the FDA related to our clinical development program for QS T. The recommendations received were in response to various clinical, Chemistry, Manufacturing and Controls and user study submissions that we made through November 2014. We believe that we have already factored many of the recommendations cited in the advice letter into the protocol of the ongoing phase III study and into the protocols for planned human use studies as a result of guidance provided by FDA at the May 2014 Type C meeting. Based on a single reported occurrence of hives in our phase II study, which the FDA characterized as an apparent allergic reaction, as well as the known safety experience with other parenteral testosterone products, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to QS T with 200 subjects exposed for six months and 100 subjects exposed for a year. We do not believe that the adverse event of hives reported in the phase II study was related to the study drug. Based on the number of subjects in previous studies and in the current phase III study, we anticipate that we may need approximately 70 additional subjects exposed to QS T for six months. We are assessing the FDA's comments in the advice letter and their impact on the timing of the filing of a NDA for QS T with the FDA. The timing, cost and design of the study to obtain the additional 70 subjects and data required will be determined based on further discussion with the FDA.

On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in QST-13-003. The protocol for the study required that at the week 12 endpoint: (i) at least 75% of all patients' C_{avg} are within the normal range of 300 to 1100 ng/dL, with a lower limit of a 95% 2-sided confidence interval of greater than or equal to 65%, (ii) at least 85% of patients' C_{max} are less than1500 ng/dL and (iii) no more than 5% of patients had a C_{max} greater than 1800 ng/dL. The primary endpoint of the population that received one or more doses of QS T was met by 139 out of 150 patients, equating to 92.7% with a 95% confidence interval of 87.3% to 96.3%. Among the 137 patients that completed all 12 weeks of dosing and PK sampling, 98.5% were within the pre-defined range. The top-line results are summarized in the table below.

Population/Analysis	C_{avg} Lower limit of the 95% 2-sided C. I.	C_{avg} % in range 300 – 1100 ng/dL n (%)	C_{max} <1500 ng/dL n (%)	C_{max} >1800 ng/dL n (%)
Primary analysis* N=150	87.3%	139 (92.7%)	137 (91.3%)**	0%
Completers N=137	94.8%	135 (98.5%)	137 (100%)	0%
Protocol-Required Outcomes	≥65%	75%	≥85%	≤5%
* All patients with 1 or more doses, C_{avg} 0-168 hours post week 12 injection or last measured concentration carried forward **Patients without a C_{max} determination at week 12 are assigned above 1500 ng/dL				

Overall, the regimen demonstrated a mean (± standard deviation) steady state concentration of testosterone of 553.3 ± 127.3 ng/dL at 12 weeks.

Participants in the study will remain on QS T and will be followed for an additional 40 weeks, and the collection of safety data is ongoing. One hundred fifty patients have received at least one dose of study drug and to date, there have been no reported deaths and one serious adverse event ("SAE") of hospitalization for worsening depression. This patient received a single dose of QS T, and the SAE was not considered to be related to study drug. Thus far, there have been no reported adverse events consistent with urticaria (hives).

In addition to the clinical trial program, there is an ongoing Human Factors program to demonstrate safe and reliable at-home usability of QS T. Study populations include trained and untrained subjects, including patients, non-patient caregivers and health care providers. The goals of the program are to optimize and document reliable and proper administration in study subjects in the setting of at-home use in order to support the approvability of the product.

We have also recently initiated feasibility studies with potential partners for delivery of their viscous drug products using our Vibex® QS auto injector.

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 devices for a product containing exenatide and for an undisclosed product. 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® device for a product containing epinephrine and have scaled up the commercial tooling and molds for this product. During 2014, 2013 and 2012, we received approximately $5,200,000, $1,600,000 and $850,000, respectively, from Teva for this tooling as well as other development work for this program. From a regulatory standpoint Teva filed this product as an ANDA, and the FDA accepted the filing as such. Currently, Teva is conducting its own development work on the drug product (epinephrine). An amendment to the ANDA was filed with the FDA in December 2014, the review timing of which is completely dependent on the FDA.

Vibex® with Sumatriptan

Teva filed Vibex® with Sumatriptan as an ANDA in 2006, and the FDA rejected the filing as such. The FDA's rejection was based primarily on the opinion that the device was sufficiently different from 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. In the fourth quarter of 2009, Teva transferred ownership of the ANDA to us, and we submitted acceptance of ownership to FDA. We have been conducting user studies for the newly designed device. In the fourth quarter of 2013, we received a complete response letter from the FDA with additional items to be addressed in our filing. We submitted this new data in the first half of 2014. We announced in January 2015 that we received a complete response letter from the FDA that provided revisions to the labeling and minor deficiencies. We submitted our response in March 2015, the review timing of which is completely dependent on the FDA. We will need to make a decision about moving forward with commercial scale tooling and molds prior to launch.

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. In 2014, we completed drug development and delivered devices for a drug stability program to support a regulatory filing to be made during 2015.

Exenatide disposable pen injector

We have designed and produced pen injectors for the exenatide pen injector product. Teva believes the regulatory pathway for this product is an ANDA pathway. Teva initiated drug stability and completed the device development program and filed an ANDA with the FDA in the second half of 2013. The ANDA was accepted by the FDA and is currently under FDA review. There is also a concurrent development program which was initiated in 2011 for this product in Europe. In December 2014, Amylin and AstraZeneca filed a complaint alleging patent infringement against Teva resulting in a thirty-month stay on FDA's approval of the ANDA; the stay will expire in April 2017 unless the litigation is ended prior to that time.

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 2015, 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 use third parties to manufacture our products and product candidates and have agreements with those third parties to provide those services. We are responsible for device manufacturing and are in compliance with current Quality System Regulations ("QSR") established by the FDA and by the Medical Device Directive established by the European Commission. Injector and disposable parts are manufactured by third-party suppliers. Assembly and packaging of all of our products, including our needle-free device for all of our partners and OTREXUP™, is performed by third-party suppliers under our direction. Product release is performed by us. 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. We have contracted with Phillips-Medisize Corporation ("Phillips"), an international outsource provider of design and manufacturing services, to produce clinical and commercial quantities of our Vibex® QS T auto injector device and our pen injector device for an undisclosed Teva product. 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 Pharmascience Inc., formerly Uman Pharma (Montreal, Canada) to supply commercial quantities of methotrexate pre-filled syringes for the U.S and Canadian markets for OTREXUP™. We have contracted with Sharp Corporation, an international contract packaging company, to assemble and package OTREXUP™. All of our pharmaceutical manufacturing and packaging suppliers are subject to compliance with Current Good Manufacturing Practices ("cGMP").

Distribution

In connection with the launch of OTREXUP™ we have contracted with a third-party logistics provider, Cardinal Health 105, Inc., a/k/a Specialty Pharmaceutical Services ("Cardinal"), for key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In addition, we will utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services.

Trade

In connection with the launch of OTREXUP™ we have contracted with numerous wholesale distributors such as McKesson, Cardinal and Amerisource Bergen to distribute our OTREXUP™ product to the retail pharmacies as well as the Veterans Administration and other governmental agencies. In addition to shipping our product, the major distributors will provide inventory and sales reports as well as other services. In exchange for these services we pay fees to certain distributors based on a percentage of wholesale acquisition cost.

Third Party Reimbursement and Pricing

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors increasingly are challenging the prices charged for medical products and services and implementing other cost containment mechanisms. This is especially true in markets where generic options exist. It is, and will be, time consuming and expensive for us to go through the process of maintaining or seeking reimbursement to the consumer for our products from Medicaid, Medicare and private payors. Our products and those of our partners may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis, potentially resulting in contract changes with these major payors.

Third-party payers may use tiered reimbursement which may adversely affect demand for OTREXUP™ by placing it in a more expensive patient co-payment tier. We cannot be certain that OTREXUP™ will successfully be placed on the list of drugs covered by particular health plan formularies. Additionally, with the introduction of another methotrexate/auto injector, third-party payers are currently demanding, and will most likely continue to demand more aggressive contractual terms from Antares for favorable formulary placement for Otrexup. Some 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™ in this market segment.

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.

Sales and Marketing

OTREXUP™

On October 14, 2013 we announced the approval of OTREXUP™ (methotrexate) injection by the FDA, and in January 2014 we announced the launch of OTREXUP™. We have worldwide marketing rights for OTREXUP™ and commercialize OTREXUP™ on our own in the U.S. for the treatment of RA. We plan to begin marketing OTREXUP™ for pJIA in 2015. We have an internal sales and marketing organization. During 2014, we had a contracted field force comprised of approximately 25 sales representatives to market the product in the U.S. to key rheumatology specialists. In December 2014, we terminated the contract with the contract sales organization, and in January 2015, we began to hire sales representatives to fill 32 territories. We have entered into agreements with other vendors for commercialization services such as third-party contracting and distribution. We have provided LEO Pharma the exclusive right to commercialize OTREXUP™ in the U.S. for the treatment of psoriasis. We intend to enter into licensing or additional distribution arrangements for commercialization of our products outside the U.S.

Partnered Products

Revenue from Teva also included development and product revenue related to license agreements with Teva for our Vibex® system and for our pen injector device. Revenue from Actavis in 2014 resulted from Gelnique 3% royalties, in 2013 revenue from Actavis resulted from Gelnique 3% product sales and royalties, and in 2012 resulted from Gelnique 3% product sales, manufacturing start-up and other development activities, royalties and a milestone payment that was recognized in 2012. Product sales to Actavis ended in the first quarter of 2013, as Actavis assumed all manufacturing of Gelnique 3% in 2013 as contracted.

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®) (4 mg formulation)**	**Growth Retardation (Europe, Asia Pacific)**	**Needle Free Zomajet® 2 Vision**
Ferring	**hGH (Zomacton®) (10 mg formulation)**	**Growth Retardation (Europe, Asia Pacific)**	**Needle Free Zomajet® Vision X**
Ferring	**hGH (Tev-Tropin®) 5 mg, 10 mg**	**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 Product #1**	**Undisclosed (North America, Europe & others)**	**Pen Injector**
Teva	**Exenatide**	**Diabetes (North America, Europe & others)**	**Pen Injector**
Actavis	**Oxybutynin**	**U.S. and Canada**	**Gelnique 3%**
Meda	**Estradiol**	**Hormone replacement therapy (North America, other countries)**	**Elestrin® Gel**
Pfizer	**Undisclosed**	**Consumer Health**	**Undisclosed**
Population Council	**Nestorone®/Estradiol**	**Contraception (Worldwide)**	**Nestragel™**
Ferring	**Undisclosed**	**Undisclosed (Worldwide)**	**Transdermal Gel**
LEO Pharma	**Methotrexate**	**Dermatology (U.S.)**	**OTREXUP™**
Undisclosed	**Undisclosed**	**Undisclosed (Worldwide)**	**Undisclosed**

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 ANI to develop and commercialize four of our gel technology products for use in hormone replacement therapy in North America and other countries. ANI 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. Currently we expect that Elestrin®, which is sublicensed by Meda, 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 2016 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. We have the option to renew the agreement in 2016.

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 U.S. 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. We have multiple patents that have been granted by the USPTO which cover this product and expire in 2031. We have and plan to continue to file patent applications covering this product.

In July 2006, we entered into a joint development agreement with the Population Council, an international, non-profit research organization, to develop contraceptive formulation products containing Nestorone®, by using the 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 are looking for 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 U.S. 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 extended through September 2013. In May 2013, the agreement was amended to provide for one-year automatic renewals unless terminated by either party six months ahead of the expiring term. In December 2014, Ferring acquired the U.S. rights from Teva and assumed Teva's obligations under the Supply Agreement.

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 exenatide and an undisclosed patient-administered pharmaceutical product. 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 2014, 2013, 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. Currently the expiration date of the last to expire patent is 2029, and we have filed patent applications that, if granted, would expire in 2034 and 2035.

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.

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 under which Daewoong will commercialize our oxybutynin gel 3% product in South Korea, once approved. This agreement was terminated in 2014.

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 U.S. 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.

In November 2013, we entered into a promotion and license agreement with LEO Pharma. Under this agreement we granted LEO Pharma the exclusive right to promote OTREXUP™ to dermatologists for symptomatic control of severe recalcitrant psoriasis in adults in the U.S. LEO Pharma is responsible for promotion and marketing activities in dermatology and we are responsible for the supply of OTREXUP™ product and samples. We received from LEO Pharma a non-refundable upfront payment of $5.0 million and received a second milestone payment of $5.0 million upon launch of the product and meeting other performance obligations in March 2014. Additionally, we may receive a $10.0 million milestone payment upon realizing a defined level of net sales in a calendar year. The Company will pay LEO Pharma a percentage of net sales generated in dermatology as evidenced by psoriasis prescriptions.

In September 2014, we entered into development and license agreement with an undisclosed party. Under this agreement, we will receive a royalty from commercial sales, milestone payments upon the achievement of certain events as well as a purchase price for each device sold.

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 and Accord Healthcare. In several European countries, Canada, and South Korea, Medac International or its licensees market methotrexate in prefilled syringes (Metoject®) and in 2013 launched an auto injector with methotrexate in those territories. On July 14, 2014, Medac Pharma, a privately held pharmaceutical company, announced FDA approval of an NDA for their product candidate, Rasuvo™, a subcutaneous injectable methotrexate in a ready-to-use injection device for use in the treatment of rheumatoid arthritis, poly-articular course juvenile arthritis and psoriasis. The product was subsequently launched on October 6, 2014 and is available in 10 dosage strengths, ranging from 7.5 mg to 30 mg in 2.5 mg increments. 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.

Competition in the U.S. testosterone replacement market includes Abbvie's Androgel® and Androgel® 1.62%, Lilly's Axiron®, Endo Pharmaceuticals' Fortesta®, Delatestryl®, Testim®(and the authorized generic), Striant® and Testopel®, Pfizer's Depo®-Testosterone, Actavis' Androderm®, Upsher-Smith's Vogelxo™ and several generic testosterone in oil products sold by Actavis, Sandoz, Mylan, Bedford Labs, Teva and others. In addition, at least three additional oral treatments for low testosterone levels are either in development or under active review at the FDA. Clarus Therapeutics is developing an oral formulation of testosterone undecanoate, Rextoro™ and Lipocine is also developing an oral formulation of testosterone undecanoate. Repros Therapeutics, Inc. submitted an NDA to

the FDA on February 2, 2015 for Androxal®, a single isomer of clomiphene citrate under development for the treatment of secondary hypogonadism in overweight men wishing to restore normal testicular function. In 2014, Endo Pharmaceuticals received U.S. FDA approval of testosterone undecanoate injection, Aveed™. Endo Pharmaceuticals licensed testosterone undecanoate injection from Bayer, which markets the product as Nebido® in Europe and elsewhere. Trimel Pharmaceuticals recently received U.S. FDA approval of Natesto™, an intra-nasal testosterone formulation. Endo Pharmaceuticals subsequently acquired the exclusive commercial rights to the Natesto™ product in the U.S. and Mexico.

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%), Actavis' 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), Actavis' transdermal oxybutynin patch Oxytrol® and Allergan's Botox® (onabotulinumtoxinA).

