ANTARES PHARMA, INC.
Form 10-K
March 14, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016

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

Commission file number 1-32302

ANTARES PHARMA, INC.

(Exact name of registrant as specified in its charter)

A Delaware corporation I.R.S. Employer Identification No. 41-1350192

100 Princeton South, Suite 300, Ewing, NJ 08628
Registrant's telephone number, including area code: (609) 359-3020

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

Title of each class	Name of each exchange on which registered
Common Stock	NASDAQ Capital Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO

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

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

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

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

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

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

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

Aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2016, was $148,641,000 (based upon the last reported sale price of $1.05 per share on June 30, 2016, on the NASDAQ Capital Market).

There were 155,242,371 shares of common stock outstanding as of March 1, 2017.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2017 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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Note Regarding 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 and sales of OTREXUP® (methotrexate) injection;
- our expectations regarding the ability of our partner, Teva Pharmaceutical Industries, Ltd. ("Teva"), to successfully commercialize Sumatriptan Injection USP;
- our expectations regarding product development and potential approval by the United States ("U.S.") Food and Drug Administration ("FDA") of VIBEX QuickShot® Testosterone injection ("QST");
- our expectations regarding continued product development with Teva and potential FDA approval of VIBEX® Epinephrine Pen ("epinephrine auto injector"), teriparatide disposable pen injector and exenatide disposable pen injector, and Teva's ability to successfully commercialize each of those products;
- our expectations regarding continued product development with our partner AMAG Pharmaceuticals, Inc. ("AMAG"), and potential FDA approval of an auto injector for Makena®;
- our expectations regarding trends in pharmaceutical drug delivery characteristics;
- our anticipated continued reliance on contract manufacturers to manufacture our products;
- our anticipated continued reliance on third parties to provide certain services for our products including logistics, warehousing, distribution, invoicing, contract administration and chargeback processing;
- 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 flows 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;

- 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 significant uncertainties, you should not regard the forward-looking statements in this annual report as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, if at all.

PART I

Item 1. BUSINESS

Overview

Antares Pharma, Inc. ("Antares," "we," "our," "us" or the "Company") is an emerging, specialty pharmaceutical company focused on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. Our strategy is to identify new or existing approved drug formulations and apply our drug delivery technology to enhance the drug compounds and delivery methods. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems for improved safety and efficacy, reduced side effects, and enhanced patient comfort and adherence. Our subcutaneous injection technology platforms include the VIBEX® pressure-assisted auto injector system suitable for branded and generic injectable drugs in unit dose containers, reusable needle-free spring-action injector devices, and disposable multi-dose pen injectors for use with standard cartridges. We have a portfolio of proprietary and partnered products, including several approved commercial products and five product candidates in advanced stages of development and under active FDA review. We have formed significant strategic alliances and partnership arrangements with industry leading pharmaceutical companies including Teva, AMAG, Ferring Pharmaceuticals Inc. and Ferring B.V. (together "Ferring").

We launched our proprietary product OTREXUP® (methotrexate) injection, which utilizes our VIBEX® auto injector, in the U.S. in February 2014. OTREXUP® was the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector, 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, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg and 25 mg of OTREXUP®.

Antares, with our partner Teva, launched Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine and cluster headache in adults, in June 2016. We received FDA approval of our Abbreviated New Drug Application ("ANDA") for 4 mg/0.5 mL and 6 mg/0.5 mL single-dose prefilled syringe auto-injectors, a generic equivalent to Imitrex® STATdose Pen®, in December 2015. Sumatriptan Injection USP represents the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform and is distributed by Teva under the terms of a license, supply and distribution arrangement.

We also make reusable, needle-free injection devices that administer injectable drugs, which are currently marketed through our partners Ferring and JCR for use with human growth hormone (hGH) in certain parts of the world. In addition, we have two gel-based products commercialized through other partners pursuant to licensing agreements, under which we are entitled to receive royalties on sales.

We are developing QuickShot® Testosterone ("QST") for testosterone replacement therapy and submitted a 505 (b) (2) New Drug Application ("NDA") with the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a Prescription Drug User Fee Act ("PDUFA") target date for completion of its review by October 20, 2017. We conducted a 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, and we previously announced positive top-line pharmacokinetic ("PK") results that showed that the primary endpoint was achieved. Based upon a written response we received from the FDA related to our clinical development program for QST, we conducted an additional supplemental safety study, "QST-15-005". The study included 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. In September 2016, we announced the successful completion of the QST-15-005 study. The results of

these two studies formed the clinical basis of our NDA submission for QST.

We are collaborating with Teva on a VIBEX® auto injector pen containing epinephrine used for the treatment of severe allergic reactions (anaphylaxis). Teva submitted an amendment to the VIBEX® epinephrine pen ANDA in December 2014 and received a Complete Response Letter ("CRL") from the FDA in February 2016 in which, according to Teva, the FDA identified certain major deficiencies. Teva has advised us that it submitted a response to the CRL and expects that any approval or launch will not take place before the end of 2017 or beginning of 2018.

Our other combination product development projects in collaboration with Teva include a multi-dose pen for a generic form of BYETTA® (exenatide injection) for the treatment of diabetes, and another multi-dose pen for a generic form of Forteo® (teriparatide [rDNA origin] injection) for the treatment of osteoporosis. Teva filed an ANDA for exenatide, which was accepted by the FDA in October 2014 and is currently under FDA review. In 2016, we announced that Teva had settled the patent litigation with AstraZeneca Pharmaceuticals, LP, AstraZeneca AB, and Amylin Pharmaceuticals, LLC (collectively "AstraZeneca"), relating to certain AstraZeneca U.S. patents and their drug, BYETTA® (exenatide). AstraZeneca and Teva entered into a settlement and license

agreement pursuant to which AstraZeneca granted Teva a license to manufacture and commercialize the generic version of BYETTA® described in Teva's ANDA. The settlement allows Teva to commercialize their exenatide product in the U.S. beginning October 15, 2017 or earlier under certain circumstances. Teva also filed an ANDA for a generic version of Forteo®, which was accepted by the FDA and is currently under review. In response to Teva's paragraph IV certification contained in Teva's ANDA for teriparatide, Eli Lilly and Company ("Lilly") filed a lawsuit against Teva alleging infringement of six U.S. patents related to Forteo® resulting in a 30-month stay in FDA approval of the ANDA. The stay will expire in August 2018 unless the litigation is resolved sooner.

