ANTARES PHARMA, INC.
Form 10-K
March 08, 2016

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, 2015

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For transition period from to

Commission file number 1-32302

ANTARES PHARMA, INC.

(Exact name of registrant as specified in its charter)

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 o 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 o 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 o

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 o

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. o

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

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

Aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2015, was $294,965,000 (based upon the last reported sale price of $2.08 per share on June 30, 2015, on the NASDAQ Capital Market).

There were 154,848,512 shares of common stock outstanding as of March 1, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2016 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

ANTARES PHARMA, INC.

FORM 10-K

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PART I

Item 1. BUSINESS

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 o 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 development including clinical trial results, and potential approval by the United States ("U.S.") Food and Drug Administration ("FDA") of VIBEX® QuickShot® for Testosterone injection ("VIBEX® QS T");
- our expectations regarding product development and potential FDA approval of VIBEX® Epinephrine Pen ("epinephrine auto injector") and Teva Pharmaceutical Industries, Ltd.'s ("Teva") ability to successfully commercialize the epinephrine auto injector;
- our expectations regarding our, and our partner Teva's ability to successfully commercialize and launch VIBEX® Sumatriptan (sumatriptan injection);
- our expectations regarding continued product development with our partners, including Teva and AMAG Pharmaceuticals, Inc. ("AMAG");
- 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;
- timing and results of our clinical trials;
- our future cash flow and our ability to support our operations;
- the impact of new accounting pronouncements and our expectations and estimates with regard to current accounting practices, including estimates of OTREXUP™ prescription data provided by third-party sources, which are used in our revenue recognition methods; 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. Forward-looking statements involve known and unknown risks, uncertainties and assumptions, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

- delays in product introduction and marketing or interruptions in supply;

- a decrease in business from our major customers and partners;
- our inability to compete successfully against new and existing competitors or to leverage our research and development capabilities and our marketing capabilities;

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- our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers;
- our inability to effectively protect our intellectual property;
- costs associated with future litigation and the outcome of such litigation;
- our inability to attract and retain key personnel;
- changes or delays in the regulatory process;
- adverse economic and political conditions; and
- our ability to obtain additional financing, reduce expenses or generate funds when necessary.

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 the development and commercialization of self-administered parenteral pharmaceutical products and technologies. Our subcutaneous injection technology platforms include VIBEX® disposable pressure-assisted auto injectors, Vision® reusable needle-free injectors, and disposable multi-use pen injectors. We have multiple internal product development programs as well as significant partnership arrangements with several industry leading pharmaceutical companies. We have formed strategic alliances with Teva Pharmaceutical Industries, Ltd. ("Teva"), Ferring Pharmaceuticals Inc. and Ferring B.V. (together "Ferring"), JCR Pharmaceuticals Co., Ltd. ("JCR"), and AMAG Pharmaceuticals, Inc. ("AMAG"). We develop and apply our drug delivery systems in collaborations with these pharmaceutical partners to enhance our partners' drug compounds and delivery methods.

We develop and manufacture novel, pressure-assisted injector devices, with and without needles, which allow patients to self-inject drugs. We make a reusable, needle-free spring action injection device, known as the ZOMA-Jet™ or Twin-Jector®, which is marketed through our partners for use with human growth hormone (hGH). 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 various branded and generic injectables. We also developed disposable multi-dose pen injectors for use with standard cartridges. We have entered into multiple licenses for these devices mainly in the U.S., Europe and Canada with Teva.

In February 2014, we launched our proprietary product OTREXUP™ (methotrexate) injection, which was the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP,™ which utilizes our VIBEX® auto injector, 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.™

In December 2015, the FDA approved our Abbreviated New Drug Application (ANDA) for 4 mg/0.5 mL and 6 mg/0.5 mL Sumatriptan Injection USP, indicated for adults for the acute treatment of migraine and cluster headache. Sumatriptan Injection USP represents the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform. Under the terms of a license, supply and distribution arrangement, the VIBEX® Sumatriptan product will be distributed by Teva, and is currently expected to be launched in 2016.

We are collaborating with Teva on a combination product development project for a VIBEX® auto injector pen containing epinephrine. Teva submitted an amendment to the VIBEX® epinephrine pen ANDA in December 2014 and received a Complete Response Letter ("CRL") from the FDA on February 23, 2016 in which, according to Teva, the FDA identified certain major deficiencies. Teva is evaluating the CRL and intends to submit a response. Due to the major nature of the CRL, Teva expects that its epinephrine product will be substantially delayed from their previously anticipated launch date in the second half of 2016 and that any launch will not take place before 2017.

Our other combination product development projects in collaboration with Teva include a VIBEX® exenatide multi-dose pen, and another undisclosed multi-dose pen. Teva filed an ANDA for exenatide, which was accepted by the FDA in October 2014 and is currently under FDA review.

We are currently conducting clinical studies of VIBEX® QS T, for testosterone replacement therapy. In February 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. In October 2015, we announced that the last patient in study QST-13-003 received their week 52 treatment, which marked the end of the treatment and follow up phase of this study. Based upon a written response we received from the FDA related to our clinical development program for QS T, we are currently conducting an additional study, QST-15-005, to support the filing of our expected 505 (b) (2) New Drug Application ("NDA") for QS T. The study includes a screening phase, a treatment titration phase and a treatment phase for evaluation of safety and tolerability assessments, including laboratory assessments, adverse events and injection site assessments. We completed enrollment in study QST-15-005 in October 2015 and anticipate that the last patient in the study will complete their final visit in the second quarter of 2016. We believe we will file the NDA for QS T in late 2016 or early 2017.