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), and Zorptive (EMD Serono). While all hGH products currently available in the U.S. 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, 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 (Actavis), 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.

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 societal healthcare costs. In addition, it is becoming increasingly recognized that conventional needles and syringes are inherently unreliable, difficult to use for patients with limitations in manual dexterity, use-training sensitive, 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 versions 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 provide pharmaceutical companies with the opportunity 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.

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 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.

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 2031. In addition to issued patents and patent applications, we are also protected by trade secrets in all of our technologies.

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

Government Regulation

Any potential products discovered, developed and manufactured by us or our collaborative partners must comply with comprehensive regulation by the FDA in the U.S. 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 enforcement actions ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, manufacturing shut downs, quarantines, 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 filing under Section 505(b)(2) of the FD&C Act where there is an acceptable reference or 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. The combination of the drug, its dosage form and label claims, and differences, if any, from the reference product 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 U.S. 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 and facilities;
- submission to the FDA of an NDA; and
- FDA review of the NDA or product license application in order to determine, among other things, whether the drug is safe and effective for its intended uses.

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

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

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

Pivotal or phase III adequate and well-controlled trials are undertaken in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for the purpose of registering the new drug. The FDA may suspend or terminate clinical trials at any point in this process if it concludes that patients are being exposed to an unacceptable health risk or if they decide it is unethical to continue the study. Results of pre-clinical and clinical trials must be summarized in comprehensive reports for the FDA. In addition, the results of phase III studies are 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 U.S., the EU and Japan.

FDA approval of our own and our collaborators' products is required before the products may be commercialized in the U.S. 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 relate to the active ingredients, the drug product and/or the labeling, or significant manufacturing changes. 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. For example, on March 3, 2015, FDA announced that FDA is requiring labeling changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use. FDA also stated that health care professionals should make patients aware of this possible risk when deciding whether to start or continue a patient on testosterone therapy. FDA also announced that it is requiring manufacturers of approved testosterone products to conduct a well-designed

clinical trial to more clearly address the question of whether an increased risk of heart attack or stroke exists among users of these products. We do not know how or whether these requirements will impact our clinical development program for QS T.

FDA approval is required before a generic drug equivalent can be marketed. We seek approval for such products by submitting an ANDA or 505(b)(2) to the FDA. When processing an ANDA, the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. "Bioavailability" indicates the extent of absorption of a drug product in the blood stream. "Bioequivalence" indicates that the active drug substance that is the subject of the ANDA submission is equivalent to the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

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

Before approving a product, either through the NDA or ANDA route, the FDA also requires that our procedures and operations or those of our contracted manufacturer conform to 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. New track and trace requirements became effective in January 2015, will be implemented over a ten-year period, and will require new systems to track the distribution of drug products.

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 products, such as OTREXUP™ (methotrexate) for injection, or products marketed by our partners, such as Gelnique 3%™ (oxybutynin gel 3%) and Elestrin® (estradiol gel), as well as our products being developed by our partners such as Nestragel™ (nestorone and estradiol gel) and the undisclosed Pfizer product are subject to the above regulations. Drug-device combination products developed by us, such as OTREXUP™, Vibex® QS T, and Vibex® QS M, and those being developed by our partner, Teva, are subject to the NDA, ANDA, sNDA, sANDA 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 Biologic Product License Application. 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. The device specific information is filed with FDA as part of the drug approval submission or it may be filed separately in 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 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.

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. FDA also requires reporting of recalls and other field actions taken to reduce a risk to health or to remedy a violation caused by a device that may present a risk to health. 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 U.S., 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 U.S., it must either be approved for marketing in the U.S. 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.

Our Minneapolis Quality Management System has 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 1, 2015, we had 93 full-time employees. Of the 93 employees, 39 are primarily involved in research, development and manufacturing activities, 37 are primarily involved in commercialization, with the remainder engaged in executive and administrative capacities. Although we believe that we are appropriately sized to focus on our mission, we intend to add personnel with specialized expertise, as needed.

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

Available Information

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

Item 1A. RISK FACTORS

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

Risks Related to Our Operations

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

We incurred net losses of $35,151,715 and $20,506,776 in the fiscal years ended 2014 and 2013, respectively. In addition, we have accumulated aggregate net losses from the inception of business through December 31, 2014 of $208,447,656. The costs for research and product development of OTREXUP™, 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 could be harmed.

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

In the fourth quarter of 2012, we sold 14,259,868 shares of common stock at a price of $4.00 per share in a public offering. The sale of common stock resulted in net proceeds of $53,328,188 after deducting offering expenses of $3,711,284. In addition, we received proceeds from warrant and stock option exercises of $3,105,102 and $2,326,838 in 2014 and 2013, 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 or impossible to raise additional funds through debt or equity financings.

At December 31, 2014, we had cash and investments of $40,031,327. 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, and your equity interest in the company may be diluted. 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 sell OTREXUP™;
- our ability to successfully develop and obtain regulatory approval for our own product candidates such as Vibex® QS T, Vibex® QS M and Vibex® sumatriptan;
- the success of our partners in selling our products;
- our ability to successfully sell future products if we choose not to partner the product;
- our ability to manufacture, or have manufactured, 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;

- 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 and that of our partners to obtain regulatory approvals and where applicable to obtain an AB-rating;
- 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 launched OTREXUP™ in February 2014 and as a company, we have limited sales and marketing experience.

We launched OTREXUP™ in February 2014. Although we have hired highly qualified personnel with specialized expertise, as a company, we have limited experience commercializing pharmaceutical products on our own. In order to commercialize OTREXUP™, we have been building our sales, marketing, distribution, managerial and other non-technical capabilities and have made arrangements with third parties to perform these services when needed. In January 2015, we hired sales representatives and district managers to fill our 32 sales territories. We have provided LEO Pharma the exclusive right to commercialize OTREXUP™ in the U.S. for the treatment of psoriasis. To the extent we are relying on third parties to commercialize OTREXUP™, we may receive less revenues or incur more expenses than if we had commercialized OTREXUP™ ourselves. In addition, we may have limited control over the sales efforts of any third parties involved in our commercialization efforts. 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 partner fails 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 sales representatives, managed care, medical affairs and pharmacovigilance teams. The establishment and development of commercialization capabilities to market OTREXUP™ has been and will continue to be expensive and time-consuming. As we continue to develop these capabilities, we will have to compete with other pharmaceutical companies to recruit, hire, train and retain sales and marketing personnel. If we have underestimated the necessary sales and marketing capabilities or have not established the necessary infrastructure to support successful commercialization, 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 achieve the sales expected, we may lose the substantial investment made in OTREXUP™.

We have made and are continuing to make substantial expenditures commercializing OTREXUP™. We are devoting substantial resources to building our manufacturing and assembly equipment for OTREXUP™ as well as continued investment in commercial supply inventories of OTREXUP™ to support commercialization, including our recent hiring of sales representatives and district managers. We have and expect to continue to devote substantial resources to establish and maintain a marketing capability for OTREXUP™. If we are unsuccessful in our commercialization efforts and do not achieve the sales levels of OTREXUP™ that we expect, we may be unable to recover the large investment we have made in research, development, manufacturing, inventory and marketing efforts, and our business and financial condition could be materially adversely affected.

Our commercialization partner, LEO Pharma, may not successfully commercialize OTREXUP™ in the U.S. for the treatment of psoriasis.

LEO Pharma is solely responsible for all promotional and marketing activities in the U.S. related to OTREXUP™ for psoriasis. If LEO Pharma fails to adequately market and promote OTREXUP™ or is unsuccessful in its efforts, we may receive less revenue than we desire or may receive less than if we had commercialized the product ourselves. We may disagree with LEO Pharma as to sales and marketing tactics or the manner in which

LEO Pharma is positioning OTREXUP™. A breach by either party, or disagreement with LEO Pharma, may lead to termination of the agreement, which could have a material adverse effect on our sales level of OTREXUP™.

We will rely on third parties to perform many necessary services for OTREXUP™, including services related to the distribution, invoicing, storage and transportation of our products.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which are out of our direct control. For example, we rely on Cardinal to provide key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management, and, as a result, most of our finished goods inventory is stored at a single warehouse maintained by the service provider. We place substantial reliance on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

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 drug/device combination product, OTREXUP™, or any other of our products or product 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 manufacturers 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.

In addition, 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 held by a contract manufacturer. FDA approval of the new manufacturer and manufacturing site would also be required.

We have entered into multiple commercial supply agreements with third-party manufacturers, including, without limitation:

- the supply of the methotrexate drug substance;
- the manufacture of prefillable syringes;
- the manufacture of device components;
- the production of the methotrexate drug substance in pre-filled syringes;
- the manufacture and partial assembly of Vibex® auto injectors; and
- the final assembly and packaging of OTREXUP™ in Vibex® auto injectors.

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.

We depend on these third-party manufacturers to comply with 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. Our third-party manufacturers may also fail to pass the audits by our internal quality and regulatory group. 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 are dependent on numerous third parties in our supply chain for the commercial supply of OTREXUP™, most of which are currently single source suppliers, and if any of these single-source suppliers are not able to satisfy demand and alternative sources are not available, the manufacturing and distribution of OTREXUP™ could be delayed and our business could be harmed.

We currently have the following single source suppliers in our supply chain for the commercial supply of OTREXUP™:

- Supplier of the active pharmaceutical ingredient ("API") for methotrexate;
- Pharmascience for supply of commercial quantities of methotrexate pre-filled syringes;
- Nypro for the supply of commercial quantities of the Vibex® auto injectors;
- Sharp for assembly and packaging of OTREXUP™;
- Cardinal for services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management.

Our supplier for the pre-filled syringes of methotrexate and our supplier of methotrexate API are single source suppliers to us. If any of these manufacturers is unable to supply its respective component for any reason, including due to violations of the FDA's QSR requirements, our ability to manufacture the finished OTREXUP™ product will be adversely affected and our ability to meet the distribution requirements for any product sales of OTREXUP™ and the resulting revenue therefrom will be negatively affected. Accordingly, there can be no assurance that any failure in any part of our supply chain will not have a material adverse effect on our ability to generate revenue from OTREXUP™, which in turn could have a material adverse effect on our business, results of operations and financial condition.

To mitigate some of the short-term risk of relying on single source suppliers, we intend to build a safety stock of component and finished goods inventories. However, there can be no assurance that these inventories will be adequate or that we will be able to maintain our desired level of safety stock. Additionally, maintaining a high level of safety stock exposes us to additional risks such as excess and obsolete inventory if the sales volume of OTREXUP™ does not meet our forecasts.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for OTREXUP™, or any of our other product candidates for which we may receive regulatory approval, their commercial success may be severely hindered.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the U.S. and in international markets. Third-party coverage and reimbursement for OTREXUP™ or any of our other product candidates for which we may receive regulatory approval may not be available or adequate in either the U.S. or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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, a pen product with exenatide, and an undisclosed pen product. 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. Additionally, Teva is attempting to get an “AB” therapeutic equivalence rating for Vibex® with epinephrine, which would allow for substitution of their generic for Mylan’s branded product at the pharmacy. If Teva does not attain the AB rating, the revenue potential for Vibex® with epinephrine may be more limited than if an “AB” rating is attained.

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, 2014, we derived approximately 33% of our revenue from Teva and 18% from Ferring. For the year ended December 31, 2013, we derived approximately 66% of our revenue from Teva and 19% from Ferring. The revenue from Teva was product sales, royalties and license and development revenue. 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 and increase our continuing losses from operations. If OTREXUP™ is not successful and 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.

None of our significant license or collaboration agreements is perpetual in nature. Each has a specified termination date and may be terminated in advance of the termination date or renewal date by either party under different circumstances, for example a breach by us.

We have 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.

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 device manufacturing for our Vibex® auto injector for OTREXUP™ has involved high volume production of numerous complex parts as well as assembly of those parts. Our planned future device business may necessitate changes and additions to our contract manufacturing and assembly process or the use of a secondary manufacturer 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 MRP 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.

Any failure by Nypro or Phillips, 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.

We have not yet contracted with any third party for the manufacture of Vibex® with Sumatriptan. As a result, if we receive approval from FDA for this product, its launch could be delayed in light of the long lead time necessary to locate a third-party manufacturer, negotiate contract terms with that third party and manufacture the product.

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 and those of our third-party collaboration partners.

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 medical doctors do not prescribe our products or the medical profession or patients do not accept our products, our ability to grow or maintain our revenues will be limited.

Our business is dependent on market acceptance of our products and those of our partners by physicians, healthcare payors, patients and the medical community. Medical doctors' willingness to prescribe, and patients' willingness to accept, our products and those of our partners depend on many factors, including:

- perceived safety and efficacy of our products;
- convenience and ease of administration;
- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- availability of alternative treatments;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of our products;
- publicity concerning our products or competing products; and
- third-party coverage or reimbursement for our products and those of our partners.

Even though we have received regulatory approval for OTREXUP™ and for our transdermal gel products, and even if we receive regulatory approval and satisfy the above criteria for any of our product candidates, physicians may not prescribe, and patients may not accept, our products if we do not promote our products effectively. Factors that could affect our success in marketing our products include:

- the adequacy and effectiveness of our sales force and that of any co-promotion partners or international partner's sales force;
- the adequacy and effectiveness of our production, distribution and marketing capabilities and those of our international partners;
- the success of competing treatments or products, including generics; and
- the availability and extent of reimbursement from third-party payors for our products and those of our partners.

If any of our products or product candidates fails to achieve market acceptance, we may not be able to market and sell the products successfully, which would limit our ability to generate revenue and could harm our business.

Because transdermal gels are not a widely understood method of drug delivery, our partners and consumers may have little experience with such products. 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 significant royalties in this product area.

The failure of our licensees to perform under any of our 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, Pfizer and LEO Pharma and other undisclosed partners for future milestone, sales and royalty revenue. Any or all of these partners may never commercialize a product with our technologies, may be unsuccessful in commercializing a product, 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, we may never be able to achieve profitable operations.

Competitors in the methotrexate, the treatment of migraines, 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 branded 505(b)2 products. 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 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 Pharmaceuticals and Becton Dickinson, along with other companies. We also compete generally with other 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 from several branded and generic products, many from larger companies that have more experience and greater resources than does our Company. In October 2014, Medac launched Rasuvo™, a product that competes directly with OTREXUP™ and could reduce the market penetration of OTREXUP™.

In addition, 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™.

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™.

There also are numerous competitive products on the market to treat migraines. There are currently seven triptans marketed in the U.S. indicated for treatment of migraine. Five are available as generics and two retain patent exclusivity. According to Catamaran, patent protection for Eletriptan (Relpax, Pfizer) will expire in December 2016, while patent protection for Almotriptan (Axert, Janssen) ends in June 2017.

Healthcare professionals frequently prescribe triptans to stop migraine attacks , such as GSK's Imitrex (sumatriptan) and Amerge (naratriptan); Pfizer's Relpax (eletriptan), Merck & Co., Inc.'s ("Merck") 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).