In partnership with AMAG, we are currently developing a variation of our VIBEX® QuickShot® subcutaneous 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, the manufacturing and supply of the device, and assembly and packaging of the final product. AMAG initiated a PK study in October 2016 and disclosed positive top line results of the study in February 2017. According to AMAG, the study successfully demonstrated comparable bioavailability between subcutaneous injection of Makena® compared to intra muscular injection. AMAG anticipates submitting its Supplemental New Drug Application ("sNDA") for the subcutaneous auto injector for use with Makena® in the second quarter of 2017 and expects a six-month review by the FDA.

Corporate Information

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.

Segment and Geographic Information

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

Our Product Portfolio

The following table provides an overview and brief description of our products and product opportunities:

Product	Drug	Partner	Indication	Territory	Status
OTREXUP®	Methotrexate	None	Rheumatoid Arthritis; pJIA, Psoriasis	U.S.	Approved/ Marketed
Sumatriptan Injection USP (generic equivalent to Imitrex® STATdose Pen®)	Sumatriptan succinate (4mg and 6mg)	Teva	Migraines	U.S.	Approved/ Marketed
ZOMA-Jet™ Needle-free Injector	hGH (5 mg and 10 mg)	Ferring	Growth Retardation	U.S.	Approved/ Marketed
ZOMA-Jet™ Needle-free Injector	hGH (4 mg and 10 mg)	Ferring	Growth Retardation	Worldwide	Approved/ Marketed
Twin-Jector® EZ II Needle-free Injector	hGH	JCR	Growth Retardation	Japan	Approved/ Marketed
VIBEX® QuickShot® Auto Injector (QST)	Testosterone	None	Testosterone Replacement Therapy	U.S.	NDA Filed
VIBEX® Auto Injector	Epinephrine	Teva	Anaphylaxis	U.S.	ANDA Filed
Disposable Pen Injector	Exenatide	Teva	Diabetes	U.S.	ANDA Filed
Disposable Pen Injector	Teriparatide	Teva	Osteoporosis	U.S., Europe	ANDA Filed Approved[(1)]
Makena® QuickShot® Auto Injector	Hydroxy-progesterone caproate	AMAG	Reduced Risk of Preterm Birth	Worldwide	Clinical

(1) Teva completed a decentralized procedure registration process in Europe. Applications for marketing authorizations are ongoing in each of the respective countries of application.

Our Strategy and Market Opportunity

Our business strategy is to apply our proprietary drug delivery injection technology to new or existing approved drug formulations to enhance the drug compounds and delivery methods. We believe this strategy offers a distinct value to patients, physicians, pharmaceutical partners and our shareholders. Our focus is primarily on the market for delivery of self-administered injectable drugs, comprised of non-biologic, small molecule drugs and biological products or biosimilars. We believe our technology platforms have potential in both the branded and generic marketplace.

Injection is a common drug delivery pathway, and 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, combined with our strategy to partner with pharmaceutical manufacturers of injectable products outside of our therapeutic focus offers us additional potential to profit from our proprietary injector systems in multiple markets in the future.

We believe that our injection device technology platforms work well in the branded marketplace, in which companies typically develop a new drug formulation and sell the product under a branded name once approved, as well as the generics market. Generic drugs are the pharmaceutical and therapeutic equivalents of branded products and are generally marketed under their generic (chemical) names rather than by brand names. Typically, a generic drug may not be marketed until the expiration of applicable patent(s) on the corresponding branded product, unless a resolution of patent litigation results in an earlier opportunity to enter the market. Generic drugs are the same as branded products in dosage form, safety, efficacy, route of administration, quality, performance

characteristics and intended use, but they are sold generally at prices below those of the corresponding branded products. Generic drugs provide a cost-effective alternative for consumers, while maintaining the same high quality, efficacy, safety profile, purity and stability of the branded product. An ANDA is required to be filed and approved by the FDA in order to manufacture a generic drug for sale in the United States. There are a large number of injectable branded products losing patent protection in the U.S. 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 auto injector, and teriparatide 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.

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. Additionally, 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.

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 advanced drug delivery systems result in improved safety and efficacy, reduced side effects, and enhanced patient comfort and adherence.

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.

According to the report Injectable Drug Delivery Market by MarketsandMarkets, it is estimated that the global injectable drug delivery market will grow to $624.5 billion by 2021, representing a compounded annual growth rate of 11.5% from 2016-2021. This expected growth is attributable to several factors, including label expansion for approved products, increasing the patient pool for such products, a pipeline of injectable medications at various stages of clinical development, and the increasing incidence of certain diseases that will necessitate the utilization of injectable medications.

Our Competitive Strengths

We have a proven business model of applying our patented drug delivery injection technology to new and existing therapeutic products. Our management team has unique industry knowledge and insight into combination drug/device products, and is experienced in creating business alliance opportunities, identifying product candidates for enhancement and navigating the various regulatory approval pathways. We believe our business model for developing and commercializing proprietary and partnered products has been validated by the FDA approvals of our

NDA for OTREXUP® and ANDA for Sumatriptan Injection USP and the launch of those products.

We strive to protect and enhance the proprietary technologies that we believe are important to our business and rely on know-how and continuing technological innovation to develop, strengthen, and maintain our competitive position. When appropriate, we have obtained, or seek protection for our products and proprietary information by means of U.S. and international patents and trademarks. These patents consist primarily of design, formulation and method-of-use patents. Our intellectual property portfolio includes numerous patents and additional patent applications pending in the U.S. and other countries. Our patents have expiration dates ranging from 2017 to 2034. In addition to the patents and patent applications, we rely on trade secret protection in all of our technologies and strive to preserve confidentiality of those trade secrets and inventions.

Our 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 maternal health. 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. The key competitive advantages of the VIBEX® system include:

- 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 two license agreements with Teva for our VIBEX® system, one for an epinephrine auto injector and the other for Sumatriptan Injection USP. Our proprietary product OTREXUP® also uses the VIBEX® auto injector system for delivery of methotrexate.