In partnership with AMAG Pharmaceuticals, Inc., we are currently developing a variation of our VIBEX® QuickShot® auto injector for use with AMAG's progestin hormone drug Makena® (hydroxy-progesterone caproate injection) under a license, development and supply agreement. Under this arrangement, AMAG is responsible for the clinical development and preparation, submission and maintenance of all regulatory applications, to manufacture and supply the drug, and to market, sell and distribute the product. We are responsible for the design and development of the auto-injection device, to manufacture and supply the device, and to assemble and package the final product.

We also have two gel-based products which are commercialized through partners. We have an oxybutynin gel product, Gelnique™ for the treatment of overactive bladder ("OAB"), which is currently marketed in the U.S. under a licensing agreement with Actavis plc ("Actavis"). 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	Regulatory Status
OTREXUP™	Methotrexate	None	RA; pJIA Psoriasis	U.S.	Approved
ZOMA-Jet™ Needle-free Injector	hGH (5 mg and 10 mg)	Ferring	Growth Retardation	U.S.	Approved
ZOMA-Jet™ Needle-free Injector	hGH (4 mg and 10 mg)	Ferring	Growth Retardation	Europe, Asia Pacific	Approved
Twin-Jector® EZ II Needle-free Injector	hGH	JCR	Growth Retardation	Japan	Approved
Elestrin®	Estradiol	Meda		U.S.	Approved

			Hormone Replacement Therapy		
Oxybutynin Gel 3%	Oxybutynin	Actavis	OAB	U.S.	Approved
VIBEX® Auto Injector	Sumatriptan	Teva	Migraines	U.S., Canada	Approved
VIBEX® Auto Injector	Epinephrine	Teva	Anaphylaxis	U.S.	Filed
Disposable Pen Injector	Exenatide	Teva	Diabetes	U.S.	Filed
Disposable Pen Injector	Undisclosed	Teva	Undisclosed	U.S. and Europe	Clinical
VIBEX® QuickShot® (“QS”)	Hydroxy-progesterone caproate	AMAG	Reduced Risk of Preterm Birth	Worldwide	Clinical
Auto Injector					
VIBEX® QS T	Testosterone	None	Testosterone Replacement Therapy	U.S.	Clinical
VIBEX® QS M 3	Undisclosed	None	Undisclosed	Undisclosed	Pre-clinical

Antares is a Delaware corporation with principal executive offices located at 100 Princeton South Corporate Center, Suite 300, Ewing, New Jersey 08628. We have two wholly owned subsidiaries in Switzerland (Antares Pharma AG and Antares Pharma IPL AG). On January 31, 2001, we completed a business combination to acquire the operating subsidiaries of Permatec Holding AG, headquartered in Basel, Switzerland. Upon completion of the transaction, our name was changed from Medi Ject Corporation to Antares Pharma, Inc.

We have a single reportable operating segment, drug delivery, which includes self-administered parenteral pharmaceutical products and technologies. See Note 2 to the Consolidated Financial Statements in Part II, Item 8 about segment financial information.

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. We believe 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 (AstraZeneca), Bydureon (AstraZeneca)
Growth deficiency	Genotropin (Pfizer), ZOMACTON (Ferring), 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 (Mylan), 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 other injectable single and multi-source drug products currently on the market that we believe 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.

OTREXUP™ is indicated for use in adults with severe, active RA or children with active polyarticular juvenile arthritis ("pJIA") who are intolerant of or had an inadequate response to first line therapy, including full dose non steroidal anti inflammatory agents, 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 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 30 to 60 years in women. In men, it often occurs later in life. According to Symphony Health Solutions, a healthcare data and analytics company, U.S. sales of biologic drug products approved to treat rheumatoid arthritis were approximately $20.0 billion in 2015. 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 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 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 2015 report by Symphony Healthcare found that approximately 7% 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 prescribed by nearly 2,000 physicians. The Company's 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. Commercial sales of OTREXUP™ commenced in early 2014, with good initial clinical adoption/utilization, and reimbursement status among payer organizations that is consistent with other in-class products. In 2014, Medac Pharma Inc. ("Medac Pharma"), a privately held pharmaceutical company, announced FDA approval of an NDA for their product, 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 2015 was approximately $2.8 billion according to a Symphony Health Solutions report. Injectable TRT grew from $212.0 million in 2013 to $237.0 million in 2015, an increase of almost 12%. 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 four out of 10 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 30% 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 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, and the potential benefits of therapy include improved sexual 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 of TRT, such as Androgel, Testim, Fortesta, Axiron, dermal patches and buccal delivery are frequently prescribed versions of TRT. 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. Additionally, there are three oral formulations currently under various stages of development to treat testosterone deficiency. The companies developing these products are Repros Therapeutics, Clarus Therapeutics and Lipocine.

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. See Research and Development below and Part II Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations for a discussion of research and development for VIBEX® QS T.