Sumatriptan is currently available in an oral formation, a nasal spray (Imitrex, GSK and generic), a needless injector (Sumavel, Astellas/Zogenix), and a transdermal patch (Zecuity, Teva). Several manufacturers offer versions of injectable sumatriptan with a delivery device, including GSK (Imitrex StatDose), Pfizer (Alsuma) Zogenix, Inc. (Sumavel DosePro), and Sun Pharma (generic sumatriptan autoinjector) and recently Dr. Reddy's Laboratories (generic sumatriptan autoinjector). Two companies, Par Pharmaceutical Companies, Inc. 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.

Although we have applied for, and/or have received, several patents and trademarks, 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.

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.

Based on a Medac press release in January 2014, we became aware that Medac submitted an NDA to the FDA for an auto-pen containing methotrexate. On February 28, 2014, Antares sued Medac and its foreign parent, medac GmbH (together, "Medac"), in the United States District Court for the District of Delaware alleging infringement. Antares is asserting four patents. On March 14, 2014, Antares filed a motion for preliminary injunction seeking to enjoin Medac from selling its methotrexate auto-pen product if and when such product is approved for sale in the U.S., pending the final resolution of the litigation. Two of Antares' asserted patents were at issue in the preliminary injunction. On July 10, 2014, the District Court denied Antares' motion for preliminary injunction. Antares filed an appeal of the denial of the motion for preliminary injunction with the U.S. Court of Appeals for the Federal Circuit (the "Court of Appeals"), appealing the decision as to only one patent (RE44,846, the "'846 patent"). The '846 patent has 37 claims, and four were the subject of the appeal. On November 17, 2014, the Court of Appeals ruled that the District Court properly denied Antares' motion for preliminary injunction because Antares cannot show likelihood of success on the merits, stating that four claims of the one patent on appeal are invalid for failure to satisfy the original patent requirement of 35 U.S.C. § 251. On December 17, 2014, Antares filed a petition seeking a rehearing by the Court of Appeals, and on February 23, 2015, the Court of Appeals denied the petition for rehearing. There is no assurance of success with any patent litigation, and it could be costly and time consuming and depending on the ultimate outcome of the litigation may have an adverse effect on results of operations and OTREXUP™ market penetration.

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. As with any litigation where claims may be 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, U.S. 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. For example, Medac filed a patent infringement suit against Antares, LEO Pharma and, its parent company, LEO Pharma A/S in the United State District Court for the District of New Jersey. On November 18, 2014, Medac and Medac GmbH filed a motion for preliminary injunction seeking to enjoin Antares, LEO Pharma and LEO Pharma A/S from selling OTREXUP in the U.S., pending the final resolution of the litigation. See Legal Proceedings in Part I, Item 3 for a further discussion of the litigation.

On July 1, 2014, Antares filed a petition with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office seeking an *inter partes* review of Medac's '231 patent challenging the validity of the'231 patent. On January 6, 2015, the PTAB issued an order instituting an *inter partes* review of all claims of the '231 patent.

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. On August 28, 2009, King and Meridian had 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. King and Meridian filed an amended complaint, in the same litigation as the '012 patent, adding the '432 patent. Trial was held in February and March, 2012, and 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 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 time and costs seeking approval for our products, which could delay the realization of revenue and, ultimately, decrease our revenues from such products.

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

Applicants for FDA approval often must submit extensive clinical data and supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted 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 Vibex® QS T (testosterone) and QS M 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.

Additionally, based on the written recommendations from the FDA related to our clinical development program for QS T we may need approximately 70 additional subjects exposed to QS T for six months. We are assessing the FDA's comments in the advice letter and their impact on the timing of the filing of a NDA for QS T with the FDA. The timing, cost and design of the study to obtain the additional 70 subjects and data required will be determined based on further discussion with the FDA, but could negatively affect our business if we incur significant costs or delays.

Our business and product development may also be adversely affected by the result and timing of the FDA's review of Teva's ANDA for its epinephrine product and exenatide pen product as we cannot market or sell our injector for use with this drug product in the U.S until it has been approved by the FDA. Additionally, Teva is attempting to get an "AB" therapeutic equivalence rating for Vibex® with epinephrine, which would allow for substitution of their generic for Mylan's branded product at the pharmacy. If Teva does not attain the AB rating, the revenue potential for Vibex® with epinephrine may be more limited than if an "AB" rating is attained. In January 2015, Mylan Specialty, L.P. submitted a Citizen Petition to FDA requesting that FDA not approve Teva's ANDA for a generic epinephrine auto injector until a rigorous review under the established standards for proposed generic emergency use auto injectors is conducted.

We had designed the Vibex® device for a product containing sumatriptan and had completed the majority of the commercial tooling and molds for the product. In the fourth quarter of 2013, we received a complete response letter from the FDA with additional items to be addressed in our filing. We submitted this new data in the first half of 2014. We announced in January 2015 that we received a complete response letter from the FDA that provided revisions to the labeling and minor deficiencies. We submitted a response in March 2015, the review timing of which is completely dependent on the FDA. We will need to make a decision about moving forward with commercial scale tooling and molds prior to launch. We cannot control the timing of FDA's review of our response

or of the ANDA. The submission of our response to the complete response letter does not ensure that the FDA will approve the product, and without FDA approval, we cannot market or sell our injector for use with sumatriptan in the U.S.

In other jurisdictions, we, and the pharmaceutical companies with whom we are developing technologies (both drugs and devices), must obtain required regulatory approvals from regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market the products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues may not materialize or may decline. We may not be able to obtain all necessary regulatory approvals. Additionally, clinical data that we generate or obtain from partners from FDA regulatory filings may not be sufficient for regulatory filings in other jurisdictions and we may be required to incur significant costs in obtaining those regulatory approvals.

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

Drug/device combination products indicated for the treatment of systemic or local conditions, 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 filing under Section 505(b)(2) where there is an acceptable reference product or 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. 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) or the ANDA route. Both the 505(b)(2) and ANDA regulatory pathways are 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 or an ANDA. Additionally, it is customary to reference the most similar predicate products when submitting a 505(b)(2) or ANDA application in order to potentially reduce testing requirements. However, it is important to know 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; and
- 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 Office of Combination Products ("OCP") to address the challenges associated with the review and regulation of combination products. The OCP assists in determining strategies for the approval of drug/delivery combinations and assuring agreement within the FDA on review responsibilities. We may seek approval for a product including an injector and a generic pharmaceutical by filing an ANDA claiming bioequivalence and the same labeling as a comparable referenced product or as a filing under Section 505(b)(2) if there is an acceptable reference product. In reviewing the ANDA filing, the agency may decide that the unique nature of combination products allows them to dispute the claims of bioequivalence and/or same labeling resulting in our re-filing the application under Section 505(b)(2). If such combination products require filing under Section 505(b)(2) we may incur delays in product approval and may incur additional costs associated with testing including clinical trials. The result of an approval for a combination product under Section 505(b)(2) may result in additional selling expenses and a decrease in market acceptance due to the lack of substitutability by pharmacies or formularies. In addition, approval under the 505(b)(2) or ANDA regulatory pathway is not a guarantee of an exclusive position for the approved product in the marketplace.

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 are 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 in a reasonable time, or at all, 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 or who are manufacturing products on our behalf, 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, quarantines 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.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure (or "sunshine") laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the referral of an individual for the furnishing or arranging for the furnishing of any item or service, or the purchase, lease, order, arrangement for, or recommendation of the purchase, lease, or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- the civil federal False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the criminal federal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present of a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- the Veterans Health Care Act of 1992 that requires manufacturers of "covered drugs" to offer them for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs, on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects manufacturers to contractual remedies as well as administrative, civil and criminal sanctions;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the federal Physician Payment Sunshine Act, created under the PPACA, and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, with data collection required beginning August 1, 2013 and reporting to CMS required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, changed by the PPACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts and failure to report accurate pricing information exposes us to federal False Claims Act liability;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare

professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects; and

- the Drug Supply Chain Security Act of 2013 imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, and will be implemented over a 10-year period. Among the requirements of this legislation, manufacturers will be required to provide certain information regarding the drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufactures will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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 Office of Prescription Drug Promotion ("OPDP"), the FDA's marketing surveillance department within the Center for Drug Evaluation and Research, must approve marketing claims asserted by our pharmaceutical company partners. If we or a pharmaceutical company partner fails to obtain from OPDP 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 OPDP.

Risks Related to our Common Stock

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

As of March 4, 2015, we had options outstanding that are exercisable, at exercise prices ranging from $0.47 to $4.57 per share, for an aggregate of approximately 7,245,000 shares of our common stock. Purchasers of our common stock could therefore experience dilution of their investment upon exercise of the above options.

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

As of March 4, 2015, our officers and directors beneficially owned an aggregate of approximately 15,962,000 shares (or approximately 11.9%) 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.

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 currently lease approximately 13,700 square feet of office space in Ewing, New Jersey for our corporate headquarters facility, having amended our lease to add approximately 2,700 square feet, which we occupied beginning in April 2014. This lease will terminate in October 2019.

We currently lease approximately 18,000 square feet of office, laboratory and manufacturing space in Plymouth, a suburb of Minneapolis, Minnesota. This lease will terminate in March 2022.

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.

Item 3. LEGAL PROCEEDINGS

On March 7, 2014, Medac Pharma and Medac GmbH (together, "Medac ") filed suit against Antares, LEO Pharma and its parent company, LEO Pharma A/S (LEO Pharma and LEO Pharma A/S together referred to as the "LEO Entities") in the United States District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac's U.S. Patent 8,664,231 (the "'231 patent") that was issued by the U.S. Patent and Trademark Office on March 4, 2014. The complaint states that the '231 patent relates to a concentration of more than 30mg/mL. Medac alleges that OTREXUP™ infringes the 231 patent, and demands that Antares and the LEO Entities be enjoined from making, using, selling, importing or offering OTREXUP and pay unspecified amounts of compensatory damages, treble damages and attorneys' fees. On November 18, 2014, Medac filed a motion for preliminary injunction seeking to enjoin Antares and the LEO Entities from selling OTREXUP in the United States, pending the final resolution of the litigation. The Company intends to defend itself vigorously.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock trades on the NASDAQ Capital Market under the symbol "ATRS". 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
2014:		
First Quarter	$ 4.95	$ 3.50
Second Quarter	$ 3.65	$ 2.67
Third Quarter	$ 2.85	$ 1.83
Fourth Quarter	$ 2.72	$ 1.88
2013:		
First Quarter	$ 4.30	$ 3.36
Second Quarter	$ 4.20	$ 3.43
Third Quarter	$ 4.58	$ 3.96
Fourth Quarter	$ 4.69	$ 3.64

Common Shareholders

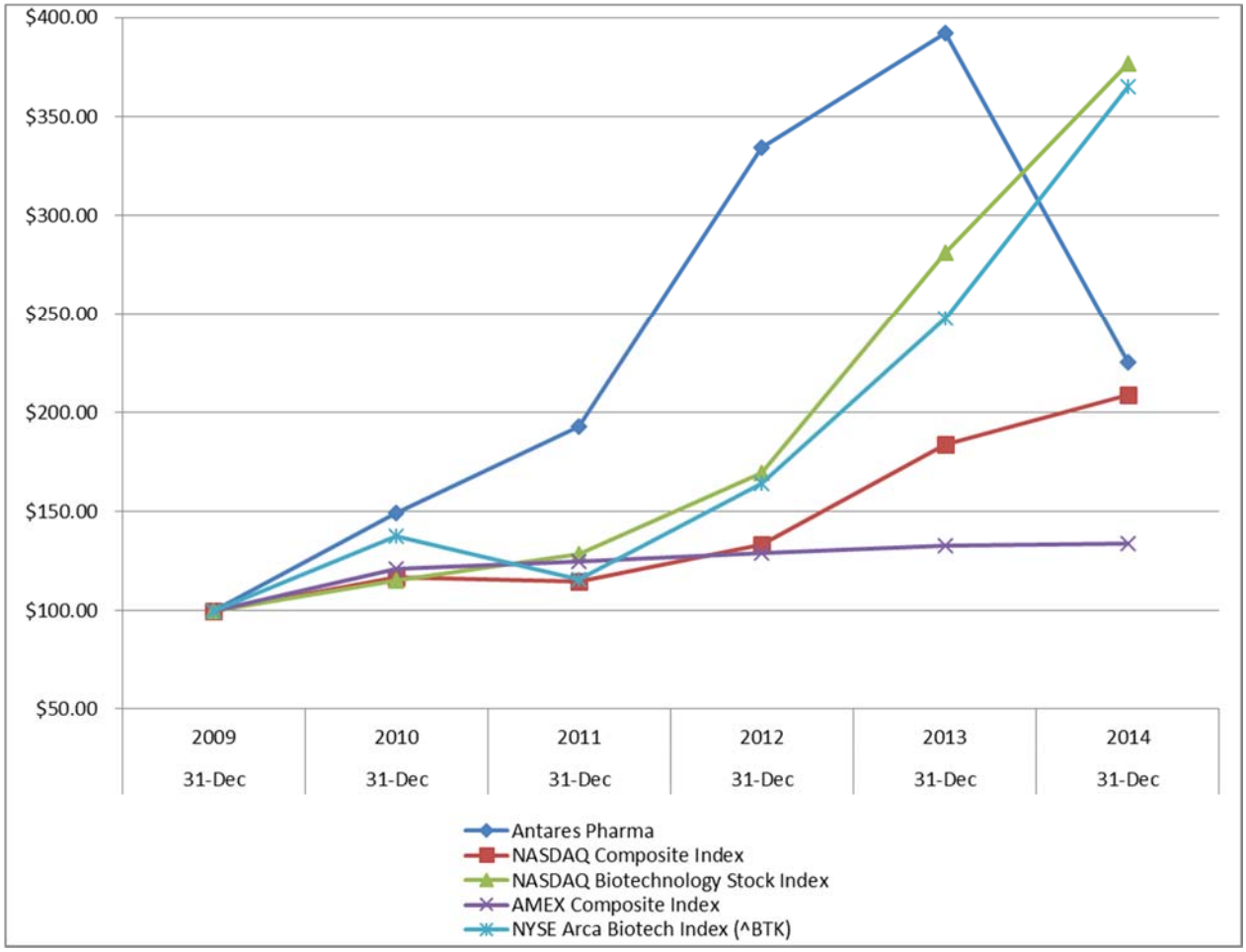
As of March 6, 2015, we had 81 shareholders of record of our common stock as well as approximately 17,000 shareholders in street name.

Dividends

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

Performance Graph

The graph below provides an indication of cumulative total stockholder returns ("Total Return") for the Company as compared with the NASDAQ Composite Index, the NASDAQ Biotechnology Stock Index, the Amex Composite Index, and the NYSE Arca Biotechnology Index (formerly Amex Biotechnology 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, 2009, through December 31, 2014. 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 NYSE Arca Biotechnology Index on December 31, 2009 (based upon the closing price of each). Total Return assumes reinvestment of dividends.



	December 31,					
	2009	**2010**	**2011**	**2012**	**2013**	**2014**
Antares Pharma, Inc.	$ 100.00	$ 149.12	$ 192.98	$ 334.21	$ 392.11	$ 225.44
NASDAQ Composite Index	100.00	116.91	114.81	133.07	184.06	208.71
NASDAQ Biotechnology Stock Index	100.00	115.01	128.59	169.61	280.89	376.68
Amex Composite Index	100.00	121.01	124.84	129.08	132.95	133.94
NYSE Arca Biotechnology Index	100.00	137.73	115.85	164.21	247.36	365.04

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 audited consolidated financial statements for the years ended December 31, 2014, 2013, 2012, 2011 and 2010 and should be read in conjunction with those statements (amounts expressed in thousands, except per share amounts).