Our latest advancement in our proprietary line of VIBEX® auto injectors is the VIBEX® QuickShot® (“QS”) auto injector system, which offers a dose capacity of 1 mL or greater in a compact design. VIBEX® QS is designed to enhance performance on the attributes most critical to patient acceptance, which are speed, comfort and discretion. VIBEX® QS achieves these advancements by incorporating a novel triggering mechanism and space-saving spring configuration. The unique 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® QST for delivery of testosterone as replacement therapy in men who have testosterone deficiency, and a VIBEX® QS auto injector under joint development with AMAG for use with its progestin hormone drug Makena® used to lower the risk of preterm birth.

Disposable Pen Injector System

Our multi-dose, disposable pen injector technology 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 deliver up to thirty days of drug. We have licensed our pen injector device technology to Teva for two potential products: an exenatide multi-dose pen for the treatment of diabetes (a generic version of BYETTA®) and a multi-dose pen for the treatment of osteoporosis (a generic form of Forteo®.)

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,

which 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. We currently sell our needle-free injector devices to Ferring and JCR for use with hGH.

Our Products and Products in Development

Approved and Marketed Products

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. OTREXUP® (methotrexate) injection is the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. Our initial NDA approved in October 2013, covered the 10 mg, 15 mg, 20 mg and 25 mg dosage strengths. To date, we have received FDA approval for eight dosage strengths, including 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg and 25 mg of OTREXUP®.

OTREXUP® is indicated for use in adults with severe, active rheumatoid arthritis ("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. pJIA is the most common rheumatic disease in childhood, and according to the Arthritis Foundation, juvenile arthritis affects nearly 300,000 children in the U.S. Methotrexate is also used to treat psoriasis, which 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 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. 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.

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.

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. OTREXUP® provides physicians and patients a convenient, practical and virtually painless 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 over 2,800 physicians. Our marketing data reveals 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.

Competition in the methotrexate market includes tablets and parenteral forms that are currently marketed in the U.S. by several generic manufacturers, including Teva, Pfizer, Inc. ("Pfizer"), Mylan, Inc. ("Mylan"), Bedford Laboratories ("Bedford"), Hospira and Accord Healthcare. In several European countries, Canada, and South Korea, Medac International or its licensees market methotrexate in prefilled syringes (Metoject®) and has also launched an auto injector with methotrexate in those territories. 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.

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.

Distribution – 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 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.

Sales and Marketing – We have the worldwide marketing rights for OTREXUP® and commercialize OTREXUP® on our own in the U.S. We have an internal commercial organization that includes approximately 50 employees directly involved in our sales efforts. We have entered into agreements with vendors for certain 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.

Trade – In connection with the launch of OTREXUP® we have contracted with numerous wholesale distributors such as Cardinal, McKesson Corporation ("McKesson") and Amerisource Bergen Corporation 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 payors 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 or in a more preferential position on their 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 Medicaid 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, it may be subject to prior authorization. Physicians may not be inclined to prescribe it to their Medicaid patients, and even if they do prescribe it, Medicaid may not authorize payment, thereby diminishing the potential market for OTREXUP® in this market segment.

Similarly, in order to ensure coverage by Medicare Part D and commercial pharmacy benefit plans, we participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We offer discount card programs to patients for OTREXUP® in which patients receive discounts on their prescriptions. We utilize a contract service provider to process and pay claims to patients for actual coupon usage. We also provide discounts to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs, and discounts to federal grantees and safety net providers referred to as covered entities pursuant to our pharmaceutical pricing agreement with the Department of Health and Human Services and the 340B drug discount program, which is required as a condition of Medicaid coverage. Government agencies ordering under the FSS and covered entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back the difference between the current wholesale acquisition cost and the price the entity paid for the product.

Sumatriptan Injection USP

We, with our partner Teva, announced the launch of Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine and cluster headache in adults, in June 2016. We received FDA approval of our ANDA for the 4 mg/0.5 mL and 6 mg/0.5 mL single-dose prefilled syringe auto-injectors, a generic equivalent to Imitrex® STATdose Pen®, in December 2015. We have a license, supply and distribution agreement with Teva, under which Teva is responsible for the manufacture and supply of the drug, and we manufacture the device and do final assembly and packaging of the final product. Teva is responsible for commercialization and distribution.

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.

The total U.S. retail anti-migraine market was $5.3 billion in 2016 according to Symphony Health Solutions. The majority of patients who use triptans take oral tablets. Oral drugs accounted for $4.6 billion of the total, and injectable products accounted for approximately $335 million of the total market. While oral triptans have benefited many migraine sufferers, they are most consistently effective when taken at a relatively early stage in the migraine attack. Studies have shown that injectable sumatriptan is more effective and rapid-acting in the treatment of migraine headache that has reached the moderate to severe level of intensity.

According to Symphony, about 6% 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 formulation, a nasal spray (Imitrex, GSK and generic) and a needleless injector (Sumavel, Astellas/Zogenix). There is extensive competition in the sumatriptan marketplace and several manufacturers offer versions of injectable sumatriptan with a delivery device, including GSK (Imitrex STATdose Pen®), Pfizer (Alsuma), ENDO Pharmaceuticals (Sumavel DosePro), and Sun Pharma (generic sumatriptan autoinjector) and Dr. Reddy's Laboratories generic sumatriptan auto-injector (Zembrace SymTouch). One company, Sandoz, Inc. ("Sandoz") markets an authorized generic version of GSK's Imitrex STATdose Pen®. 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.

Sales, Marketing & Distribution – We have a license, supply and distribution agreement with Teva for the auto injector product containing sumatriptan. We manufacture the device and perform final assembly and packaging of the product. Teva manufactures and supplies the drug and distributes the finished combination product in the U.S. Teva also has an option for distribution rights in other territories. Under the agreement, we received an upfront payment and a milestone payment upon commercial launch, and are compensated at cost for shipments of product to Teva. In addition, net profits from sales of the product, after deduction of product sales allowances such as discounts, rebates and chargebacks, are 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.

ZOMA-Jet™ (hGH Needle-Free Injectors)

ZOMA-Jet™ is our needle-free auto injector, which was designed to deliver human growth hormone ("hGH") treatment to children without the use of a needle. 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. We believe this method of administration is a particularly

attractive alternative to the needle and syringe for the following patient groups:

- 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 Europe, Asia, the U.S. 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. 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.

According to Symphony Health Solutions, hGH sales in the U.S. were $2.1 billion in 2016. There is significant competition within the hGH market between major pharmaceutical companies such as 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.