ZOMA-Jet™ (hGH)

ZOMA-Jet™ 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 $1.8 billion in 2015. There is significant competition within the hGH market between major pharmaceutical companies such as F. Hoffmann-La Roche AG, Pfizer, Novo Nordisk, Inc, Sandoz, 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 ZOMA-Jet™ 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 ZOMA-Jet™ 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 ZOMA-Jet™ 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 ZOMA-Jet™ 2 Vision for their 4 mg formulation and ZOMA-Jet™ Vision X for their 10 mg formulation. In December 2014, Ferring acquired the U.S. rights to Tev-Tropin® from Teva and assumed Teva's obligations under the device supply agreement. On March 31, 2015, we announced that Ferring had received FDA approval of a name change to ZOMACTON (somatropin [rDNA origin] for injection, and the needle free delivery system to be marketed in the U.S. as ZOMA-Jet™. Ferring also received approval from the FDA to market the 10 mg needle free injection device which, along with the consumables, is supplied by Antares to Ferring.

VIBEX® with Epinephrine

We have a license, development and supply agreement with Teva for our VIBEX® system which we have designed for a product containing epinephrine. We have scaled-up the commercial tooling and molds for this product, and have shipped pre-launch quantities of devices to Teva. We are awaiting FDA approval of the product as a generic substitute of Mylan's branded product, EpiPen®. Teva submitted an amendment to the VIBEX® epinephrine pen ANDA in December 2014 and received a CRL from the FDA on February 23, 2016 in which, according to Teva, the FDA identified certain major deficiencies. Teva is evaluating the CRL and intends to submit a response. Due to the major nature of the CRL, Teva expects that its epinephrine product will be substantially delayed from the previously anticipated launch date in the second half of 2016 and that any launch will not take place before 2017.

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 $2.2 billion in 2015 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

In December 2015, we received FDA approval of our ANDA for 4 mg/0.5 mL and 6 mg/0.5 mL Sumatriptan Injection USP for the acute treatment of migraine and cluster headache in adults. The reference listed drug in the ANDA was GlaxoSmithKline's Imitrex® Injection. We have a license, supply and distribution agreement with Teva for our VIBEX® system, under which Teva will supply the drug and commercialize and distribute the finished product. We are currently preparing for commercialization of the product. According to Symphony Health Solutions, the total U.S. retail anti-migraine market was $5.6 billion in 2015. Oral drugs accounted for $4.8 billion of the total, and injectable products accounted for approximately $200 million of the total market.

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 14% 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), ENDO Pharmaceuticals (Sumavel DosePro), and Sun Pharma (generic sumatriptan autoinjector) and Dr. Reddy's Laboratories generic sumatriptan auto-injector (Zembrace SymTouch). 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.

VIBEX® QuickShot® (hydroxyprogesterone caproate injection)

We have a development and license agreement with AMAG Pharmaceuticals, Inc. to develop and supply a subcutaneous auto injector system for use with its progestin drug Makena® (hydroxyprogesterone caproate) indicated for the prevention of preterm birth in women who are pregnant with one baby and who have delivered one baby too early in the past. Currently, Makena® is administered by a healthcare provider intramuscularly through a 21 gauge needle.

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 for an exenatide pen injector with Teva, 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 1 diabetes, 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 2015 were approximately $350 million according to Symphony Health Solutions. Bydureon, a long acting form of the medication Byetta, had approximately $822 million in U.S. sales in 2015, 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.

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 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 VIBEX® auto injector 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 products based on the VIBEX® QS system, including the VIBEX® QS T for delivery of testosterone as replacement therapy in men who have testosterone deficiency, VIBEX® QS M with an undisclosed drug for treatment of a CNS indication, and VIBEX® QS for use with the progestin hormone drug Makena® used to lower the risk of preterm birth.

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 have begun to scale up tooling and molds for potential 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: an undisclosed pen device under development for use in U.S. and Europe, and 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 conduct clinical, regulatory, formulation development, parenteral device development and commercial development activities for internal and partnered products. We have several products at various stages of development as highlighted in our "Products and Product Opportunities" schedule in the Overview section above. Additionally, see Collaborative Arrangements and License Agreements in this Item 1 for a discussion of pharmaceutical partners that are developing compounds using our technology. For a discussion of amounts we have spent on research and development activities, see Research and Development in Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations. The following is a discussion of our significant research and development programs.

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

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 testosterone deficient 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 had 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 were 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 were evaluated after 12 weeks of treatment.

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

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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 remained on QS T and were followed for an additional 40 weeks for the collection of safety data. One hundred fifty patients have received at least one dose of study drug. To date, there has been one reported death, which was caused by suicide, and the Company cannot rule out the role of the study drug. There was one serious adverse event ("SAE") of hospitalization for worsening depression in a patient with a history of depression. This patient received a single dose of QS T, and the investigator concluded that the SAE was not considered to be related to the study drug. The Company has concluded that the single dose exposure makes it unlikely that the SAE was related to the study drug and more likely to be due to the patient's history of depression and recent discontinuance of antidepressants.

After we initiated study QST-13-003, but before we announced positive top-line pharmacokinetic results in February 2015, 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 had already factored many of the recommendations cited in the advice letter into the protocol of the ongoing QST-13-003 study and into the protocols for planned human use studies as a result of guidance provided by the FDA at the May 2014 Type C meeting. Based on a single reported occurrence of hives in our phase II study, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to QS T with approximately 200 subjects exposed for six months and approximately 100 subjects exposed for a year. We assessed the FDA's comments in the advice letter and their impact on the timing of the filing of a New Drug Application ("NDA") for QS T with the FDA. Based on the number of subjects in previous studies and in the current QST-13-003 study, we concluded that we would need additional subjects exposed to QS T for six months. The timing and design of the study to obtain the additional subjects and data required was determined based on further discussion with the FDA. We submitted our response to the FDA's written recommendations in early March 2015.