	At December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Balance Sheet Data:					
Cash and cash equivalents	$ 34,029	$ 39,067	$ 52,097	$ 19,358	$ 9,848
Investments	6,002	30,022	33,129	15,038	-
Total assets	68,773	88,932	95,527	41,963	15,141
Accumulated deficit	(208,448)	(173,296)	(152,789)	(141,362)	(136,974)
Total stockholders' equity	41,196	70,714	86,551	31,144	6,627

	Year Ended December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Statement of Operations Data:					
Product sales	$ 13,196	$ 10,958	$ 9,138	$ 7,630	$ 5,774
Development revenue	7,246	4,139	7,422	4,462	2,127
Licensing fees	3,709	849	2,141	1,221	2,856
Royalties	2,351	4,672	3,874	3,145	2,062
Revenues	26,502	20,618	22,575	16,458	12,819
Cost of product sales	9,360	6,990	6,117	3,623	2,799
Cost of development revenue	1,877	2,207	3,403	3,174	1,474
Research and development	18,638	15,263	14,921	6,699	8,803
Selling, general and administrative	31,740	17,008	9,585	7,399	5,769
Operating expenses	50,378	32,271	24,506	14,098	14,572
Operating loss	(35,113)	(20,850)	(11,451)	(4,437)	(6,026)
Net other income (expense)	(14)	43	24	49	(65)
Net loss before income taxes	(35,127)	(20,807)	(11,427)	(4,388)	(6,091)
Income tax provision (benefit)	25	(300)	-	-	-
Net loss applicable to common shares	$ (35,152)	$ (20,507)	$ (11,427)	$ (4,388)	$ (6,091)
Net loss per common share (1) (2)	$ (0.27)	$ (0.16)	$ (0.10)	$ (0.05)	$ (0.07)
Weighted average number of common shares	130,550	126,897	110,185	96,995	83,170

(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.

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."

Overview

Antares Pharma, Inc. ("Antares," "we," "our," "us" or the "Company") is an emerging, specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies. We have numerous partnerships with pharmaceutical companies as well as multiple internal product development programs.

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 have 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 cartridges. We have entered into multiple licenses for these devices mainly in the United States ("U.S."), Europe and Canada with Teva Pharmaceutical Industries, Ltd. ("Teva").

We developed the Vibex® auto injector for our product OTREXUP™ (methotrexate) injection. In February 2014, we launched OTREXUP™ (methotrexate) injection, which is the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP™ is indicated for adults with severe active rheumatoid arthritis ("RA"), children with active polyarticular juvenile idiopathic arthritis ("pJIA") and adults with severe recalcitrant psoriasis. To date, we have received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP™. We have worldwide marketing rights for OTREXUP™ and commercialize OTREXUP™ on our own in the U.S. for the treatment of RA. We have provided LEO Pharma, Inc. ("LEO Pharma") an exclusive license to commercialize OTREXUP™ in the U.S. for the treatment of psoriasis.

We are currently conducting clinical studies of Vibex® QS T, for testosterone replacement therapy. On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males. We also have initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system ("CNS") indication.

We also are developing VIBEX® Sumatriptan for the acute treatment of migraines which if approved will be sold by Teva. In January 2015, we received a complete response letter from FDA regarding our Abbreviated New Drug Application ("ANDA") for VIBEX® Sumatriptan, providing revisions to labelling and citing minor deficiencies, and we submitted our response in March 2015.

Our development projects in collaboration with Teva include VIBEX® epinephrine, an exenatide multi-dose pen, and another undisclosed multi-dose pen. In December 2014, Teva submitted the final amendment to the VIBEX® epinephrine ANDA, and FDA accepted Teva's filing of an ANDA in October 2014 for exenatide, formerly referred to as Teva "Pen 2".

We also make a reusable, needle-free, spring-action injector device known as the Tjet® and Zomajet®, which is marketed for use with human growth hormone ("hGH"). We have had success in achieving distribution of our device for use with hGH through licenses to pharmaceutical partners, Ferring Pharmaceuticals BV ("Ferring") and JCR Pharmaceuticals Co., Ltd. ("JCR"), and it has resulted in product sales and royalties. Ferring commercializes our needle-free injection system with their 4 mg and 10 mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X worldwide. Ferring purchased the U.S. rights to 5 mg Tev-Tropin from Teva in the fourth

quarter of 2014. Tev-Tropin 10 mg is pending FDA approval. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

We also have a portfolio of gel-based products which are commercialized through various partners. We received FDA approval in December 2011 for an oxybutynin gel product, Gelnique 3%™, for the treatment of overactive bladder ("OAB"). We have a licensing agreement with Actavis plc ("Actavis") under which Actavis is currently marketing Gelnique 3%™ in the U.S. Elestrin® (estradiol gel) is currently marketed by Meda Pharmaceuticals, Inc. ("Meda") in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

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.

Otrexup Revenue Recognition

In February 2014, we began detailing OTREXUP™ to health care professionals in the U.S. and began shipping to wholesale pharmaceutical distributors, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Given the limited sales history of OTREXUP™, we currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on product shipments of OTREXUP™ until the right of return no longer exists, which occurs at the earlier of the time OTREXUP™ units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. We estimate patient prescriptions dispensed using third-party market prescription data. These third-party sources poll pharmacies, hospitals, mail order and other retail outlets for OTREXUP™ prescriptions and project this sample on a national level. If we underestimate or overestimate patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

We recognized $7,309,603 in OTREXUP™ product revenue, which is net of estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. We had a deferred revenue balance of $1,061,947 at December 31, 2014 for OTREXUP™ product shipments, which is net of estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs.

We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we have sufficient history to estimate product returns. When we are able to reasonably estimate our product returns, we will recognize a one-time increase in net revenue related to the recognition of revenue previously deferred, net of appropriate allowances for estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs.

Product Sales Allowances

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. Our product sales allowances include:

Wholesaler Distribution Fees. We pay distribution fees to certain wholesale distributors based on contractually determined rates. We accrue the fee on shipment to the respective wholesale distributors and recognize the fee as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks. Through December 31, 2014, we have been subject to a minimal amount of chargebacks. We provide discounts primarily to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back the difference between the current wholesale acquisition cost and the price the entity paid for the product. We will estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

Rebates. We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. As of December 31, 2014, rebates have been primarily related to Medicare and Medicaid programs. Under these rebate programs, we will pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue for these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. We offer discount card programs to patients for OTREXUP™ in which patients receive discounts on their prescriptions. We utilize a contract service provider to process and pay claims to patients for actual coupon usage. We make estimates of actual coupon usage based on previous experience and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Other Revenue Recognition

A significant portion of our revenue relates to sales of products other than OTREXUP™ 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 arrangements that are often complex as they may involve license, development, manufacturing and commercialization 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 $10,807,596 at December 31, 2014, 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.

	2014	2013	2012
Product sales	$ 13,195,577	$10,957,932	$ 9,137,573
Development fees	10,629,418	3,561,063	4,054,993
Licensing fees and milestone payments	5,200,000	5,200,000	2,215,716
Royalties	2,351,071	4,671,711	3,874,284
Billings received and/or accrued per contract	31,376,066	24,390,706	19,282,566
Deferred billings received and/or accrued	(12,275,178)	(7,629,270)	(3,075,758)
Deferred revenue recognized	7,400,777	3,857,064	6,368,770
Total revenue as reported	$ 26,501,665	$20,618,500	$22,575,578

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 2014, 2013 or 2012. The gross carrying amount and accumulated amortization of patents, which are our only intangible assets subject to amortization, were $4,468,167 and $1,583,142, respectively, at December 31, 2014 and were $2,635,706 and $1,290,529, respectively, at December 31, 2013. The Company's estimated aggregate patent amortization expense for the next five years is $523,000, $539,000, $539,000, $539,000 and $314,000 in 2015, 2016, 2017, 2018 and 2019, respectively.

We have $1,095,355 of goodwill recorded as of December 31, 2014 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, 2014, which was approximately $339,000,000, 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, 2014 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 2014, 2013 and 2012 resulted in no impairment losses.

Inventory Valuation

Inventory is valued using the first-in, first-out method, assuming full absorption of direct and indirect manufacturing costs and normal capacity utilization of our internal manufacturing operations.

We state inventories at the lower of cost or market. Inventory valuation is based on our judgment of probable future commercial use and net realizable value. We continually evaluate and provide reserves for inventory on hand that is in excess of expected future demand. These reserves are based on estimates of forecasted product demand and the likelihood of consumption in the normal course of business, considering the expiration dates of the inventories on hand, planned production volumes and lead times required for restocking of customer inventories. Although we make every effort to ensure that our forecasts and assessments are reasonable, changes to these assumptions are possible. In such cases, our estimates may prove inaccurate and result in an understatement or overstatement of the reserves required to fairly state such inventories. In connection with evaluation of our OTREXUP™ inventory during 2014, we increased our reserve for excess, dated or obsolete inventory to $3,600,000 at December 31, 2014 from $50,000 at December 31, 2013.

Results of Operations

Years Ended December 31, 2014, 2013 and 2012

Revenues

	2014	2013	2012
OTREXUP™	$ 7,309,603	$ -	$ -
Needle-free injector devices and components	4,409,158	3,495,992	5,434,771
Auto injector and pen injector devices	1,476,816	6,952,072	603,620
Other product sales	-	509,868	3,099,182
Total product sales	13,195,577	10,957,932	9,137,573
Development revenue	7,246,080	4,139,672	7,422,412
Licensing revenue	3,708,938	849,185	2,141,309
Royalties	2,351,071	4,671,711	3,874,284
Total revenue	$ 26,501,665	$20,618,500	$22,575,578

OTREXUP™

In 2014, we began recognizing product revenues from sales of OTREXUP™ made by us and by LEO Pharma under our license and promotion agreement. We began detailing OTREXUP™ to rheumatologists in February 2014, and LEO Pharma began detailing to dermatologists in mid-March 2014. In 2014, we recognized OTREXUP™ net product sales of $7,309,603 based on prescription data.

We sell OTREXUP™ in a package of four pre-filled, single-dose disposable auto injectors to wholesale pharmaceutical distributors, our customers. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of OTREXUP™ to our customers until the right of return no longer exists, which occurs at the earlier of the time OTREXUP™ units are dispensed through patient prescriptions or expiration of the right of return.

We had a deferred revenue balance of $1,061,947 at December 31, 2014 for OTREXUP™ product shipments to wholesalers, which is net of estimated wholesaler fees, stocking allowances, prompt pay discounts, rebates and patient discount programs. We will continue to recognize revenue upon the earlier to occur of prescription units

dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred.

Needle-free injector devices and components

Our sales of reusable needle-free injector devices and disposable components were generated primarily from sales to Ferring and Teva. Ferring uses our needle-free injector with their 4 mg and 10 mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. Teva used our Tjet® needle-free device with their 5 mg hGH Tev-Tropin® marketed in the U.S. The 2014 increase in sales of devices and disposable components was due to increases in sales to Ferring and the 2013 decrease was due to decreases in sales to both Ferring and Teva. In April 2014, Teva initiated a recall of the drug product, Tev-Tropin® (not the device which we supply) and had halted sales of the drug earlier in the year. The recall had a negative effect on the level of product sales to Teva. Ferring purchased the U.S. rights to Tev-Tropin® from Teva in the fourth quarter of 2014. We do not know when sales of Tev-Tropin® 5 mg will resume. Tev-Tropin® 10 mg is pending FDA approval. We do not control our partners' inventory levels of our hGH injectors or disposable components and this can cause significant fluctuations in product sales.

Auto injector and pen injector devices

Revenues in 2014, 2013 and 2012 included $927,250, $450,275 and $310,720, respectively, of sales of pre-commercial pen injector devices to Teva for use with exenatide and an undisclosed product. Revenues in 2014 and 2013 included $399,566 and $6,201,797, respectively, of sales to Teva of our Vibex® auto injector for Teva's generic epinephrine auto injector product. We anticipate shipping additional auto injectors to Teva for their generic epinephrine product beginning in the first quarter of 2015. In addition, product revenue in 2014 included $150,000 of pre-commercial auto injector devices to another customer and 2013 included $300,000 of revenue that had previously been deferred.

Other product sales

Product sales in 2013 and 2012 included $509,868 and $3,099,182, respectively, of sales of our topical oxybutynin gel 3% product to Actavis in connection with their marketing of Gelnique 3%. Product sales to Actavis ended after the first quarter of 2013, as Actavis assumed all manufacturing of Gelnique 3% per our contract with Actavis.

Development Revenue

Development revenues typically represent amounts earned under arrangements with partners in which we develop new products on their behalf. Frequently, we receive payments from our partners that are initially deferred and recognized as revenue over a development period or upon completion of defined deliverables. Development revenue was $7,246,080, $4,139,672 and $7,422,412 for the years ended December 31, 2014, 2013 and 2012, respectively. The development revenue in 2014, 2013 and 2012 included $6,532,063, $3,974,879 and $3,627,157, respectively, related to the Teva auto injector and pen injector programs. The revenue in 2012 also included $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.

Licensing Revenue

Licensing revenues represent the amounts recognized from up-front or milestone payments received from partners that are initially deferred. Licensing revenue was $3,708,938, $849,185 and $2,141,309 for the years ended December 31, 2014, 2013 and 2012, respectively. The licensing revenue in 2014 and 2013 was primarily due to revenue recognized in connection with our license and promotion agreement with LEO Pharma executed in November of 2013, which is being recognized over a 35 month period. 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 2012 and revenue recognized in connection with our license agreement with Actavis. The licensing revenue in

each year also included revenue recognized that was previously deferred in connection with license agreements with Teva, Ferring and other customers.

Royalties

Royalty revenue was $2,351,071, $4,671,711 and $3,874,284 for the years ended December 31, 2014, 2013 and 2012, respectively. We receive royalties from Teva and Ferring related to needle-free injector device sales and/or hGH sales, from Meda Pharma on sales of Elestrin® and from Actavis on sales of Gelnique 3%. In 2014, 2013 and 2012 our royalties related to needle-free injector device sales and/or hGH sales accounted for approximately 55%, 66% and 71%, respectively, of our overall royalty revenue. The decrease in 2014 compared to 2013 was primarily the result of receiving no royalties from Teva after the first quarter of 2014. Our royalties from Teva are based on Teva's sales of their hGH drug, Tev-Tropin®. Teva initiated a recall of the drug product, Tev-Tropin® (not the device which we supply), at the end of April and had halted sales of the drug earlier in the year. We do not know when sales of Tev-Tropin® will resume. The increase in royalties in 2013 was spread relatively evenly among each of our three products.