Sales, Marketing & Distribution –The ZOMA-Jet™ device has been sold for use with hGH in more than 30 countries through supply and distribution agreements with our partners Ferring and JCR, and formerly through our partner Teva. Under these arrangements, we receive revenues from the sale of devices to our partners and royalties on sales of their hGH products. 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 our existing device supply agreement. Ferring 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™ March 2015. 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. JCR markets hGH in Japan as the Twin-Jector® EZ II Needle-free Injector.

Products in Development

VIBEX® QST (testosterone)

VIBEX® QuickShot® Testosterone ("QST") 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. We submitted a 505 (b) (2) New Drug Application ("NDA") for QST with the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a PDUFA target date for completion of its review by October 20, 2017.

The U.S. testosterone replacement therapy ("TRT") market in 2016 was approximately $2.3 billion according to a Symphony Health Solutions report. Injectable TRT grew from $232.0 million in 2015 to $264.0 million in 2016, an increase of almost 14%. There is significant competition within the TRT market among many pharmaceutical companies including Abbvie, Inc. (formerly Abbott), Lilly, Endo, Pfizer, Sandoz, Mylan, 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. 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 ("Repros"), Clarus Therapeutics ("Clarus") 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® QST, 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® QST 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® QST and the details of our clinical studies and results.

Competition in the U.S. testosterone replacement market includes Abbvie's Androgel® and Androgel® 1.62%, Lilly's Axiron®, Endo's Fortesta®, Delatestryl®, Testim®(and the authorized generic), Striant® and Testopel®, Pfizer's Depo®-Testosterone, Allergan plc ("Allergan") Androderm®, Upsher-Smith's Vogelxo™ and several generic testosterone in oil products sold by Actavis, Sandoz, Mylan, Bedford, Teva and others. In addition, at least three additional oral treatments for low testosterone levels are either in development. Clarus is developing an oral formulation of testosterone undecanoate, Rextoro™ and Lipocine, Inc. ("Lipocine") is also developing an oral formulation of testosterone undecanoate. Repros Therapeutics, Inc. ("Repros") 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. Lipocine, Repros and Clarus have each received CRLs to their NDAs from the FDA. Each company has reported that they are evaluating next steps in their respective clinical development processes.

In 2014, Endo received U.S. FDA approval of testosterone undecanoate injection, Aveed.™ Endo licensed testosterone undecanoate injection from Bayer, which markets the product as Nebido® in Europe and elsewhere. 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.

Makena® (hydroxyprogesterone caproate injection) Auto Injector

We have a development and license agreement with AMAG to develop and supply an auto injector device for the subcutaneous administration of the drug Makena® (hydroxyprogesterone caproate), which is the only FDA approved therapy 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. The Makena® auto injector utilizes our VIBEX® QuickShot® injection technology.

Currently, Makena® is administered weekly by a healthcare professional, intramuscularly through a large-gauge needle, with treatment beginning between 16 weeks and 20 weeks and six days of gestation and continuing until 36 weeks and six days of gestation or delivery, whichever happens first. The Makena® subcutaneous auto injector we are developing in collaboration with AMAG is expected to provide greater convenience and easier administration for healthcare providers administering the therapy as an alternative to or replacement of the current intramuscular administration method. The development of the subcutaneous auto-injector is part of AMAG's broader next-generation program exploring alternative injection methods, sites and formulations.

AMAG initiated a PK study for the Makena® auto injector in October 2016 and announced positive top-line results from the study in February 2017. According to AMAG, the study successfully demonstrated comparable bioavailability between subcutaneous injection of Makena® compared to intra muscular injection. AMAG anticipates submitting its sNDA for the subcutaneous auto injector for use with Makena® in the second quarter of 2017 and expects a six-month review by the FDA.

According to AMAG, revenue from Makena® was over $334 million in 2016, and is expected to grow to over $400 million in 2017. Makena® is a progestin whose active ingredient is hydroxyprogesterone caproate ("HPC"), which is a synthetic chemical structurally related to progesterone. Progestins, such as HPC, and progesterone belong to a class of drugs called progestogens. Progestogens have been studied to reduce preterm birth and have shown varying results depending upon the subjects enrolled. The Society for Maternal Fetal Medicine Publications Committee published clinical guidelines for the use of progestogens to reduce the risk of preterm birth in the American Journal of Obstetrics and Gynecology in May 2012. Preterm birth is defined as a birth prior to 37 weeks of pregnancy. According to the Centers for Disease Control and Prevention preterm births affected nearly 400,000 babies, or one of every ten infants born in the U.S.

Makena® was approved by the FDA in February 2011 and was granted orphan drug exclusivity through February 3, 2018. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000. The company that first obtains FDA approval for a

designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application for the same drug for the same orphan indication during the exclusivity period, except in very limited circumstances.

VIBEX® with Epinephrine

We have a license, development and supply agreement with Teva for a VIBEX® injector we designed for a product containing epinephrine. 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. Our partner Teva filed an ANDA seeking FDA approval of the product as a generic substitute of Mylan's branded product EpiPen®. We have scaled-up the commercial tooling and molds for this product, and have shipped pre-launch quantities of devices to Teva. 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 has advised us that they submitted a response to the CRL and expects that any approval or launch will not take place before the end of 2017 or beginning of 2018.

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 $2.7 billion in 2016 with the EpiPen® accounting for 99% of the total. While Mylan reported that EpiPen® had a 90% world market share in 2015, there are other companies and alternative products competing in or poised to enter the market. For example, in January 2017, CVS announced that a low-cost epinephrine auto-injector option, the authorized generic for Adrenaclick® manufactured by Impax Laboratories, is available at all CVS Pharmacy locations. Kaléo announced the availability of AUVI-Q® (Epinephrine Injection, USP) Auto-Injector in the U.S. beginning in February 2017, and Adamis Pharmaceuticals recently announced FDA acceptance of a resubmission of its epinephrine pre-filled syringe NDA.

Disposable Pen Injector with Exenatide

We have a license, development and supply agreement with Teva for two disposable pen injector products, including a pen injector with exenatide for the treatment of diabetes. Teva filed an ANDA for a generic version of BYETTA®, which was accepted by the FDA and is currently under FDA review. Teva settled patent litigation with AstraZeneca relating to certain AstraZeneca U.S. patents and their drug, BYETTA® (exenatide). AstraZeneca and Teva entered into a settlement and license agreement pursuant to which AstraZeneca granted Teva a license to manufacture and commercialize the generic version of BYETTA® described in Teva's ANDA. The settlement allows Teva to commercialize their exenatide product in the U.S. beginning October 15, 2017 or earlier under certain circumstances.