In May 2015, we received a written update from the FDA related to our clinical development program for QS T. We believe, based on the update received from the FDA, there is an agreed upon path forward for the completion of an additional study to support the filing of a New Drug Application for QS T. In June 2015, we finalized and submitted the protocol for the study, and in August 2015, we enrolled the first patients in the study, which is known as QST-15-005. The study includes a screening phase, a treatment titration phase and a treatment phase for evaluation of safety and tolerability assessments, including laboratory assessments, adverse events and injection site assessments. The study is a dose-blind, multiple-dose, concentration controlled 26-week supplemental safety and pharmacokinetic study of QuickShot® Testosterone. Patients meeting all eligibility criteria will be assigned to receive 75 mg of QS T once weekly for six weeks. According to the protocol, adjustments to dose may be made at week seven based upon the week six C_{trough} value. QS T will be provided to clinical sites at dosage strengths of 100 mg, 75 mg and 50 mg to be utilized in dose titration.

In October 2015, we announced that the last patient in study QST-13-003 received their week 52 treatment, which marked the end of the treatment phase of this study. In early November 2015, the Company also announced that enrollment was complete in study QST-15-005. At that time, 108 patients had received a dose of QS T. Following completion of screening, 133 patients were dosed with QS T. The Company believes that upon successful completion of this study we should be able to meet or exceed the FDA's recommendation for the larger safety database as discussed above. We anticipate the last patient in the study will complete their final visit in the second quarter of 2016.

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.

Device Development Projects. We, along with our pharmaceutical partners, are engaged in research and development activities related to our VIBEX® disposable pressure assisted auto injectors, our QS 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. We also have a license, development and supply agreement with AMAG for our QS device containing Makena® indicated for reduced risk of preterm birth. 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, and development of commercial tooling and assembly. The following is a summary of the development stage for the four products in development with Teva and the development stage of our product with AMAG.

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. 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. Teva received a complete response letter on February 23, 2016 relating to its epinephrine ANDA in which, according to Teva, the FDA identified certain major deficiencies. Teva is evaluating the CRL and intends to submit a response. Due to the major nature of the CRL, Teva expects that its epinephrine product will be substantially delayed from the previously anticipated launch date in the second half of 2016 and that any launch will not take place before 2017.

VIBEX® with Sumatriptan

We have designed the VIBEX® device for a product containing sumatriptan and have scaled up the commercial tooling and molds for this product. In December 2015, the FDA approved our ANDA for 4 mg/0.5 mL and 6 mg/0.5 mL Sumatriptan Injection USP, indicated for adults for the acute treatment of migraine and cluster headache. Sumatriptan Injection USP represents the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform. The VIBEX® Sumatriptan product will be distributed under the terms of a license, supply and distribution arrangement with Teva, and is currently expected to be launched in 2016.

Disposable pen injector

We previously provided clinical supplies for an undisclosed 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 device development and delivered devices for a drug stability program to support a regulatory filing.

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 in October 2014 and is currently under FDA review. 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.

VIBEX® QS with Makena® (hydroxyprogesterone caproate injection)

We are in the process of developing a variation of our VIBEX® QuickShot® auto injector for use with the progestin hormone drug Makena® under a license, development and supply agreement with AMAG. Under this arrangement, AMAG is responsible for the clinical development and preparation, and submission and maintenance of all regulatory applications. We are responsible for the design and development of the auto-injection device.

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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 believe we are currently 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. Below is a summary of our production, manufacturing, assembly and packaging arrangements with third parties:

- We utilize Minnesota Rubber and Plastics ("MRP"), a contract manufacturing company, to manufacture and assemble our needle-free devices and certain related disposable component parts for our partners Ferring and JCR.
- We utilize 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 the Teva exenatide pen product.
- We are working with ComDel Innovation, Inc. ("ComDel"), a provider of integrated solutions for product development, tooling, and manufacturing, to provide manufacturing services for the VIBEX® with sumatriptan 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., also known as 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 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 ZOMACTON®, Elestrin® 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™

We have the worldwide marketing rights for OTREXUP™ and commercialize OTREXUP™ on our own in the U.S. We have an internal sales and marketing organization that includes approximately 50 employees directly involved in our commercialization and sales efforts. In 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 vendors for commercialization services such as third-party contracting and distribution. We may enter into licensing and or additional distribution arrangements for commercialization of our products outside the U.S.

For a discussion regarding revenues related to our products and services, as well as our revenues by geographic areas, see Results of Operations Revenues in Part II, Item 7 Management’s Discussion and Analysis of Financial Condition and Note 10 to the Consolidated Financial Statements.