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 $9,359,457, $6,990,186 and $6,116,726 for the years ended December 31, 2014, 2013 and 2012, respectively, resulting in product gross margins of 29%, 36% and 33%, respectively. The product gross margins for 2014 were reduced as a result of increases to the reserve for potential excess, dated or obsolete OTREXUP™ inventories of $3,550,000. The slight gross margin increase in 2013 was due to the significant reduction in sales of our topical oxybutynin gel 3% product to Actavis, which was sold at a lower gross margin than is realized on injector related product sales. This gross margin increase was partially offset by the gross margin impact of the increase in initial sales to Teva of pre-launch quantities of our Vibex® auto injector for Teva's generic epinephrine auto injector product, which was sold at a lower gross margin than our other injector related products but at a slightly higher gross margin than our oxybutynin gel 3% product.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. Cost of development revenue was $1,877,238, $2,207,044 and $3,403,746 for the years ended December 31, 2014, 2013 and 2012, respectively. Approximately $1,829,000, $2,105,000 and $2,760,000 of development costs were recognized in 2014, 2013 and 2012, respectively, in connection with revenue recognized related to auto injector and pen injector development programs with Teva. In 2012, development costs of approximately $589,000 were related to certain manufacturing readiness activities under the Actavis license agreement.

Research and Development

Research and development expenses consist of external costs for studies and analysis activities, design work and prototype development, FDA fees, and salaries and overhead costs. Research and development expenses were $18,638,016, $15,263,371 and $14,921,552 for the years ended December 31, 2014, 2013 and 2012, respectively. The expenses in 2014 include FDA user fees totaling approximately $1,250,000 recorded in the fourth quarter, which includes an invoice received in December 2014 from the FDA for $970,840 related to the twelve month period ended September 30, 2014 for which approximately $243,000 should have been recorded for the year ended December 31, 2013. The Company has evaluated this out of period adjustment and has determined that it is not material to the Company's financial position or results of operations for 2014. The expenses in 2012 included a fee of approximately $2,000,000 paid in connection with the New Drug Application submitted to the FDA in December 2012. In 2014, research and development expenses were driven primarily by external expenses in connection with development of Vibex® QS T for testosterone replacement therapy. In 2013, expenses were generated in connection with both the Vibex® QS T and OTREXUP™ projects and in 2012 OTREXUP™ was the primary development project. The balance of the research and development expenses in each year consisted of external expenses in connection with other development projects and general operating expenses associated with research and development activities.

Selling, General and Administrative

Selling, general and administrative expenses were $31,740,249, $17,008,216 and $9,585,053 for the years ended December 31, 2014, 2013 and 2012, respectively. The increases each year were primarily due to expenses related to OTREXUP™ market research, product branding, commercialization and pre-commercialization activities. In addition, personnel costs increased as a result of hiring new employees to build our sales and marketing organization in connection with commercialization of OTREXUP™. In 2014 we used a third-party contract sales organization, Quintiles, Inc. ("Quintiles"), to commercialize OTREXUP™ for RA in the U.S. In January 2015, we hired our own internal sales force to replace Quintiles. The increase in expenses in 2014 was also partially due to an increase in legal fees associated with the Medac litigation discussed in Note 10 to the consolidated financial statements.

Liquidity and Capital Resources

We have reported net losses of $35,151,715, $20,506,776 and $11,427,450 in the fiscal years ended 2014, 2013 and 2012, respectively. We have accumulated aggregate net losses from the inception of business through December 31, 2014 of $208,447,656. 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 2014 and 2013, we received proceeds of $3,105,102 and $2,326,838, respectively, from the exercise of warrants and stock options, which resulted in the issuance of 2,669,224 and 2,452,254 shares of our common stock, respectively.

In 2012, we sold 14,259,868 shares of common stock at a price of $4.00 per share in a public offering. The sale of common stock resulted in net proceeds of $53,328,188 after deducting offering expenses of $3,711,284. Proceeds from this offering were raised for further development and commercialization of OTREXUP™, 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.

At December 31, 2014 we had cash and investments of $40,031,327. 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.

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 $26,333,301, $14,968,151 and $10,472,988 for the years ended December 31, 2014, 2013 and 2012, respectively. Net operating cash outflows were primarily the result of net losses of $35,151,715, $20,506,776 and $11,427,450 in 2014, 2013 and 2012, respectively, adjusted by noncash expenses and changes in operating assets and liabilities.

In 2014, the net loss increased by $14,644,939 to $35,151,715 from $20,506,776 in 2013. This increase was primarily the result of an increase in selling, general and administrative expenses due mainly to the launch of OTREXUP™, an increase in research and development expenses due primarily to spending associated with our Vibex® QS T development program, and expenses incurred in connection with the Medac litigation.

In 2013, the net loss increased by $9,079,326 to $20,506,776 from $11,427,450 in 2012. This increase was primarily due to an increase in sales and marketing spending associated with the commercialization of OTREXUP™, an increase in personnel costs associated mainly with employee additions related to increased sales and marketing and research and development activities, and a reduction in gross profit. The increase in the net loss was partially reduced by a decrease in external direct research and development expenses.

Noncash expenses totaled $7,458,978, $3,203,597 and $2,442,313 in 2014, 2013 and 2012, respectively. The increase in 2014 was primarily due to an increase in the inventory reserve of $3,550,000 for potential excess and obsolete OTREXUP™ inventory. The 2014 increase was also impacted by an increase in depreciation and amortization of $665,937, due primarily to depreciation on OTREXUP™ production equipment and amortization of capitalized patent defense costs. The increase in 2013 was primarily due to an increase in stock-based compensation expense of $409,728, an increase in depreciation and amortization of $327,252 and an increase in amortization of premiums and discounts of $143,733. The increase in depreciation and amortization was due to depreciation of OTREXUP™ production equipment which began in 2013 and due to an increase in patent amortization.

In 2014, the change in operating assets and liabilities generated cash of $1,359,436. Increases in deferred revenue of $5,487,873 and accounts payable of $2,688,054 were offset by increases in inventory of $2,948,873, accounts receivable of $2,478,494 and deferred costs of $1,538,148. The increase in deferred revenue was primarily due to a $5,000,000 payment received from LEO Pharma in early 2014 and payments received under Teva development programs, less amounts recognized as revenue during the year. The accounts receivable increase was in large part the result of sales to OTREXUP™ distributors and the inventory increase was related to purchases and production of OTREXUP™ inventory. The increase in deferred costs resulted from costs incurred in connection with development programs with Teva.

In 2013, the change in operating assets and liabilities generated cash of $2,335,028. This was mainly due to an increase in accounts payable of $2,528,740, accrued expenses and other liabilities of $2,534,293 and deferred revenue of $3,196,862, partially offset by an increase in inventories of $5,460,365. Accounts payable and accrued expenses increased at December 31, 2013 compared to December 31, 2012 mainly in connection with commercialization activities and inventory production in preparation for the launch of OTREXUP™. The increase in deferred revenue was primarily related to the $5,000,000 payment received from LEO Pharma in November 2013.

In 2012, the change in operating assets and liabilities used cash of $1,487,851. 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.

Net Cash Provided by (Used in) Investing Activities

In 2014, cash provided by investing activities was $18,346,897, resulting from proceeds from maturities of investments of $24,000,000, offset by purchases of equipment, molds, furniture and fixtures of $4,663,313 and additions to patent rights of $989,790. In 2013, cash used in investing activities was $293,121, consisting of purchases of investments of $21,129,535, purchases of equipment, molds, furniture and fixtures of $2,743,253, additions to patent rights of $420,333, and proceeds from maturities of investments of $24,000,000. 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 in 2014 were primarily for Vibex® QS T auto injector device molds and assembly equipment. In 2013 and 2012, the purchases of equipment, molds, furniture and fixtures were primarily for OTREXUP™ auto injector device molds and assembly equipment. The investment purchases in 2014, 2013 and 2012 were U.S. Treasury bills or U.S. Treasury notes with maturity dates of less than twenty-four months at date of purchase and were classified as held-to-maturity because we had the positive intent and ability to hold the securities to maturity.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled $2,950,705, $2,222,509 and $64,878,685 for the years ended December 31, 2014, 2013 and 2012. In 2014, we received proceeds of $3,105,102 from the exercise of warrants and stock options, and we made payments of $154,397 for employee withholding taxes on net share settlement of equity awards. In 2013, we received proceeds of $2,326,838 from the exercise of warrants and stock options, and we made payments of $104,329 for employee withholding taxes on net share settlement of equity awards. 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, and we made payments of $28,916 for employee withholding taxes on net share settlement of equity awards. A portion of shares held by employees that vested in 2014, 2013 and 2012 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 38,768, 30,153 and 11,165 in 2014, 2013 and 2012, respectively, and were based on the value of the shares on their vesting date as determined by the Company's closing stock price.

Our contractual cash obligations at December 31, 2014 are associated with operating leases and are summarized in the following table:

	Payment Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	After 5 years
Total contractual cash obligations	$ 3,534,779	$ 604,508	$1,210,606	$1,188,671	$ 530,993

Off Balance Sheet Arrangements

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

Research and Development Programs

Our current research and development activities are primarily related to Vibex® QS T and device development projects.

Vibex® QS T. We are developing Vibex® QS T for self-administered weekly injections of testosterone enanthate in a preservative free formulation for men requiring testosterone replacement. 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 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 (Investigational New Drug application) meeting with the FDA as part of preparing to initiate clinical development of Vibex® QS T, establishing an agreed upon clinical path forward. In September 2013, we announced that the first patients were dosed in a clinical study evaluating the pharmacokinetics of testosterone enanthate administered weekly by subcutaneous injection at doses of 50 mg and 100 mg via the Vibex® QS T auto injector device in adult males with testosterone deficiency. The study enrolled 39 patients at nine investigative sites in the U.S. We announced our top-line results of this study on February 20, 2014. The results are considered positive in that Vibex® QS T treatment resulted in most patients achieving average levels of testosterone within the normal range from the first dose onward. Vibex® QS T was also safe and well-tolerated by all dosed patients.

On November 3, 2014, we announced that the last patient has been enrolled in a double-blind, multiple-dose, phase III study (QST-13-003) to evaluate the efficacy and safety of Vibex® QS T administered subcutaneously once each week to testosterone-deficient adult males. Patients enrolled in this study had a documented diagnosis of hypogonadism or testosterone deficiency defined as having testosterone levels below 300 ng/dL. The study includes a screening phase, a treatment titration and efficacy phase and an extended treatment phase. One hundred fifty

patients are enrolled in this study. Patients meeting all eligibility criteria were assigned to receive a starting dose of Vibex® QS T once weekly for six weeks. Adjustments to dose could be made at week seven based upon the week six pre-dose blood level. The efficacy of Vibex® QS T and dose adjustment to regulate testosterone levels will be evaluated after 12 weeks of treatment.

On January 13, 2015, we announced that we received written recommendations from the FDA related to our clinical development program for QS T. The recommendations received were in response to various clinical, Chemistry, Manufacturing and Controls and user study submissions that we made through November 2014. We believe that we have already factored many of the recommendations cited in the advice letter into the protocol of the ongoing phase III study and into the protocols for planned human use studies as a result of guidance provided by FDA at the May 2014 Type C meeting. Based on a single reported occurrence of hives in our phase II study, which the FDA characterized as an apparent allergic reaction, as well as the known safety experience with other parenteral testosterone products, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to QS T with 200 subjects exposed for six months and 100 subjects exposed for a year. We do not believe that the adverse event of hives reported in the phase II study was related to study drug. Based on the number of subjects in previous studies and in the current phase III study, we anticipate that we may need approximately 70 additional subjects exposed to QS T for six months. We are assessing the FDA's comments in the advice letter and their impact on the timing of the filing of a NDA for QS T with the FDA. The timing, cost and design of the study to obtain the additional 70 subjects and data required will be determined based on further discussion with the FDA.

On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in QST-13-003. The protocol for the study required that at the week 12 endpoint: (i) at least 75% of all patients' C_{avg} are within the normal range of 300 to 1100 ng/dL, with a lower limit of a 95% 2-sided confidence interval of greater than or equal to 65%, (ii) at least 85% of patients' C_{max} are less than1500 ng/dL and (iii) no more than 5% of patients had a C_{max} greater than 1800 ng/dL. The primary endpoint of the population that received one or more doses of QS T was met by 139 out of 150 patients, equating to 92.7% with a 95% confidence interval of 87.3% to 96.3%. Among the 137 patients that completed all 12 weeks of dosing and PK sampling, 98.5% were within the pre-defined range. The top-line results are summarized in the table below.

Population/Analysis	**C_{avg} Lower limit of the 95% 2-sided C. I.**	**C_{avg} % in range 300 – 1100 ng/dL n (%)**	**C_{max} <1500 ng/dL n (%)**	**C_{max} >1800 ng/dL n (%)**
Primary analysis* N=150	87.3%	139 (92.7%)	137 (91.3%)**	0%
Completers N=137	94.8%	135 (98.5%)	137 (100%)	0%
Protocol-Required Outcomes	≥65%	75%	≥85%	≤5%
* All patients with 1 or more doses, C_{avg} 0-168 hours post week 12 injection or last measured concentration carried forward **Patients without a C_{max} determination at week 12 are assigned above 1500 ng/dL				

Overall, the regimen demonstrated a mean (± standard deviation) steady state concentration of testosterone of 553.3 ± 127.3 ng/dL at 12 weeks.

Participants in the study will remain on QS T and will be followed for an additional 40 weeks, and the collection of safety data is ongoing. One hundred fifty patients have received at least one dose of study drug and to date, there have been no reported deaths and one serious adverse event ("SAE") of hospitalization for worsening depression. This patient received a single dose of QS T, and the SAE was not considered to be related to study drug. Thus far, there have been no reported adverse events consistent with urticaria (hives).

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 use with exenatide and one undisclosed product. 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 entering the commercial stage of development. 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.

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 2015, 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® 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 operating costs related to managing our research and development projects.

Recently Issued Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-12, *Compensation – Stock Compensation: Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could be Achieved after the Requisite Service Period*, which provides explicit guidance for the accounting treatment for these types of awards. The ASU requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. This update is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. The Company does not expect the adoption of this ASU will have a material impact on its consolidated financial statements.