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 BYETTA® (exenatide) by AstraZeneca in 2016 were approximately $284 million according to Symphony Health Solutions. BYDUREON®, a long acting form of the medication BYETTA®, had approximately $776 million in U.S. sales in 2016, according to Symphony Health Solutions.

Disposable Pen Injector with Teriparatide

We are also developing with Teva, under a license, development and supply agreement, a multi-dose disposable pen injector with teriparatide for the treatment of osteoporosis. Teva filed an ANDA for a generic version of Forteo® (teriparatide [rDNA origin] injection), which was accepted by the FDA and is currently under review. In response to Teva's paragraph IV certification contained in Teva's ANDA for teriparatide, Lilly filed a lawsuit against Teva alleging infringement of six U.S. patents related to Forteo® (teriparatide [rDNA origin] injection) resulting in a 30-month stay in FDA approval of the ANDA. The stay will expire in August 2018 unless the litigation is resolved sooner. Teva also successfully concluded a decentralized procedure registration process in Europe for the teriparatide injection product for the treatment of osteoporosis. Applications for marketing authorizations in Europe are ongoing. Under the license, development and supply agreement, we are responsible for the manufacturing and supply of the multi-dose pen device. We have begun scaling up tooling and molds for commercial production.

Teriparatide is used for the treatment of osteoporosis in postmenopausal women and men at increased risk of fracture and for glucocorticoid induced osteoporosis in men and women. According to Lilly's 2016 annual report on Form 10-K, 2016 global sales of Forteo® grew to $1.5 billion, of which $779 million was recorded in the U.S. and $729 million in the rest of the world.

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 under Development" section above. 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® QuickShot® Testosterone ("QST"). We are developing QST 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 QST, 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 QST 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 QST treatment resulted in most patients achieving average levels of testosterone within the normal range from the first dose onward. QST 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 QST 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 QST 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 QST 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 QST 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 of the PK study are summarized in the table below.

Population/Analysis	C_{avg} Lower limit of the	C_{avg} % in range 300 – 1100 ng/dL n (%)	C_{max} <1500 ng/dL n (%)	C_{max} >1800 ng/dL n (%)

	95% 2-sided C. I.					
Primary analysis* N=150	87.3	%	139 (92.7	%)	137 (91.3 %)**	0 %
Completers N=137	94.8	%	135 (98.5	%)	137 (100 %)	0 %
Protocol-Required Outcomes	≥65	%	75	%	≥85 %	≤5 %

* All patients with 1 or more doses, C_{avg} 0-168 hours post week 12 injection or last measured concentration carried forward

** Patients without a C_{max} determination at week 12 are assigned above 1500 ng/dL

Overall, the regimen demonstrated a mean (± standard deviation) steady state concentration of testosterone of 553.3 ± 127.3 ng/dL at 12 weeks. Participants in the study remained on QST and were followed for an additional 40 weeks for the collection of safety data.

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 QST. 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 2 study, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to QST 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 NDA for QST 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 QST 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 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 March 2016, we announced that the pharmacokinetic results of QST-13-003 were final and reported the results from the 52-week safety study. The safety population, defined as patients who received at least one dose of study drug, was comprised of 150 patients. The most common adverse reactions (incidence ≥5%) in this phase 3 study were increased hematocrit, hypertension, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. Serious adverse events (SAE's) reported included one case each of worsening depression, vertigo and suicide. None of the SAE's were considered to be related to the study drug by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to study drug. There have been no reported adverse events consistent with urticaria (hives), pulmonary oil micro embolism ("POME"), anaphylaxis or major adverse cardiovascular events in this study.

In May 2015, we received an additional written update from the FDA related to our clinical development program for QST. Based on that update received from the FDA, we concluded there was an agreed upon path forward for the completion of an additional study to support the filing of a NDA for QST. 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 was a dose-blind, multiple-dose, concentration controlled 26-week supplemental safety and pharmacokinetic study of QST, which included 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 assessment. Patients meeting all eligibility criteria were assigned to receive 75 mg of QST once weekly for six weeks. According to the protocol, adjustments to dose could be made at week seven based upon the week six C_{trough} value. QST was provided to clinical sites at dosage strengths of 100 mg, 75 mg and 50 mg to be utilized in dose titration.

In early November 2015, the Company announced that enrollment was complete in study QST-15-005. The safety population, defined as patients who received at least one dose of the study drug, consisted of 133 patients dosed with QST. In June 2016, we announced that the last patient had completed treatment under the 26-week safety and pharmacokinetic phase 3 study QST-15-005, and in September 2016 we announced the results of the study. The most common adverse reactions (incidence ≥5%) in the QST-15-005 study were increased hematocrit, upper respiratory tract infection and injection site ecchymosis. There were four patients with treatment emergent SAE's, which included one patient with transient visual impairment determined not to be drug related, one patient with appendicitis that was not drug related and one patient with deep vein thrombosis (DVT). The investigator attributed DVT as possibly drug related, which is consistent with known testosterone class SAE's. The fourth patient had multiple hospitalizations related to septic arthritis and coronary artery disease, with a complicated clinical course post-angioplasty. These multiple reported events from the fourth patient were deemed not to be drug related. There were no reported adverse events consistent with urticaria, POME or anaphylaxis. The safety data collected also included an assessment of pain. Of the 965 injections assessed, pain was reported one time. In that instance, the pain reported was classified as mild.

Based upon the completion of our clinical and development work and the results of the studies detailed above, we submitted a 505 (b) (2) New Drug Application for QST with the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a PDUFA target date for completion of its review by October 20, 2017.

Partnered Development Projects. We, along with our pharmaceutical partners, are engaged in research and development activities related to our VIBEX® disposable pressure assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our VIBEX® system for a product containing epinephrine and for our pen injector devices for use with generic versions of BYETTA® (exenatide) and Forteo® (teriparatide). We also have a license, development and supply agreement with AMAG for our auto injector device for use with its drug Makena®. 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. We expect development related to these products to continue, however, the development timelines are generally controlled by our partners and the extent of near-term and future development will be dependent on decisions made by our partners. The following is a summary of the development stages for each of the products in development with Teva and AMAG.