Collaborative Arrangements and License Agreements

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

Partner	Drug	Market Segment	Product
Ferring	hGH (ZOMACTON®)	Growth Retardation	Needle Free
	(4 mg formulation)	(Europe, Asia Pacific)	ZOMA-Jet™ 2 Vision
Ferring	hGH (ZOMACTON®)	Growth Retardation	Needle Free
	(10 mg formulation)	(Europe, Asia Pacific)	ZOMA-Jet™ Vision X
Ferring	hGH (ZOMACTON®)	Growth Retardation	Needle Free ZOMA-Jet™
	5 mg, 10 mg	(United States)	

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	Undisclosed (North America, Europe & others)	Pen Injector
Teva	Exenatide	Diabetes (North America, Europe & others)	Pen Injector
Actavis	Oxybutynin	OAB (United States)	Gelnique 3%
Meda	Estradiol	Hormone replacement therapy (North America, other countries)	Elestrin® Gel
Ferring	Undisclosed	Undisclosed (Worldwide)	Transdermal Gel
AMAG	Makena® (Hydroxyprogesterone caproate)	Maternal Health (Worldwide)	VIBEX® QS Auto Injector

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The table above summarizes agreements under which our partners are selling products, conducting clinical evaluation, and performing development of our products. For competitive reasons, our partners may not divulge their name, the product name or the exact stage of clinical development.

In June 2000, we granted an exclusive license to BioSante (now ANI) to develop and commercialize 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 to us on commercial sales of the products. Currently we expect that Elestrin®, which is sublicensed by Meda, will be the only product commercialized 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 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 2015, 2014, and 2013, 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. On October 5, 2015, we received a written notice of termination of the Agreement from Pfizer. Accordingly, the Agreement terminated on November 5, 2015.

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 commercialize and 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. The agreement was terminated in June 2015 and we regained the exclusive U.S. marketing rights to OTREXUP™.

In September 2014, we entered into a development and license agreement with Lumara Health, Inc., which was subsequently acquired by AMAG, to develop and supply an auto injector system for use with a progestin drug (hydroxyprogesterone caproate) indicated for the prevention of pre-term labor in pregnant women. Under the agreement, we granted an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, and received an upfront payment for our license and development activities. We are also entitled to milestone payments upon the achievement of pre-determined amount of net sales of the product.

AMAG is responsible for the clinical development and preparation, submission and maintenance of all regulatory applications, to manufacture and supply the drug to be used in the product, and to market, distribute and sell the product. We are the exclusive supplier of the auto-injection system devices for the product and are responsible for the manufacture and supply of the devices and final assembly and packaging of the finished product. Under the arrangement, we will receive payment for each device, and royalties based on the net sales of products commencing on product launch in a particular country until the product is no longer developed, marketed, sold or offered for sale in such country. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of products and decrease after the expiration of licensed patents or where there are generic equivalents to the auto injector product being sold in a particular country.

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.

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, and received a complete response letter in November 2015. 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. Acerus Pharmaceuticals, formerly known as Trimel Pharmaceuticals, received U.S. FDA approval of Natesto,™ an intra-nasal testosterone formulation in 2014. Endo Pharmaceuticals subsequently acquired the exclusive commercial rights to the Natesto™ product in the U.S. and Mexico, and terminated the agreement effective June 30, 2016.

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 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 do not 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 exenatide 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.

Recent trends in the pharmaceutical industry include merger and acquisition activity leading to further market consolidation. In many cases, the resulting pharmaceutical companies are bigger and have more financial, technical and market strength and resources increasing competitive pressure in the industry.

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 2017 to 2034. 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.

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, also known as the master access 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.

Our products, our products marketed by our partners, as well as our products being developed by our partners are most often categorized as “drug-device combination products” and are subject to the NDA, ANDA, sNDA, sANDA and 505(b)(2) drug approval process and regulations, as well as the device approval processes cited above.

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, 2016, we had 108 full-time employees. Of the 108 employees, 44 are primarily involved in research, development and manufacturing activities, 49 are primarily involved in commercialization and sales, 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 $20,658,846 and $35,151,715 in the years ended December 31, 2015 and 2014, respectively. In addition, we had an accumulated deficit at December 31, 2015 of $229,106,502. The costs for research and development of our products, product candidates and drug delivery technologies, and certain product candidates of our partners, 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.

At December 31, 2015, we had cash and investments of $47,910,901. The combination of our current cash and investments balance and projected product sales, product development fees, license revenues, milestone payments and royalties should provide us with sufficient funds to support operations for at least the next twelve months. However, if funds are not sufficient to support operations in the future, we may need to raise additional funds through debt or equity financings (such as issuing additional equity or debt, including notes convertible into our common stock) 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. For example, on May 11, 2015, we completed an underwritten offering of 23,000,000 shares of common stock at a price of $2.00 per share in a public offering. On May 5, 2015, the day we launched the offering, the closing price per share of our common stock was $2.30. If we are unable to obtain 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 and VIBEX® QS M;
- our and our partners' ability to obtain regulatory approval, and where applicable to obtain an AB-rating, of partnered products including VIBEX® epinephrine, exenatide and others;
- the success of our partners in launching new products such as VIBEX® Sumatriptan and selling our existing products;
- our ability to successfully sell future products if we choose not to partner the product;
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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 to attract and retain 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. Effective June 23, 2015, we regained the exclusive U.S. marketing rights to OTREXUP™ for the treatment of psoriasis, after the LEO Pharma agreement was terminated for its exclusive right to commercialize OTREXUP™ in the U.S. for this field. We have limited commercial resources and may incur incremental sales and marketing costs if we choose to market OTREXUP™ for the treatment of psoriasis in the U.S. and may be unsuccessful in this commercial strategy. To the extent we rely on third parties to commercialize OTREXUP™ in the future, 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 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 maintaining the necessary commercial infrastructure, including sales representatives, managed care, medical affairs and pharmacovigilance teams. The 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 have and expect to continue to devote substantial resources to establish and maintain a sales and 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.