On May 28, 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

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, 2014, 2013 and 2012 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.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ANTARES PHARMA, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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. and subsidiaries (the Company) as of December 31, 2014 and 2013, 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, 2014. We also have audited the Company's internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control – Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

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

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

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Antares Pharma, Inc. and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles. Also in our opinion, Antares Pharma, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control – Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ KPMG LLP

Minneapolis, Minnesota
March 12, 2015

ANTARES PHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2014	December 31, 2013
Assets		
Current Assets:		
Cash and cash equivalents	$ 34,028,889	$ 39,067,236
Short term investments	6,002,438	24,014,305
Accounts receivable	3,510,051	1,034,492
Inventories	5,859,924	6,461,051
Deferred costs	1,913,921	375,773
Prepaid expenses and other current assets	2,322,464	1,706,678
Total current assets	53,637,687	72,659,535
Equipment, molds, furniture and fixtures, net	10,828,741	6,952,251
Patent rights, net	2,885,024	1,345,177
Goodwill	1,095,355	1,095,355
Long term investments	-	6,008,169
Other assets	325,955	871,444
Total Assets	$ 68,772,762	$ 88,931,931
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 10,071,504	$ 6,378,712
Accrued expenses and other liabilities	5,635,559	5,453,075
Deferred revenue	8,520,517	4,531,220
Total current liabilities	24,227,580	16,363,007
Deferred revenue – long term	3,349,026	1,855,196
Total liabilities	27,576,606	18,218,203
Stockholders' Equity:		
Preferred Stock: $0.01 par; authorized 3,000,000 shares, none outstanding	-	-
Common Stock: $0.01 par; authorized 200,000,000 shares; 131,743,365 and 128,740,604 issued and outstanding at December 31, 2014 and 2013, respectively	1,317,433	1,287,406
Additional paid-in capital	249,032,066	243,375,465
Accumulated deficit	(208,447,656)	(173,295,941)
Accumulated other comprehensive loss	(705,687)	(653,202)
	41,196,156	70,713,728
Total Liabilities and Stockholders' Equity	$ 68,772,762	$ 88,931,931

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2014	2013	2012
Revenue:			
Product sales	$ 13,195,577	$ 10,957,932	$ 9,137,573
Development revenue	7,246,080	4,139,672	7,422,412
Licensing revenue	3,708,938	849,185	2,141,309
Royalties	2,351,070	4,671,711	3,874,284
Total revenue	26,501,665	20,618,500	22,575,578
Cost of revenue:			
Cost of product sales	9,359,457	6,990,186	6,116,726
Cost of development revenue	1,877,238	2,207,044	3,403,746
Total cost of revenue	11,236,695	9,197,230	9,520,472
Gross profit	15,264,970	11,421,270	13,055,106
Operating expenses:			
Research and development	18,638,016	15,263,371	14,921,552
Selling, general and administrative	31,740,249	17,008,216	9,585,053
Total operating expenses	50,378,265	32,271,587	24,506,605
Operating loss	(35,113,295)	(20,850,317)	(11,451,499)
Other income (expense):			
Interest income	76,661	111,577	63,195
Foreign exchange gain (loss)	156	(8,853)	14,414
Other, net	(90,237)	(59,183)	(53,560)
Total other income (expense)	(13,420)	43,541	24,049
Net loss before income taxes	(35,126,715)	(20,806,776)	(11,427,450)
Income tax provision (benefit)	25,000	(300,000)	-
Net loss	$ (35,151,715)	$ (20,506,776)	$ (11,427,450)
Basic and diluted net loss per common share	$ (0.27)	$ (0.16)	$ (0.10)
Basic and diluted weighted average common shares outstanding	130,549,701	126,897,247	110,185,077

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,		
	2014	2013	2012
Net loss	$ (35,151,715)	$ (20,506,776)	$ (11,427,450)
Foreign currency translation adjustment	(52,485)	12,143	(70,020)
Comprehensive loss	$ (35,204,200)	$ (20,494,633)	$ (11,497,470)

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years Ended December 31, 2012, 2013 and 2014

	Common Stock				Accumulated	
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Income (Loss)	Total Stockholders' Equity
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**
Exercise of warrants and options	2,452,254	24,523	2,302,315	-	-	2,326,838
Stock-based compensation	339,326	3,393	2,327,538	-	-	2,330,931
Net loss	-	-	-	(20,506,776)	-	(20,506,776)
Other comprehensive loss	-	-	-	-	12,143	12,143
December 31, 2013	**128,740,604**	**$ 1,287,406**	**$ 243,375,465**	**$ (173,295,941)**	**$ (653,202)**	**$ 70,713,728**
Exercise of warrants and options	2,669,223	26,692	3,078,410	-	-	3,105,102
Stock-based compensation	333,538	3,335	2,578,191	-	-	2,581,526
Net loss	-	-	-	(35,151,715)	-	(35,151,715)
Other comprehensive loss	-	-	-	-	(52,485)	(52,485)
December 31, 2014	**131,743,365**	**$ 1,317,433**	**$ 249,032,066**	**$ (208,447,656)**	**$ (705,687)**	**$ 41,196,156**

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2014	**2013**	**2012**
Cash flows from operating activities:			
Net loss	$ (35,151,715)	$ (20,506,776)	$ (11,427,450)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,224,217	558,280	231,028
Loss on disposal of equipment, molds, furniture and fixtures	39,983	-	119,429
Stock-based compensation expense	2,624,742	2,435,260	2,025,532
Increase in inventory reserve	3,550,000	-	-
Amortization of premiums and discounts	20,036	210,057	66,324
Changes in operating assets and liabilities:			
Accounts receivable	(2,478,494)	1,198,643	310,813
Inventories	(2,948,873)	(5,460,365)	(118,365)
Prepaid expenses and other current assets	(617,121)	(1,222,962)	(177,714)
Deferred costs	(1,538,148)	381,792	444,279
Other assets	545,059	(821,975)	(18,012)
Accounts payable	2,688,054	2,528,740	724,802
Accrued expenses and other current liabilities	221,086	2,534,293	687,297
Deferred revenue	5,487,873	3,196,862	(3,340,951)
Net cash used in operating activities	(26,333,301)	(14,968,151)	(10,472,988)
Cash flows from investing activities:			
Proceeds from maturities of investments	24,000,000	24,000,000	12,000,000
Purchase of investments	-	(21,129,535)	(30,166,239)
Purchases of equipment, molds, furniture and fixtures	(4,663,313)	(2,743,253)	(3,256,632)
Additions to patent rights	(989,790)	(420,333)	(244,761)
Net cash provided by (used in) investing activities	18,346,897	(293,121)	(21,667,632)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	-	-	53,328,188
Proceeds from exercise of warrants and stock options	3,105,102	2,326,838	11,579,413
Taxes paid from net share settlement of equity awards	(154,397)	(104,329)	(28,916)
Net cash provided by financing activities	2,950,705	2,222,509	64,878,685
Effect of exchange rate changes on cash and cash equivalents	(2,648)	8,935	1,067
Net increase (decrease) in cash and cash equivalents	(5,038,347)	(13,029,828)	32,739,132
Cash and cash equivalents:			
Beginning of year	39,067,236	52,097,064	19,357,932
End of year	$ 34,028,889	$ 39,067,236	$ 52,097,064
Noncash investing activities:			
Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	$ 1,118,925	$ 985,365	$ -
Additions to patent rights recorded in accounts payable and accrued expenses	$ 949,631	$ -	$ -

See accompanying notes to consolidated financial statements.

1. Description of Business

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

The Company develops and manufactures for itself and with partners, novel, pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. Antares has 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. Antares also developed a disposable multi-dose pen injector for use with standard cartridges. The Company has entered into multiple licenses for these devices mainly in the United States ("U.S."), Europe and Canada with Teva Pharmaceutical Industries, Ltd. ("Teva").

The Company has developed the Vibex® auto injector for its product OTREXUP™ (methotrexate) injection. In February 2014, Antares launched OTREXUP™ (methotrexate) injection, which is the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP™ is indicated for adults with severe active rheumatoid arthritis ("RA"), children with active polyarticular juvenile idiopathic arthritis ("pJIA") and adults with severe recalcitrant psoriasis. To date, Antares has received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP™. The Company has worldwide marketing rights for OTREXUP™ and commercializes OTREXUP™ on its own in the U.S. for the treatment of RA. The Company has provided LEO Pharma, Inc. ("LEO Pharma") an exclusive license to commercialize OTREXUP™ in the U.S. for the treatment of psoriasis.

The Company is currently conducting clinical studies of Vibex® QS T, for testosterone replacement therapy. On February 25, 2015, Antares announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males. The Company also has initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system ("CNS") indication.

Antares also is developing VIBEX® Sumatriptan for the acute treatment of migraines which if approved will be sold by Teva. In January 2015, the Company received a complete response letter from FDA regarding its Abbreviated New Drug Application ("ANDA") for VIBEX® Sumatriptan, providing revisions to labelling and citing minor deficiencies, and the Company submitted its response in March 2015.

The Company's development projects in collaboration with Teva include VIBEX® epinephrine, an exenatide multi-dose pen, and another undisclosed multi-dose pen. In December 2014, Teva submitted the final amendment to the VIBEX® epinephrine ANDA, and FDA accepted Teva's filing of an ANDA in October 2014 for exenatide, formerly referred to as Teva "Pen 2".

The Company also makes a reusable, needle-free, spring-action injector device known as the Tjet® and Zomajet®, which is marketed for use with human growth hormone ("hGH"). Antares has had success in achieving distribution of our device for use with hGH through licenses to pharmaceutical partners, Ferring Pharmaceuticals BV ("Ferring") and JCR Pharmaceuticals Co., Ltd. ("JCR"), and it has resulted in product sales and royalties. Ferring commercializes our needle-free injection system with their 4 mg and 10 mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X worldwide. Ferring purchased the U.S. rights to 5 mg Tev-Tropin from Teva in the fourth quarter of 2014. Tev-Tropin 10 mg is pending FDA approval. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

The Company also has a portfolio of gel-based products which are commercialized through various partners. Antares received FDA approval in December 2011 for an oxybutynin gel product, Gelnique 3%™, for the treatment of overactive bladder ("OAB"). The Company has a licensing agreement with Actavis plc ("Actavis") under which Actavis is currently marketing Gelnique 3%™ in the U.S. Elestrin® (estradiol gel) is currently marketed by Meda

Pharmaceuticals, Inc. ("Meda") in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

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.

Certain prior year amounts have been reclassified in the consolidated financial statements to conform to the current year presentation. These reclassifications were made to present selling, general and administrative expenses in one line in the consolidated statements of operations. In prior years, sales and marketing expenses and general and administrative expenses were presented in separate lines. These reclassifications had no effect on previously reported net income or total operating expenses.

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, OTREXUP™ revenue recognition based on estimated patient prescriptions dispensed, inventory valuation, valuation of equity instruments used in stock-based compensation, 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). 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 foreign exchange gain (loss) in the consolidated 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. At December 31, 2014, over 98% of the Company's accounts receivable balance is due from OTREXUP™ distributors and its large pharmaceutical partners Teva and Ferring. Each of these companies has historically paid timely and has 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 $37,000 of bad debt expense in 2014 and no bad debt expense in 2013 and 2012. The allowance for doubtful accounts balance was $10,000 at December 31, 2014 and 2013.

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 where substantially all of the Company's inventory is located. Disruption of supply from key vendors or third-party suppliers may have a material adverse impact on the Company's operations. The Company provides reserves for potentially excess, dated or obsolete inventories based on estimates of forecasted product demand and the likelihood of consumption in the normal course of business, considering the expiration dates of the inventories on hand, planned production volumes and lead times required for restocking of customer inventories. Although every effort is made to ensure that forecasts and assessments are reasonable, changes to these assumptions are possible. In such cases, estimates may prove inaccurate and result in an understatement or overstatement of the reserves required to fairly state such inventories. In connection with evaluation of OTREXUP™ inventory during 2014, the reserve for excess, dated or obsolete inventory was increased to $3,600,000 at December 31, 2014 from $50,000 at December 31, 2013.

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 $880,400, $359,471 and $145,775 for the years ended December 31, 2014, 2013 and 2012, respectively.

Goodwill

The Company has $1,095,355 of goodwill recorded as of December 31, 2014 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, 2014, which was approximately $339 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, 2014 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 2014, 2013 and 2012.

Patent Rights

The Company capitalizes the costs 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 the shorter of the life of the patent or the estimated useful life of the patent, which typically is 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.

The Company capitalizes external legal patent defense costs and costs for pursuing patent infringements when it determines that a successful outcome is probable and will lead to an increase in the value of the patent. The capitalized costs are amortized over the remaining life of the related patent. If changes in the anticipated outcome were to occur that reduce the likelihood of a successful outcome of the entire action to less than probable, the capitalized costs would be charged to expense in the period in which the change is determined. As of December 31, 2014 and 2013, approximately $1,800,000 and $100,000, respectively, of external legal patent costs were capitalized within patent rights, net.

Patent amortization expense for the years ended December 31, 2014, 2013 and 2012 was $343,817, $133,788 and $85,253, respectively, and is recorded in general and administrative expenses in the consolidated statements of operations.

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. In 2013, the Company recognized expense of $65,022 in connection with the write off of patent costs related to abandoned patents or patents no longer connected with current products. No impairment charges were recognized in 2014 or 2012. The gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, were $4,468,166 and $1,583,142, respectively, at December 31, 2014 and were $2,635,706 and $1,290,529, respectively, at December 31, 2013. The Company's estimated aggregate patent amortization expense for the next five years is approximately $523,000, $539,000, $539,000, $539,000 and $314,000 in 2015, 2016, 2017, 2018 and 2019, 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, which is a Level 1 fair value measurement. All long-term investments mature in less than two years. At December 31, 2014 the short-term investments had a fair value of $6,005,040 and a carrying value of $6,002,438. At December 31, 2013 the short-term investments had a fair value of $24,021,522 and a carrying value of $24,014,305 and the long-term investments had a fair value of $6,007,851 and a carrying value of $6,008,169.

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.

Otrexup Revenue Recognition

In February 2014, the Company began detailing OTREXUP™ to health care professionals in the U.S. and began shipping to wholesale pharmaceutical distributors, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Given the limited sales history of OTREXUP™, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, recognition of revenue is deferred on product shipments of OTREXUP™ until the right of return no longer exists, which occurs at the earlier of the time OTREXUP™ units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. Patient prescriptions dispensed are estimated using third-party market prescription data. These third-party sources poll pharmacies, hospitals, mail order and other retail outlets for OTREXUP™ prescriptions and project this sample on a national level. If patient prescriptions dispensed for a given period are underestimated or overestimated, adjustments to revenue may be necessary in future periods.

The Company recognized $7,309,603 in OTREXUP™ product revenue, which is net of estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. A deferred revenue balance of $1,061,947 was recorded at December 31, 2014 for OTREXUP™ product shipments, which is net of estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs.

The Company will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until there has been sufficient history to estimate product returns. When it becomes possible to reasonably estimate product returns, a one-time increase in net revenue will be recorded to recognize revenue previously deferred, net of appropriate allowances for estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs.

Product Sales Allowances

The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, it may be necessary to adjust these estimates, which could have an effect on product revenue in the period of adjustment. Product sales allowances include:

Wholesaler Distribution Fees. Distribution fees are paid to certain wholesale distributors based on contractually determined rates. The Company accrues the fee on shipment to the respective wholesale distributors and recognizes the fee as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks. Through December 31, 2014, the Company has been subject to a minimal amount of chargebacks. The Company expects to provide discounts primarily to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current wholesale acquisition cost and the price the entity paid for the product. The Company will estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

Rebates. The Company participates in certain rebate programs, which provide discounted prescriptions to qualified insured patients. As of December 31, 2014, rebates have been primarily related to Medicare and Medicaid programs. Under these rebate programs, the Company will pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. The

Company estimates and accrues for these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. The Company offers discount card programs to patients for OTREXUP™ in which patients receive discounts on their prescriptions that are reimbursed by the Company. The Company estimates the total amount that will be redeemed based on historical redemption experience and on levels of inventory in the distribution and retail channels and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Other Revenue Recognition

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.

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, 2014, $10,807,596 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.