Makena® (hydroxyprogesterone caproate injection) Auto Injector

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.

AMAG initiated a PK study for the Makena® auto injector in October 2016 and announced positive top-line results of the study in February 2017. According to AMAG, the study successfully demonstrated comparable bioavailability between subcutaneous injection of Makena® compared to intra muscular injection. AMAG anticipates submitting its sNDA for the subcutaneous auto injector for use with Makena® in the second quarter of 2017 and expects a six month review by the FDA.

VIBEX® with epinephrine

We, in collaboration with Teva, have developed a VIBEX® auto injector device for a product containing epinephrine. Teva is responsible for development work on the drug epinephrine, and we are responsible for development of the device. Teva filed an ANDA for the VIBEX® epinephrine pen as a generic substitute of Mylan's branded product, EpiPen®, which was accepted by the FDA, and amended in December 2014. We have scaled up the commercial tooling and molds for this product and delivered pre-launch quantities of the product in anticipation of a potential approval and launch. However, Teva received a CRL from the FDA in February 2016 in which, according to Teva, the FDA identified certain major deficiencies. Teva has advised us that it submitted a response to the CRL and expects that any approval or launch will not take place before the end of 2017 or beginning of 2018.

Exenatide disposable pen injector

We designed and produced pen injectors for an exenatide pen injector product with Teva. Teva filed an ANDA for a generic version of BYETTA®, which was accepted by the FDA in October 2014 and is currently under review. Teva settled patent litigation with AstraZeneca relating to certain AstraZeneca U.S. patents and their drug, BYETTA® (exenatide). AstraZeneca and Teva entered into a settlement and license agreement pursuant to which AstraZeneca granted Teva a license to manufacture and commercialize the generic version of BYETTA® described in Teva's ANDA. The settlement allows Teva to commercialize their exenatide product in the U.S. beginning October 15, 2017 or earlier under certain circumstances.

Teriparatide disposable pen injector

We designed and produced a multi-dose disposable pen injector for use with teriparatide and have delivered devices for a drug stability program to support a regulatory filing. Teva is developing this product for use in both Europe and the U.S. with the European clinical/regulatory team leading the development.

Teva filed an ANDA for a generic version of Forteo® (teriparatide [rDNA origin] injection), which was accepted by the FDA and is currently under review. In response to Teva's paragraph IV certification contained in Teva's ANDA for teriparatide, Lilly filed a lawsuit against Teva alleging infringement of six U.S. patents related to Forteo® (teriparatide [rDNA origin] injection) resulting in a 30-month stay in FDA approval of the ANDA. The stay will expire in August 2018 unless the litigation is resolved sooner. Teva also successfully concluded a decentralized procedure registration process in Europe for the teriparatide injection product for the treatment of osteoporosis. Applications for marketing authorizations in Europe are ongoing.

Manufacturing

We do not own any manufacturing facilities. We use third parties to manufacture our products and have arrangements 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. Assembly and packaging of all of our products is performed by third-party suppliers under our direction. All manufacturers and suppliers are monitored and evaluated by our quality department to assess compliance with regulatory requirements and our internal quality standards and

benchmarks. We perform quality review and product release.

We utilize a broad range of third party manufacturers to manufacture and supply certain components, drugs, final assembly and finished product. We have recognized the risk of such supply chain disruptions and approached the situation through risk management strategies designed to mitigate the effects of such disruptions, including, in some cases, having our products manufactured by more than one supplier or at more than one site. While this creates additional effort overseeing production at a number of facilities, we believe our manufacturing risks are better managed by utilizing a range of third party manufacturers at diverse locations. 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® QST auto injector device, our VIBEX® QuickShot® device for the Makena® auto injector product with AMAG, our VIBEX® epinephrine auto injector and our pen injector devices for the exenatide and teriparatide pen products with Teva.
- We utilize 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 ("Sharp"), an international contract packaging company, to assemble and package OTREXUP® and Sumatriptan Injection USP. All of our pharmaceutical manufacturing and packaging suppliers are subject to compliance with Current Good Manufacturing Practices ("cGMP").
- We have identified a contract manufacturer to supply commercial quantities of pre-filled syringes for our VIBEX® QST auto injector.

We have a highly experienced quality group that works with and regularly inspects or meets with our manufacturers to review the manufacturing process for our products and to provide input on quality issues.

Collaborative Arrangements and License Agreements

We have entered into significant partnering arrangements and licensing agreements with Teva, AMAG, Ferring and other pharmaceutical partners. The following is a summary of those agreements.

Teva License, Development and Supply Agreements

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 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, the latest of which will expire in 2033. We have and plan to continue to file patent applications covering this product.

In December 2007, we entered into a license, development and supply agreement with Teva under which we developed and will supply a disposable pen injector for two therapeutic products: exenatide and teriparatide. 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 2016, 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 additional patent applications that, if granted, would expire beyond that date.

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. Under the agreement, we received an upfront payment and a milestone payment upon commercial launch, which occurred in June 2016. Teva is responsible for the manufacture and supply of the drug, and we manufacture the device and do final assembly and packaging of the final product. We are compensated at cost for product shipment to Teva and Teva distributes the product in the U.S. Teva also received an option for distribution rights in other territories. In addition, net profits are 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.

Ferring Agreements

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.

In September 2006, we entered into a Supply Agreement with Teva, and in December 2014, Ferring acquired the U.S. rights from Teva and assumed Teva's obligations under the Supply Agreement. Pursuant to the agreement, Ferring is obligated to purchase all of its delivery device requirements from us for hGH marketed in the U.S. We received an upfront cash and milestone payments and are entitled to royalty payments on net sales of hGH, as well as a purchase price for each device sold. The original term of this agreement extended through September 2013, which was amended in May 2013 to provide for one-year automatic renewals unless terminated by either party six months ahead of the expiring term.

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.

AMAG Development and License Agreement

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 Makena®, 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.

Other Agreements

We have an agreement with JCR through 2017 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 2017.

We have a licensing agreement with Allergan, plc, under which we receive royalties on sales of their oxybutynin gel product Gelnique® 10%. The term of the agreement ends on the later of April 2024 or the expiration date of the last to expire patent.

We have a licensing agreement with Meda (acquired by Mylan in 2016), under which we receive royalties on sales of Elestrin®.

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.

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.