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.

We rely on third party data providers to estimate patient prescriptions dispensed for OTREXUP™ and help determine our revenue each reporting period.

Because we have limited sales history with OTREXUP,™ we rely on third party data providers, such as Symphony Health Solutions, as a basis for estimating the number of patient prescriptions of OTREXUP™ during each reporting period and use this information to calculate revenue for OTREXUP.™ While we undertake certain procedures to review the reasonableness of this information, we cannot obtain absolute assurance regarding the accuracy of the prescription or market data or over the accounting methods and controls related to the information provided to us by third parties. If patient prescriptions dispensed for a given period are underestimated or overestimated, adjustments to revenue may be necessary. As a result, we are at risk of third parties providing us with erroneous data which could have a material adverse impact on our revenue reporting and our business.

We will depend on Teva to manufacture, supply, distribute and commercialize VIBEX® Sumatriptan in the U.S.

We have entered into a license, supply and distribution agreement with Teva to distribute VIBEX® Sumatriptan, an auto injector product containing sumatriptan for the treatment of migraines. Under our arrangement, we will manufacture the auto injector and do final assembly and packaging of the final product and Teva will manufacture and supply the drug sumatriptan and distribute and commercialize the product in the U.S. Teva also has an option for rights in other territories.

There is no guarantee that our partnership with Teva to distribute VIBEX® Sumatriptan will be successful. Teva controls the manufacture and supply of the drug, sumatriptan, which is necessary for the production of VIBEX® Sumatriptan. If, at any time, Teva ceases to manufacture and supply us with sumatriptan or fails to produce sufficient supplies of the drug, we will be unable to produce a finished product or sell our auto injectors designed for this product to Teva. We will also rely on Teva to commercialize and distribute the product within the U.S. and if Teva is unsuccessful in commercializing the product, the resulting revenue may be lower than expected. Additionally, we may disagree with Teva on certain business strategies or its manufacturing and distribution decisions. Such decisions by Teva may be beyond our control and may impact the success of VIBEX® Sumatriptan and we may receive less revenue than desired or expected. We have invested significant resources in the development of VIBEX® Sumatriptan, and, if our partnership with Teva is not profitable or is terminated for any reason, we may not receive a return on our investment and may suffer significant losses.

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

We do not possess the facilities to manufacture commercial quantities of our drug/device combination product, including OTREXUP™ and VIBEX® Sumatriptan, or any other of our or our partners' products or product candidates. We must contract with manufacturers to produce products according to government regulations. The 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 and our partners' product candidates. We and our partners may fail to contract with the necessary manufacturers or we and our partners 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, technology developed by our partners, 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 our products and product candidates and our partners' products and product candidates.

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;
- failure to supply adequate quantities of product or failure to supply product meeting the required product specification or other manufacturing requirements; 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."

In addition, we may consider entering into additional manufacturing arrangements with third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to begin commercial production by these manufacturers.

We are dependent on numerous third parties in our supply chain for the commercial supply of our products and partners' products 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 our products and our partners' products could be delayed and our business could be harmed.

The availability of our products for commercial sale depends upon our ability to procure the components, raw materials, packaging materials and finished products we need from third parties. We have entered into supply agreements with numerous third party suppliers, many of which are currently our single source for the materials necessary for certain of our products. For example, 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™ or our other products which depend on third party suppliers, 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™ or our other products do 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.

Our partnered products encounter similar issues in obtaining reimbursement from third-party payors. While we are unable to control the reimbursement rate or discounts contracted with third-party payors by our partners, these rates ultimately affect our royalty payments on products such as Elestrin® and Gelnique®.

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.

We may incur significant liability if it is determined that we are promoting or have in the past promoted the “off-label” use of drugs or medical devices.

In the U.S. and certain other jurisdictions, companies may not promote drugs or medical devices for “off-label” uses, that is, uses that are not described in the product’s labeling and that differ from those that were approved or cleared by the FDA. Under what is known as the “practice of medicine,” physicians and other healthcare practitioners may prescribe drug products and use medical devices for off-label or unapproved uses, and such uses are common across some medical specialties. Although the FDA does not regulate a physician’s choice of medications, treatments or product uses, the FD&C Act and FDA regulations significantly restrict permissible communications on the subject of off-label uses of drug products and medical devices by pharmaceutical and medical device companies. The FDA, the Federal Trade Commission (“FTC”), the Office of the Inspector General of the Department of Health and Human Services (“HHS-OIG”), the Department of Justice (“DOJ”) and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. If the FDA determines that a company has improperly promoted a product “off label’, the FDA may issue a warning letter or seek other enforcement action to limit or restrict certain promotional activities or materials or seek to have product withdrawn from the market or seize product. In addition, a company that is found to have improperly promoted off-label uses may be subject to significant liability,

including civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid as well as potential liability under the federal False Claims Act and applicable state false claims acts. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by such conduct.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations and judicial case law allow companies to engage in some forms of truthful, non-misleading, and non-promotional speech concerning the off-label uses of their products. We have endeavored to establish and implement extensive compliance programs in order to instruct employees on complying with the relevant advertising and promotion legal requirements. Nonetheless, the FDA, HHS-OIG, the DOJ and/or the state Attorneys General, and qui tam relators may take the position that we are not in compliance with such requirements, and, if such non-compliance is proven, we may be subject to significant liability, including administrative, civil and criminal penalties and fines.