Share-Based Compensation

The Company utilizes share based compensation in the form of stock options, restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs"). 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 Company uses the Black-Scholes option valuation model to determine the fair value of stock options. The fair values of RSU and PSU grants containing service or performance conditions are based on the market value of the Company's Common Stock on the date of grant. The fair value of PSUs containing a market condition are estimated using a Monte Carlo simulation. Pre-vesting forfeitures are estimated in the determination of total stock-based compensation cost based on Company experience. The value of the portion of the award that is ultimately expected to vest is expensed ratably over the requisite service period as compensation expense in the consolidated statement of operations. The determination of fair value of share-based payment awards on the grant date requires significant judgment. Assumptions concerning the Company's stock price volatility and projected employee exercise behavior over the

contractual life of the award can significantly impact the estimated fair value of an award. Given the Company's limited history, such assumptions may not be reflective of the patterns that will ultimately be experienced.

Product Warranty

The Company provides a warranty on its reusable needle-free injector devices. Warranty terms for these devices sold to end-users by dealers and distributors are included in the device instruction manual included with each device sold. Warranty terms for these 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 needle-free injector 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 needle-free injector device is typically 24 months from either the date of retail sale of the device by a dealer or distributor or the date of shipment to a customer if specified by contract. The Company recognizes the estimated cost of warranty obligations at the time the products are shipped based on historical claims incurred by the Company. Actual warranty claim costs could differ from these estimates. Warranty liability activity is as follows:

	Balance at Beginning of Year	Provisions	Claims	Balance at End of Year
2014	$ 100,000	$ 5,100	$ (5,100)	$ 100,000
2013	$ 100,000	$ 50,819	$ (50,819)	$ 100,000
2012	$ 100,000	$ 72,893	$ (72,893)	$ 100,000

Research and Development

Research and development costs are expensed as incurred. In December 2014, the Company received an invoice from the FDA in the amount of $970,840 for user fees related to OTREXUP™ for the twelve month period ending September 30, 2014 for which approximately $243,000 should have been recorded for the year ended December 31, 2013. The Company had not previously recorded the expense associated with this invoice and the full amount was recorded in research and development expenses in the fourth quarter of 2014. The Company has evaluated this out of period adjustment and has determined that it is not material to the Company's financial position or results of operations for 2013 or 2014.

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. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2012, a valuation allowance was established to offset all of the Company's net deferred tax assets, and as of December 31, 2013, a valuation allowance was established to offset all of the U.S. net deferred tax assets. For the year ended December 31, 2013, the Company determined it was more likely than not that a portion of the deferred tax assets would be realized and recorded an income tax benefit of $300,000 after releasing $300,000 of the valuation allowance related to the Switzerland deferred tax assets. For the year ended December 31, 2014, the Company recorded income tax expense related to the Swiss operations of $25,000, reducing deferred tax assets to $275,000 at December 31, 2014.

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, 2014, 2013 and 2012, excluded from dilutive loss per share as their effect is anti-dilutive, are as follows:

	2014	2013	2012
Stock options and warrants	7,245,485	8,242,992	10,830,530

Recent Accounting Pronouncements

In July 2013, the FASB issued Accounting Standards Update 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists" ("ASU 2013-11"). ASU 2013-11 amends accounting guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or tax credit carryforward exists. This new guidance requires entities, if certain criteria are met, to present an unrecognized tax benefit, or portion of an unrecognized tax benefit, in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward when such items exist in the same taxing jurisdiction. The adoption of ASU 2013-11 is expected to reduce diversity in practice by providing guidance on the presentation of unrecognized tax benefits. The provisions of ASU 2013-11 are effective for fiscal years and interim periods beginning after December 15, 2013. The adoption of this update in the first quarter of 2014 did not have a material effect on the Company's consolidated financial statements.

3. Composition of Certain Financial Statement Captions

	December 31, 2014	December 31, 2013
Inventories:		
Raw material	$ 461,396	$ 1,056,054
Work in process	3,896,837	3,034,321
Finished goods	1,501,691	2,370,676
	$ 5,859,924	$ 6,461,051
Equipment, molds, furniture and fixtures:		
Furniture, fixtures and office equipment	$ 1,551,100	$ 1,501,612
Production molds and equipment	8,322,631	7,389,062
Molds and tooling in process	3,836,650	424,521
Less accumulated depreciation	(2,881,640)	(2,362,944)
	$ 10,828,741	$ 6,952,251
Patent rights:		
Patent rights	$ 4,468,166	$ 2,635,706
Less accumulated amortization	(1,583,142)	(1,290,529)
	$ 2,885,024	$ 1,345,177
Accrued expenses and other liabilities:		
Accrued employee compensation and benefits	$ 1,559,255	$ 2,348,456
Liabilities related to OTREXUP™ commercialization and development expenses	1,922,422	1,946,869
OTREXUP™ reserves for discounts, rebates, allowances	230,768	-
Other liabilities	1,923,114	1,157,750
	$ 5,635,559	$ 5,453,075

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 Plymouth, MN, a suburb of Minneapolis, MN. In December 2013, the Company entered into a lease agreement for approximately 18,000 square feet of office, research and development space in a new Plymouth location, which the Company occupied in April 2014. The leases require payment of all executory costs such as maintenance and property taxes. Rent expense incurred for the years ended December 31, 2014, 2013 and 2012 was $611,818, $453,142 and $325,971, respectively. Future minimum lease payments under operating leases with remaining terms in excess of one year as of December 31, 2014 were as follows:

	Amount
2015	$ 594,806
2016	599,539
2017	611,067
2018	622,716
2019	565,955
Thereafter	530,993
Total future minimum lease payments	$ 3,525,076

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, 2014. In the U.S., the Company incurred losses for both book and tax purposes for the year ended December 31, 2014, and, accordingly, no income taxes were provided. In Switzerland, net operating loss carryforwards were used to fully offset taxable income of approximately $200,000, $500,000 and $5,500,000 in the years ended December 31, 2014, 2013 and 2012, respectively.

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

	2014	2013	2012
U.S.	$ (35,359,378)	$ (21,568,727)	$ (16,477,710)
Switzerland	232,663	761,951	5,050,260
	$ (35,126,715)	$ (20,806,776)	$ (11,427,450)

Effective tax rates differ from statutory income tax rates in the years ended December 31, 2014, 2013 and 2012 as follows:

	2014	2013	2012
Statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes	(3.7)	(1.0)	(3.6)
Valuation allowance increase (decrease)	37.8	28.8	29.8
Effect of foreign operations	(0.2)	(0.7)	(8.5)
Change in unused net operating loss and credit carryforwards	(0.2)	(1.0)	14.0
Nondeductible items	0.4	6.5	0.6
Other	-	-	1.7
	0.1%	(1.4)%	0.0%

Deferred tax assets (liabilities) as of December 31, 2014 and 2013 consist of the following:

	2014	2013
Gross deferred tax assets:		
Net operating loss carryforward – U.S.	$ 40,428,000	$ 28,832,000
Net operating loss carryforward – Switzerland	3,128,000	4,556,000
Research and development tax credit carryforward	3,617,000	2,589,000
Deferred revenue	1,292,000	320,000
Stock-based compensation	1,677,000	1,581,000
Inventory reserve	1,356,000	18,000
Compensation accruals	425,000	38,000
Other	41,000	37,000
	51,964,000	37,971,000
Gross deferred tax liabilities - depreciation and amortization	(648,000)	(105,000)
Less valuation allowance	(51,041,000)	(37,566,000)
Net deferred tax asset	$ 275,000	$ 300,000

The valuation allowance for deferred tax assets as of December 31, 2014 and 2013 was $51,041,000 and $37,566,000, respectively. The total valuation allowance increased $13,475,000 for the year ended December 31, 2014 and increased $5,076,000 for the year ended December 31, 2013.

In 2013, management determined it was more likely than not that a portion of the deferred tax assets associated with NOL carryforwards in Switzerland will be realized; therefore, $300,000 of the valuation allowance was released as of December 31, 2013. This determination was made after considering that the Switzerland operations had generated taxable income for two consecutive years, 2013 and 2012, and after determining that it appeared likely that taxable income would continue in future years. 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. In 2014, the Switzerland operations generated taxable income of approximately $200,000 and the Company recognized tax expense of $25,000, realizing the benefit of $25,000 of deferred tax assets associated with NOL carryforwards in Switzerland.

After considering the evidence with respect to the U.S. deferred tax assets, management determined that as of December 31, 2014, it continues to be more likely than not that the U.S. deferred tax assets will not be realized and has recorded a valuation allowance against all U.S. deferred tax assets.

The Company has a U.S. federal net operating loss carryforward at December 31, 2014, of approximately $116,800,000, 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 2034. Included in the federal net operating loss is approximately $5,600,000 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 research credit carryforwards of approximately $3,600,000. These credits expire in years 2018 through 2034.

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, 2014, of approximately $23,200,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2015 through 2018, with approximately $22,700,000 expiring over the next three years.

As of December 31, 2014 and 2013, 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 2009 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.

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, 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 21,000,000 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 each option is 10 years and the options typically vest in quarterly installments over a three-year period. As of December 31, 2014, the Plan had 4,250,074 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the Plan as of December 31, 2014 and the changes during the three years then ended is as follows:

	Number of Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($)
Outstanding at December 31, 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		
Granted/Issued	1,129,380	3.99		
Exercised	(981,385)	0.72		3,319,471
Cancelled/Forfeited	(264,664)	3.48		
Outstanding at December 31, 2013	7,697,892	1.89		
Granted/Issued	2,596,201	2.89		
Exercised	(2,124,123)	1.21		3,585,453
Cancelled/Forfeited	(924,485)	3.41		
Outstanding at December 31, 2014	7,245,485	2.25	6.7	4,640,730
Exercisable at December 31, 2014	4,876,651	1.87	5.4	4,461,950

As of December 31, 2014, there was approximately $3,400,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.2 years.

Stock option expense recognized in 2014, 2013 and 2012 was approximately $2,060,000, $1,364,000 and $1,164,000, respectively. The per share weighted average fair value of options granted during 2014, 2013 and 2012 was estimated as $1.64, $2.26, $1.64, 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,		
	2014	2013	2012
Risk-free interest rate	1.6%	0.9%	0.7%
Annualized volatility	60.7%	62.0%	61.0%
Weighted average expected life, in years	6.0	6.0	5.0
Expected dividend yield	0.0%	0.0%	0.0%

Option exercises during 2014, 2013 and 2012 resulted in proceeds of $2,564,987, $692,348 and $792,203, respectively, and in the issuance of shares of common stock of 2,124,123 in 2014, 981,385 in 2013 and 965,597 in 2012. 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.

Stock Awards

The employment agreements with certain members of executive management included performance-based incentives under which the executives could be awarded shares of common stock upon the occurrence of various triggering events. As of December 31, 2013, the time period for these potential awards had expired. There were 35,000 shares awarded under these agreements in 2012.

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. In 2014, there were 150,000 shares of common stock granted to members of executive management as bonus compensation for achievements in 2013. There were no discretionary grants of common stock in 2013, and grants in 2012 totaled 60,000.

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 $8,722 and $301,017 in 2013 and 2012, respectively.

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. In 2014, no shares were granted to the directors, as all directors' compensation was paid in cash and stock options. 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 $356,000, $679,500 and $560,000 in 2014, 2013 and 2012, respectively.

Long Term Incentive Program

The Company's Board of Directors has approved a long term incentive program ("LTIP") for the benefit of the Company's senior executives. Pursuant to the LTIP, the Company's senior executives have been awarded stock options and performance stock units ("PSU") with targeted values based on values granted by the Company's peer group. In 2014, the program was modified such that the value of the annual award for each senior executive was delivered 50% in the form of PSUs, 25% in the form of shares of restricted stock units ("RSU") and 25% in the form of stock options. In the prior year, 33% of the value for each senior executive was delivered in the form of stock options, 33% of the value was delivered in the form of PSUs and 33% was delivered in the form of RSUs. 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, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the stock options table above. The RSUs vest in three equal annual installments. Expense recognized in 2014 and 2013 in connection with the

RSUs was approximately $212,000 and $125,000, respectively. The PSU awards made to the senior executives 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. In connection with PSU awards for defined performance goals considered probable of achievement, a net expense reduction of $3,000 was recognized in 2014. The net expense reduction was primarily the result of the reversal of expense associated with awards previously granted to senior executives who left the Company in 2014 where the awards will not vest. Expense recognized in 2013 in connection with the PSUs for defined performance goals considered probable of achievement was $259,000.

The 2014 awards included PSUs that will be earned based on the Company's total shareholder return ("TSR") as compared to the Nasdaq Biotechnology Index ("NBI") at the end of the performance period, which performance period is January 1, 2014 to December 31, 2016. These PSUs were granted with a grant date fair value of $2.64. The fair value of the target number of shares that can be earned is being recognized as compensation expense over the performance period, and expense of $66,280 was recognized in connection with this award in 2014. Depending on the outcome of the performance goal, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 150% of the PSUs granted.

The fair value of the TSR PSUs granted in 2014 was determined using a Monte Carlo simulation and utilized the following inputs and assumptions:

Closing stock price on grant date	$ 3.09
Performance period starting price	$ 4.08
Term of award (in years)	2.59
Volatility	50.87 %
Risk-free interest rate	0.61 %
Expected dividend yield	0.0 %
Fair value per TSR PSU	$ 2.64

The performance period starting price is measured as the average closing price over the last 20 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of the Company's common stock and the common stocks of the NBI companies and stock price volatilities of the NBI companies.

The performance stock unit awards and restricted stock granted under the long term incentive program are summarized in the following table:

	Performance Stock Units		Restricted Stock	
	Number of Shares	Weighted Average Fair Value ($)	Number of Shares	Weighted Average Fair Value ($)
Outstanding at December 31, 2011	182,000	1.66	-	-
Granted	137,715	4.26	-	-
Vested	-	-	-	-
Forfeited/Expired	-	-	-	-
Outstanding at December 31, 2012	319,715	2.78	-	-
Granted	185,185	3.96	185,185	3.96
Vested	-	-	-	-
Forfeited/Expired	(98,237)	3.32	(29,461)	3.96
Outstanding at December 31, 2013	406,663	3.19	155,724	3.96
Granted	651,980	3.02	325,991	3.02
Vested	(87,519)	2.03	(51,907)	3.96
Forfeited/Expired	(507,582)	3.26	(198,684)	3.45
Outstanding at December 31, 2014	463,542	3.08	231,124	3.07

A portion of the shares that were granted as discretionary shares or under the LTIP that vested in 2014, 2013 and 2012 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 38,768, 30,153 and 11,165 in 2014, 2013 and 2012, 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 $154,397, $104,329 and $28,916 in 2014, 2013 and 2012, 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.

Warrants

Warrant activity is summarized as follows:

	Number of Shares	Weighted Average Price ($)
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
Exercised	(1,470,869)	1.11
Cancelled	(1,000,000)	3.78
Outstanding at December 31, 2013	545,100	1.00
Exercised	(545,100)	1.00
Outstanding at December 31, 2014	-	

Warrant exercises during 2014, 2013 and 2012 resulted in proceeds of $545,115, $1,634,490 and $10,787,210, respectively, and in the issuance of 545,100, 1,470,869 and 7,056,075 shares of common stock, respectively.