Competition

The pharmaceutical, medical device and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our competitors include established biotechnology companies, specialty pharmaceutical companies and many of the major brand name and generic manufacturers of pharmaceuticals such as Teva, Mylan, Lilly and Endo. We have a wide range of competitors depending upon the branded or generic marketplace, the therapeutic product category, and the product type, including dosage strengths and route of administration. Our competitors also include third party contract medical device design and development companies such as Scandinavian Health Ltd. (“SHL”) and Owen Mumford Ltd. (“Owen Mumford”). Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. Smaller or early stage emerging companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

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.

If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. Branded products not only face

competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals typically invest far less in research and development than research-based pharmaceutical companies and therefore can price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits but also cost advantages as compared with other forms of care.

Newly introduced generic products with limited or no other generic competition typically command higher prices initially. At the expiration of the exclusivity period, other generic distributors may enter the market, resulting in a significant price decline for the drug. As a result, the maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and launch new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing capabilities.

Industry Trends

Based upon our experience, we believe the following significant trends have important implications for the growth of our business.

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.

Patented pharmaceutical products continue to be challenged by generic companies once substantial proprietary sales are generated. 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.

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. There is ongoing effort by public and private payors to reduce the cost of drugs and reduce the overall cost of health care. There continues to be greater pressure on drug manufacturers to provide greater discounts and rebates on their products. The drug distribution channels are complex and involve many different parties. Recently, such channels have undergone and continues to undergo consolidation. Drug wholesalers and retail drug chains have merged or consolidated resulting in significantly larger organizations with greater resources and bargaining power controlling multiple levels of the drug distribution network. Consequently, pharmaceutical companies are facing increasing pressure to reduce prices. Additionally, the emergence of large buying groups representing independent retail pharmacies and other drug distributors, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to demand larger price discounts on our products. For example, there has been a recent trend of large wholesalers and retailer customers forming partnerships, such as the alliance between CVS and Cardinal Health. As a result of this consolidation among wholesale distributors as well as the growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market.

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 ("FFDCA") 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, refusal of the government to approve NDAs or ANDAs, injunctive actions and civil or criminal actions or penalties.

Drug Approval Process

FDA approval of our own and our partners' products is required before the products may be commercialized in the United States. Section 505 of the FFDCA describes three regulatory pathways for marketing authorization for a new drug:

- A 505(b)(1) NDA is an application that is used for the approval of a new drug (for clinical use) that contains full reports of investigations of safety and effectiveness.
- A 505(b)(2) NDA is an application where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This alternate route for regulatory approval permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products and/or published

scientific literature. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new strength, dosage form, route of administration or indication sought by the 505(b)(2) applicant that is supported by new clinical data and/or published scientific literature.

- Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, route of administration, and dosage form as the listed drug, which has the same labeling, performance, characteristics, and intended use as the listed drug, and has been shown to be bioequivalent to the listed drug. Limited changes to these factors are permitted in some cases but must be pre-approved by the FDA via a suitability petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if, among other reasons, the FDA determines that it is not equivalent to the referenced listed innovator drug, if it is intended for a different use, or if it is not subject to an approved suitability petition. ANDA applicants are generally required to conduct bioequivalence testing to confirm chemical and therapeutic equivalence to the branded reference drug. Generic versions of drugs can often be substituted by pharmacists under prescriptions written for the branded reference drug.

For both NDAs and ANDAs, the FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, safety, potency, and purity.

The following table provides a summary description of the various regulatory pathways:

	ANDA	505(b)(2) NDA	Traditional NDA
Clinical Trials/Testing Required	Generally, bioequivalence.	Yes, to address potential differences between the branded reference product and the 505(b)(2) product, as well as bridging studies.	Yes, full reports of safety and efficacy.
Results in Orange Book Listed Patents	No	Yes, for novel formulations, other enhancements and new indications.	Yes
Exclusivity	Potential for 180 days against other generic filers if first generic to file with a paragraph IV certification. Potential for 30-month stay if the patent or listed drug application holder brings an infringement action.	Potential for three years for new clinical investigations (other than bioavailability and bioequivalence studies) that are essential to approval of the application. Potential for 30-month stay if the patent or listed drug application holder brings infringement action.	Potential for five years for a new chemical entity, or three years for new clinical investigations (other than bioavailability and bioequivalence studies) that are essential to approval of the application.
Patent Certification	Yes	Yes	No

Required			
Potential orphan drug designation	No	Yes	Yes

Drug Status

NDA Submission

The process required by the FDA before a new drug pharmaceutical product or a change to an already approved 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 Investigational New Drug ("IND") application, which must be in effect before clinical trials may begin;

- adequate and well controlled human clinical trials to establish the safety and efficacy of the drug for its intended indication(s);
- development of manufacturing processes to ensure the drug's identity, strength, quality, and purity;
- submission to the FDA of an NDA;
- FDA compliance inspections and/or clearance of all manufacturers and facilities, as well as select clinical trial sites; 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.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease. Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including cGLPs. The results of preclinical testing are submitted to the FDA as part of an IND, to support human clinical trials along with other information, including information about product chemistry, manufacturing and controls, available scientific literature, and a proposed clinical trial protocol. Some preclinical testing may continue even after the IND is submitted.

A sponsor of a proposed clinical trial must submit an IND application to the FDA before a clinical trial may commence. The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In addition, an independent Institutional Review Board ("IRB"), covering each site proposing to conduct the clinical trial or a central IRB must review and approve the plan for any clinical trial, subject communications, and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial, place a trial on hold, or discontinue a trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's or FDA's requirements.

Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRB for approval. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials, including clinical trial results within set timeframes. Moreover, under the 21st Century Cures Act, manufacturers or distributors of investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must have a publicly available policy concerning expanded access to investigational drugs.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients in accordance with the applicable protocol and all applicable laws, rules and regulations. Clinical trials are typically conducted in sequential phases, which may overlap, though in the case of a 505(b)(2) NDA, some study requirements may be abbreviated. Studies, in addition to the below, such as pediatric studies, may also be required by the FDA:

- Phase I - 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. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
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Phase II - 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 phase III in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for seeking approval of the new drug. Typically two Phase III trials are required by FDA for product approval.

In addition to the above traditional kinds of data required for the approval of an NDA, the recently passed 21st Century Cures Act, provides for FDA acceptance of new kinds of data such as patient experience data, real world evidence, and, for appropriate indications sought through supplemental marketing applications, data summaries.