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.

We partner with pharmaceutical companies, such as Teva, to develop, obtain regulatory approvals for, manufacture and sell our products and technologies along with their products. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of our and our partners' 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. While VIBEX® with sumatriptan recently received FDA approval, there is no assurance that development of these products will continue or that the other three 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, 2015, we derived approximately 39% of our revenue from Teva and 13% from Ferring. For the year ended December 31, 2014, we derived approximately 33% of our revenue from Teva and 18% 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. In addition, we derive a significant portion of our product sales revenue from shipment of OTREXUP™ to our distributors, including McKesson, which accounted for approximately 15% of total revenues in 2015.

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.

Most of our total revenues are generated from a small number of products.

We generate product sales from a limited number of individual products. If we or our partners are unable to continue to market any one or a number of those products, such as OTREXUP™ or our partnered device products, then our total revenues, results of operations and cash flows could be materially adversely affected. For example, if any of the products were to lose market share as the result of the entry of new competitors, or if the selling prices of any of these products were to decline significantly, there would be a direct negative impact on our reported revenues.

We are dependent on third parties to supply all raw materials used in our products and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We rely on third parties to supply all raw materials used in our products. In addition, we rely on third party suppliers, distributors and collaboration partners to provide services for certain core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third party suppliers and contractors are subject to FDA requirements. Our business and financial viability are dependent on the continued supply by these third party suppliers, the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third party manufacturers, distributors and collaboration partners. Any interruption or failure by our suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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. We expect that our device manufacturing for VIBEX® with sumatriptan will also involve many 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.

MRP manufactures and assembles our needle-free devices and certain related disposable component parts for our partners 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 intend to use ComDel Innovation, Inc. and other third parties to manufacture VIBEX® with Sumatriptan. We have existing relationships with many of these third parties in the context of our other products but there is no guarantee we will be able to secure favorable terms for the manufacture of this product. If we are unsuccessful in finalizing our arrangements with these third parties or in negotiating favorable contractual terms, the launch of VIBEX® with Sumatriptan could be delayed.

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 our partners' products, or the medical profession or patients do not accept our products or our partners' 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 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 or those of our partners 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.

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, AMAG and Meda 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. For example, Teva submitted an amendment to the VIBEX® epinephrine pen ANDA in December 2014 and received a CRL from the FDA in February 2016 in which, according to Teva, the FDA identified

certain major deficiencies. Due to the major nature of the CRL, Teva expects that its epinephrine product will be substantially delayed from their previously anticipated launch in the second half of 2016 and that any launch will not take place before 2017. While we assist our partners in obtaining regulatory approvals and advancing new products, we depend on these partners and cannot control their decision-making or progress in achieving such goals. Any potential loss of anticipated future revenue could have an adverse effect on our business and the value of your investment.

Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA's approval of products are uncertain.

Drug development is an inherently risky and uncertain process. Before obtaining regulatory approvals for the sale of any new product candidates, we and our partners must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Likewise, we and our partners may not be able to demonstrate through clinical trials that a product candidate's therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy could or would result in the failure to obtain regulatory approvals.

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials and such competition has delayed clinical development of our products in the past. For example, patients may not enroll in clinical trials at the rate expected or patients may drop out after enrolling in the trials or during the trials. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements, or encounter clinical trial compliance-related issues, which may also delay clinical trials. Product supplies may be delayed or be insufficient to treat the patients participating in the clinical trials, or manufacturers or suppliers may not meet the requirements of the FDA or foreign regulatory authorities, such as those relating to cGMP. We and our partners also may experience delays in obtaining, or we and our partners may not obtain, required initial and continuing approval of our clinical trials from institutional review boards. We cannot assure you that we will not experience delays or undesired results in these or any other clinical trials.

For example, we are currently conducting clinical studies of VIBEX® QS T for testosterone replacement therapy. In October 2015, we announced that the last patient in study QST-13-003 received their week 52 treatment, marking the end of treatment and the follow up phase of this study. In early November 2015, we announced that we had completed enrollment in our supplemental safety study QST-15-005. Upon successful completion of QST-15-005, we believe we should be able to satisfy the FDA's previous recommendation that we create a larger safety base of subjects exposed to QS T. However, there is no guarantee that completion of study QST-15-005 will meet the FDA's recommendations and we may need to conduct further clinical studies with additional subjects and data in the future. In addition, we may experience delays or incur additional, unexpected costs in our completion of these clinical trials which may delay or otherwise adversely impact regulatory approval of VIBEX® QS T.

We cannot assure you that the FDA or foreign regulatory agencies will approve, clear for marketing or certify any products developed by us or our partners, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. The FDA or foreign regulatory authorities may not agree with the assessment by us or our clinical partners of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals or clearances of products developed by us and our partners would adversely affect the marketing of these products and our ability to generate product revenue, which would adversely affect our financial condition and results of operations.

Before obtaining regulatory approvals for certain generic products, we and our partners must conduct limited clinical or other trials to show comparability to the branded products. A failure to obtain satisfactory results in these trials

would prevent us from obtaining required regulatory approvals.

If we are not able to establish new collaborations, we may have to alter our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to partner with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaboration partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner's resources and experience, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge

to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenues.

We face intense competition and 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.