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, 2014, 2013 and 2012, the total number of employees enrolled in the plan has increased and the Company elected to make contributions to the plan totaling approximately $373,000, $230,000 and $173,000, respectively.

8. License Agreements

Development and License Agreement

In September 2014 the Company entered into a development and license agreement with an undisclosed pharmaceutical partner, under which the Company will develop and supply an auto injector product for delivery of an undisclosed drug. Under the agreement, an upfront payment, development milestones, and royalties on the partner's product sales, as well as a purchase price for each device sold are to be received by the Company. The Company identified and evaluated a number of deliverables in the agreement and concluded that the manufacturing deliverable has stand-alone value but the license and development work do not have value on a stand-alone basis. As a result, the license and development deliverables do not qualify for treatment as separate units of accounting. Accordingly, the license and development deliverables will be accounted for as a single unit of accounting and will be recognized as revenue during the estimated development period. The Company recognized revenue in 2014 of approximately $560,000 and recorded deferred revenue of $115,000 at December 31, 2014 in connection with this agreement.

LEO Pharma Promotion and License Agreement

In November 2013, the Company entered into a promotion and license agreement with LEO Pharma. Under this agreement the Company granted LEO Pharma the exclusive right to promote OTREXUP™ to dermatologists for symptomatic control of severe recalcitrant psoriasis in adults in the U.S. LEO Pharma is responsible for promotion and marketing activities in dermatology and the Company is responsible for the supply of OTREXUP™

product and samples. The Company received from LEO Pharma a non-refundable upfront payment of $5.0 million, a milestone payment of $5.0 million and will receive a milestone payment of $10.0 million upon realizing a defined level of net sales in a calendar year. The Company will pay LEO Pharma a percentage of net sales generated in dermatology and will record the payments to LEO Pharma as sales and marketing expense.

The Company identified and evaluated a number of deliverables in the agreement and concluded that none of the deliverables have value on a stand-alone basis. As a result, these deliverables do not qualify for treatment as separate units of accounting. Accordingly, the deliverables have been accounted for as a single unit of accounting and each of the payments will be allocated to these deliverables and will be recognized as revenue over the 35 month estimated life of the agreement. The Company recognized revenue of $3,429,000 and $571,000 in the years ended December 31, 2014 and 2013, respectively, and recorded deferred revenue of $6,000,000 at December 31, 2014.

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, which was deferred, 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 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, the Company is now developing two different disposable pens, one for each product. The Company determined that the changes to the agreement as a result of the amendment was a material modification to the agreement and the accounting for the revenue and costs under this agreement was changed. 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. 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. In May 2013 the agreement was amended to provide for one year automatic renewals unless terminated by either party six months ahead of the expiring term. In the fourth quarter of 2014, Teva sold the U.S. rights to 5 mg Tev-Tropin to Ferring. Tev-Tropin 10 mg is pending FDA approval.

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 U.S. 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.

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 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.

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. Payments received in connection with milestones 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.

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.

In the fourth quarter of 2014, Ferring purchased the U.S. rights to Tev-Tropin from Teva. Tev-Tropin 10 mg is pending FDA approval.

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 assumed 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.

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.

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 under which Daewoong will commercialize the Company's oxybutynin gel 3% product in South Korea, once approved. This agreement was terminated in 2014.

ANI License Agreement (formerly BioSante)

In June 2000, the Company entered into an exclusive agreement to license four applications of its drug-delivery technology to ANI Pharmaceuticals, formerly BioSante Pharmaceuticals ("ANI"), in the U.S., Canada, China, Australia, New Zealand, South Africa, Israel, Mexico, Malaysia and Indonesia (collectively, the "ANI Territories"). ANI will use the licensed technology for the development of hormone replacement therapy products. At the signing of the contract, ANI 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 ANI under a sublicense agreement. The initial upfront payment received by the Company was for the delivery of intellectual property to ANI. 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 ANI a royalty from the sale of licensed products. The Company will also receive a portion of any sublicense fees received by ANI.

In December 2009, ANI entered into a license agreement with Azur Pharma International II Limited ("Azur"), for Elestrin®. ANI has received payments from Azur which triggered sublicense payments to the Company. Because final regulatory approval for this product was obtained by ANI and Antares had no further 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 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. 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,		
	2014	2013	2012
United States of America	$ 21,409,371	$16,479,855	$16,964,635
Europe	4,761,684	3,901,422	4,936,981
Other	330,610	237,223	673,962
	$ 26,501,665	$20,618,500	$22,575,578

Revenues by product type:

	For the Years Ended December 31,		
	2014	2013	2012
Injection devices and supplies	$ 25,245,200	$18,156,217	$12,642,537
Transdermal gel products	1,256,465	2,462,283	9,933,041
	$ 26,501,665	$20,618,500	$22,575,578

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

	2014	2013	2012
Teva	$ 8,682,384	$ 13,559,541	$7,495,978
Ferring	4,760,084	3,827,098	4,933,369
McKesson (1)	3,460,000	-	-
LEO Pharma	3,428,571	571,428	-
Actavis	449,862	1,489,942	6,770,635

(1) Represents estimated revenue based on OTREXUP™ shipments, a portion of which has not been recognized as revenue but is recorded in deferred revenue at December 31, 2014 as discussed in Note 2 to the Consolidated Financial Statements.

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

	2014	2013
Teva	$ 1,455,284	$ 436,632
Ferring	651,897	562,576
Mckesson	797,763	-
AmerisourceBergen	448,483	-

10. Legal Proceedings

In the first quarter of 2014, Medac Pharma, Inc. ("Medac Pharma") announced that it submitted a New Drug Application ("NDA") to the FDA for an auto-pen containing methotrexate. On February 28, 2014, Antares filed a complaint against Medac Pharma and Medac GmbH, the parent company of Medac Pharma, ("Medac GmbH", together with Medac Pharma, "Medac") in the United States District Court for the District of Delaware, alleging infringement four of the Company's patents. On March 14, 2014, Antares filed a motion for preliminary injunction seeking to enjoin Medac from selling its methotrexate auto-pen product if and when such product is approved for sale in the United States, pending the final resolution of the litigation. Two of Antares' asserted patents were at issue in the preliminary injunction. On July 10, 2014, the District Court denied Antares' motion for preliminary injunction. Antares has filed an appeal of the denial of the motion for preliminary injunction with the U.S. Court of Appeals for the Federal Circuit appealing the decision as to only one patent (RE44,846, the "'846 patent"). The '846 patent has 37 claims, and four were the subject of the appeal. On November 17, 2014, the Court of Appeals ruled that the District Court properly denied Antares' motion for preliminary injunction because Antares cannot show likelihood of success on the merits, stating that four claims of the one patent on appeal are invalid for failure to satisfy the original patent requirement of 35 U.S.C. § 251. On December 17, 2014, Antares filed a petition seeking a rehearing by the Court of Appeals, and on February 23, 2015, the Court of Appeals denied the petition for rehearing. During the year ended December 31, 2014, a total of approximately $1,700,000 in legal costs in connection with this suit has been capitalized. However, there is no assurance of success with any patent litigation, and it could be costly and time consuming and depending on the ultimate outcome of the litigation may have an adverse effect on results of operations and OTREXUP™ market penetration. If the Company determines that the likelihood of a successful outcome of the entire action changes and becomes less than probable, the capitalized costs would be charged to expense in the period in which the change is determined.

On March 7, 2014, Medac filed suit against Antares, LEO Pharma and its parent company, LEO Pharma A/S (LEO Pharma together with LEO Pharma A/S, the "LEO Entities") in the United States District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac Pharma's U.S. Patent 8,664,231 (the "231 patent") that was issued by the U.S. Patent and Trademark Office on March 4, 2014. The complaint states that the 231 patent relates to a concentration of more than 30mg/mL. Medac alleges that OTREXUP™ infringes the 231 patent and demands that Antares and the LEO Entities be enjoined from making, using, selling, importing or offering OTREXUP™ and pay unspecified amounts of compensatory damages, treble damages and attorneys' fees. On November 18, 2014, Medac filed a motion for preliminary injunction seeking to enjoin Antares and the LEO Entities from selling OTREXUP in the United States, pending the final resolution of the litigation. The Company intends to defend itself vigorously. Under the terms of the promotion and license agreement between the Company and the LEO Entities, the Company agreed to indemnify the LEO Entities from claims that OTREXUP™ infringes the intellectual property rights of any third party. On July 1, 2014, Antares filed a petition with the Patent Trial and

Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office seeking an *inter partes* review of Medac's '231 patent challenging the validity of the'231 patent. On January 6, 2015, the PTAB issued an order instituting an *inter partes* review of all claims of the '231 patent. Legal costs in connection with these proceedings are expensed as incurred.

11. Quarterly Financial Data (unaudited)

	First	Second	Third	Fourth
2014:				
Total revenues	$ 5,202,195	$ 6,326,785	$ 6,570,581	$ 8,402,104
Gross profit	4,025,450	4,196,705	4,063,215	2,979,600
Net loss (1)	(8,794,605)	(9,097,725)	(7,186,441)	(10,072,944)
Net loss per common share (2)	(0.07)	(0.07)	(0.05)	(0.08)
Weighted average shares	129,656,257	130,051,896	130,771,380	131,694,429
2013:				
Total revenues (3)	$ 4,528,222	$ 5,837,544	$ 5,507,824	$ 4,744,910
Gross profit (3)	2,501,079	2,356,862	2,503,222	4,060,107
Net loss	(3,408,448)	(5,103,256)	(6,359,957)	(5,635,115)
Net loss per common share (2)	(0.03)	(0.04)	(0.05)	(0.04)
Weighted average shares	126,106,713	126,462,677	127,162,064	127,835,641

(1) In December 2014, the Company received an invoice from the FDA in the amount of $970,840 for user fees related to OTREXUP™ for the twelve month period ended September 30, 2014 for which approximately $243,000 should have been recorded in the fourth quarter of 2013 and in the first, second and third quarters of 2014. The Company had not previously recorded the expense associated with this invoice and the full amount was recorded in research and development expenses in the fourth quarter of 2014 in the table above. The Company has evaluated this out of period adjustment and has determined that it is not material to the Company's financial position or results of operations for any of the quarterly periods in 2013 or 2014.

(2) 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.

(3) Total revenues in the fourth quarter of 2013 included over $1.1 million more licensing and royalty revenue than in each of the prior three quarters, resulting in a higher gross profit as there were no associated costs with these revenues. Also impacting gross profit in the fourth quarter was development revenue having a higher gross profit than development revenue in prior quarters.

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, 2014. 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 (1992).

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 (1992) criteria, management has concluded that its internal control over financial reporting was effective as of December 31, 2014 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 in Item 8 of this Annual Report on 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, 2014 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item concerning our directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2015 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 2015 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 2015 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 2015 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 2015 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 2015 annual meeting, and is incorporated herein by reference.

The following table provides information for our equity compensation plans as of December 31, 2014:

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	7,245,485	$ 2.25	4,250,074

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 2015 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 2015 annual meeting, and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements - see Part II

(2) Financial Statement Schedules

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

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

(b) Exhibits

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

Exhibit No.	Description
3.1	Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 4.1 to Form S-3 on April 12, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 19, 2008 and incorporated herein by reference.)
3.3	Amended and Restated By-laws of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 15, 2007 and incorporated herein by reference.)
3.4	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 28, 2013 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	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.)
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8+	Antares Pharma, Inc. 2008 Equity Compensation Plan, as amended (Filed as Exhibit A to the Company's Definitive Proxy Statement on Form DEF 14A filed with the Commission on April 15, 2013 and incorporated herein by reference.)
10.0	Stock Purchase Agreement with Permatec Holding AG, Permatec Pharma AG, Permatec Technologie AG and Permatec NV with First and Second Amendments dated July 14, 2000 (Filed as an exhibit to Schedule 14A on December 28, 2000 and incorporated herein by reference.)
10.1	Third Amendment to Stock Purchase Agreement, dated January 31, 2001 (Filed as exhibit 10.1 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)

10.2*	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. (Filed as Exhibit 10.13 to Form 10-K for the year ended December 31, 2012 and incorporated herein by reference.)
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. (Filed as Exhibit 10.16 to Form 10-K for the year ended December 31, 2012 and incorporated herein by reference.)
10.17+	Form of Performance Stock Unit Grant (Filed as Exhibit 10.1 to Form 8-K on May 23, 2011 and incorporated herein by reference.)
10.18+	Form of Performance Stock Unit Grant (Filed as Exhibit 10.1 to Form 8-K on July 12, 2012 and incorporated herein by reference.)
10.19+	Form of Performance Stock Unit Grant (Filed as Exhibit 10.1 to Form 10-Q on August 7, 2013 and incorporated herein by reference.)
10.20	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.)
10.21	First Amendment to Lease between Princeton South Investors, LLC and Antares Pharma, Inc., dated January 28, 2013. (Filed as Exhibit 10.22 to Form 10-K for the year ended December 31, 2012 and incorporated herein by reference.)

10.22	Second Amendment to Lease between Princeton South Investors, LLC and Antares Pharma, Inc., dated December 4, 2013. (Filed as Exhibit 10.22 to Form 10-K for the year ended December 31, 2013 and incorporated herein by reference.)
10.23	Lease Agreement between St. Paul Fire and Marine Insurance Company and Antares Pharma, Inc., dated December 20, 2013. (Filed as Exhibit 10.23 to Form 10-K for the year ended December 31, 2013 and incorporated herein by reference.)
10.24+	Employment Agreement, dated April 25, 2014, by and between Antares Pharma, Inc. and Jennifer Evans Stacey. (Filed as Exhibit 10.1 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.25+	Employment Agreement, dated June 23, 2014, by and between Antares Pharma, Inc. and Eamonn P. Hobbs. (Filed as Exhibit 10.2 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.26	Form of Indemnification Agreement between Antares Pharma, Inc. and each of its directors and executive officers. (Filed as Exhibit 10.3 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.27+	Antares Pharma, Inc. Severance Plan, dated May 29, 2014. (Filed as Exhibit 10.4 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.28+*	Form of Performance Stock Unit Grant. (Filed as Exhibit 10.5 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.29+	Employment Agreement, dated November 17, 2014, by and between Antares Pharma, Inc. and James E. Fickenscher. #
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.##
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.

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 12, 2015.

ANTARES PHARMA, INC.

/s/ Eamonn P. Hobbs
Eamonn P. Hobbs
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 12, 2015.

Signature	**Title**
/s/ Eamonn P. Hobbs Eamonn P. Hobbs	President and Chief Executive Officer, Director (Principal Executive Officer)
/s/James E. Fickenscher James E. Fickenscher	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
/s/Leonard S. Jacob Dr. Leonard S. Jacob	Director, Chairman of the Board
/s/Thomas J. Garrity Thomas J. Garrity	Director
/s/Jacques Gonella Dr. Jacques Gonella	Director
/s/Anton G. Gueth Anton G. Gueth	Director
/s/Marvin Samson Marvin Samson	Director
/s/Robert P. Roche, Jr. Robert P. Roche, Jr.	Director