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. Competitive factors include product quality and price, reputation, service, product safety, development and efficacy and access to scientific and technical information. If we fail to compete successfully in any of these areas, our business could be adversely affected and we may never be able to achieve profitable operations. It is possible that developments from our competitors will make our products or technologies uncompetitive or obsolete.

For example, 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 needle free 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 (Zembrace SymTouch). 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.

Continued consolidation in the pharmaceutical industry, and particularly in the generic pharmaceutical industry, could impact our existing partnerships, products and product candidates

There are a limited number of companies with sufficient scale and commercial reach to effectively market many of our products. Recent trends in the pharmaceutical industry suggest additional market consolidation, further concentrating financial, technical and market strength and resources and increasing competitive pressure in the industry. For example, Teva is currently in the process of acquiring the generic business of Allergan (formerly Actavis). Since we are presently working with Teva on four products, VIBEX® with epinephrine, VIBEX® with Sumatriptan, a pen product with exenatide, and an undisclosed pen product, if this transaction is consummated, it is possible that the Federal Trade Commission could require that Teva divest certain of our products as part of the transaction. The acquiring party of the product following such a divestiture may have less market power than Teva, resulting in a loss of market share and reduced pricing. Additionally, acquisitions and integrations are time and resource intensive and Teva's attention and resources could be diverted to other acquisition or integration related activities or opportunities which could potentially delay or negatively impact the success of some of our products with Teva. For other products, increased consolidation could lead to more intense competition and pricing pressure which could have a result in a substantial decrease in our revenues and harm our operating results. Consolidation may also lead to changes in personnel at our partners, potentially impacting the composition of our relationship teams at these partners and leading to material delays in the development and marketing of our products.

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. Even issued patents may later be modified or declared invalid by the U.S. Patent and Trademark Office by analogous foreign offices or in legal proceedings. In addition, any patent applications we may have made or may make relating to inventions for our actual or potential products and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for our inventions.

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

We may seek to protect our patent rights by asserting an allegation of infringement against third parties. Patent litigation is costly and time consuming and the outcome is uncertain. There is no assurance of success with any patent litigation. Depending on the ultimate outcome of the litigation it may have an adverse effect on results of operations and our market penetration. For example, 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 of two of the Company's patents for technology regarding an auto injector and an auto injector containing methotrexate. In April 2015, Antares, Medac, LEO Pharma, Inc. and LEO Pharm A/S entered into a settlement agreement pursuant to which the proceedings related to Antares' patents, as well as patent claims filed by Medac against Antares, LEO Pharma and LEO Pharma A/S, were dismissed with prejudice (the "Medac Settlement"). The settlement agreement provides for a royalty-free cross-license under the patents named in the proceedings and their families allowing the manufacture and sale of OTREXUP (methotrexate) injection and RASUVO in and for the U.S.

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

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, we incurred significant expenses in connection with our patent litigation with Medac. 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. 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. Medac's patent claims as well as Antares' petition with the PTAB were dismissed in April 2015 pursuant to the Medac Settlement. See Legal Proceedings in Part I, Item 3 for a further discussion of the litigation.

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 we may in the future pursue the development of other products 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. These product

candidates are generic versions of pre-existing brand name drugs and we may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our partners' products and/or product candidates and/or proprietary technologies infringe their intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products and medical devices are associated with significant risks of product liability claims or recalls. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class of injured patients. Further, third party payors, either individually or as a putative class, may bring actions seeking to recover monies spent on one of our products. While we have not had to defend against any product liability claims to date, as sales of our products increase, we may have product liability claims made against us. The risk of product liability claims may also increase if a company receives a warning letter from a regulatory agency. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, or at all. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical and medical device sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, [the European Medicines Agency ("EMA")] or the competent authorities of the EU member states. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension, variation, or withdrawal of approval. Any such regulatory action by the FDA, the EMA or the competent authorities of the EU member states could lead to product liability lawsuits as well.

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 are unable to retain our key personnel, and continue to attract additional professional staff, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have employment agreements with our key executives, we cannot assure you that we will succeed in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Our business and operations would suffer in the event of failures in our internal computer systems.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, attacks by computer hackers, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability or damage to our reputation, and the further commercialization and development of our products and product candidates could be delayed.

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 launched a supplemental safety study QST-15-005 with additional participants in mid-2015, enrolling its first patients in August 2015. We completed enrollment in QST-15-005 in early November 2015. We believe that, upon successful completion, QST-15-005 should satisfy the FDA's previous recommendation that we create a larger safety base of subjects exposed to QS T. However, the FDA may have additional recommendations or require further trials and the timing, cost and design of any such study could negatively affect our business if we incur significant costs or delays. Products of this nature normally carry with them the need to monitor safety in an on-going manner, called a Risk Evaluation Mitigation Strategy, or REMS. The REMS for testosterone products is well-defined, and a class-labeling letter has been issued to all approved testosterone replacement products that will likely include being part of a clinical outcomes trial intended to explore cardiovascular risks.

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 these drug products in the U.S. until they have been approved by the FDA. Teva submitted an amendment to the VIBEX® epinephrine pen ANDA in December 2014 and received a CRL from the FDA in February 2016 in which, according to Teva, the FDA identified certain major deficiencies. Teva is evaluating the CRL and intends to submit a response. Due to the major nature of the CRL, Teva expects that its epinephrine product will be substantially delayed from their previously anticipated launch date in the second half of 2016 and that any launch will not take place before 2017. 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.

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.

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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 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 ef