The FDA, an IRB, or a sponsor may suspend or terminate clinical trials at any point in this process on various grounds, including a finding that patients are being exposed to an unacceptable health risk, if they decide it is unethical to continue the study, the clinical trial is not being conducted in accordance with FDA or IRB requirements, or based on evolving business objectives or the competitive climate. 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.

Following marketing approval, sponsors may also voluntarily or be required to conduct additional studies, called Phase IV studies. For instance, the FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA.

The results of drug development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. In most cases, the submission of an NDA is subject to a substantial application user fee. Fee waivers or reductions are available in certain circumstances.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review. The FDA may request additional information rather than accept an NDA for filing. Once the submission is accepted for filing, the FDA's goal is to review 90% of all applications for non-New Molecular Entities ("NMEs"), within ten months from the submission date. The FDA, however, may give a priority review designation to drugs that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the serious conditions. A priority review means that the goal for the FDA is to review an application within six months of the submission date for non NMEs. The review process may also be extended if the FDA requests or the NDA sponsor otherwise provides substantial additional information or clarification regarding the submission.

After evaluating the NDA and all related information, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a CRL describing the application deficiencies. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

ANDA Submissions

Much like NDAs, FDA approval is required before a generic drug equivalent to a listed drug can be marketed. We seek approval for such products by submitting an ANDA. For ANDAs, applicants are not required to conduct complete clinical studies. Such applications, though, normally require bioavailability and/or bioequivalence studies. "Bioavailability" indicates the extent of absorption of a drug product as it becomes available at the site of drug action. "Bioequivalence" indicates that the active drug substance that is the subject of the ANDA submission is equivalent to the previously approved drug in terms of the availability of the drug at the site of action. While an IND, in many cases, is not required for bioavailability and bioequivalence testing, such studies must still be conducted in accordance with GCPs and under the supervision of an IRB.

Like NDAs, ANDAs must be accompanied by user fees. For generic drugs, other fees, such as fees for drug master files and manufacturing facilities, also may also be required to be paid by the applicant, manufacturer, and/or drug master file holder.

Following submission of an ANDA, the FDA has 60 days to evaluate the application to determine if it is substantially complete. If the agency finds that the application is substantially complete, it will receive the application and begin its substantive review. Under FDA's regulations, FDA will review the ANDA and send the applicant either an approval letter or a CRL within 180 days from the date the agency determined that the application was "received." In practice, however, the time for the completion of ANDA review may be substantially longer.

As further discussed below, 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.

Generally Applicable Requirements

Clinical trials for all product candidates must be conducted in accordance with Good Clinical Practices ("GCPs"). Before approving an application the FDA may inspect one or more clinical trial sites to assure compliance with GCPs.

Further, during development, the manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

For both NDAs and ANDAs, the FDA also may require submission of a risk evaluation and mitigation strategy ("REMS") or REMS, to ensure that the benefits of the drug outweigh the risks of the drug. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. Further, should new safety information arise, additional testing, product labeling, or FDA notification may be required.

Both before and after market approval is obtained, a product, its manufacturer and the holder of the application 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, clinical trial holds or suspensions, withdrawal of an approved product from the market and the imposition of criminal or civil penalties against the manufacturer and application holder, among other consequences. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or application 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.

The Hatch-Waxman Amendments

Orange Book Patent Listing

When an NDA is submitted to the FDA seeking approval of a drug, including a 505(b)(2) NDA, the applicant is required to list certain patents whose claims cover the applicant's product with FDA. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. The Orange Book listed NDA products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires and approval will not be sought until after the patent expiration; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV patent certification. The applicant may also

elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. Generally, the ANDA or 505(b)(2) NDA approval cannot be made effective by FDA until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a paragraph IV certification or if the applicant is not seeking approval of a patented method of use.

If the ANDA or 505(b)(2) applicant makes a paragraph IV certification challenging an Orange Book-listed patent, a notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers.

If the NDA holder and patent owners of the listed drug asserts an infringement of the patent in court within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from making the approval of the ANDA or 505(b)(2) application effective until the earlier of 30 months from the receipt of the paragraph IV certification, the expiration of the patent, the settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant, or such shorter or longer period as may be ordered by a court. The ANDA or 505(b)(2) application approval also will not be made effective until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below.

Non-Patent Exclusivity

The holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot make the approval of an ANDA or 505(b)(2) application that relies on the listed drug effective. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity (“NCE”), which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacological action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

The holder of an NDA, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product or a new dosage form or route of administration, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from making the approval of any ANDA or 505(b)(2) application effective for the protected modification until after that three year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

As a general matter, because the three year exclusivity is related to the product’s changed condition only, it does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Instead, three year exclusivity prohibits FDA from approving only subsequent ANDAs and 505(b)(2) NDAs that seek approval for that same changed condition and that reference the drug product with the three year exclusivity. Five year and three year exclusivity will also not delay the submission or approval of a full NDA.

In addition, an applicant submitting an ANDA to the FDA may be entitled to a 180 day market exclusivity period with respect to subsequently filed generic applications if such applicant is the first to submit a substantially complete application to FDA and whose filing includes a Paragraph IV certification that the applicable patent(s) are invalid, unenforceable and/or not infringed, obtains approval, and launches the product in the marketplace without triggering any statutory forfeiture provisions.

Orphan Drug Designation

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation provides certain benefits, such as the opportunity for grants and tax credits. If approved for the orphan designation, orphan designated drugs may receive seven years of exclusivity, which, subject to certain exceptions, protects the drug from FDA approval of another drug with the same principal molecular features for the same orphan indication.

Combination Drug/Device Regulation

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” because they contain both a drug and a device to administer the drug. The combination products are regulated as a drug, and are therefore subject to the NDA, ANDA, sNDA, sANDA and 505(b)(2) drug approval process and regulations. 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. Additionally, such products may also be subject to certain device requirements. The FDA will provide guidance on compliance with the applicable device requirements, including the Quality System Regulations ("QSRs"), relating to device manufacturing and post-market surveillance requirements. These requirements could have a substantial adverse impact on our ability to commercialize our products and our operations.

Other Post-Approval Requirements and Promotional Activities

Any product manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, reporting, including adverse experience reporting, drug shortage reporting, and periodic reporting, product sampling and distribution, advertising, marketing, and promotion, and post approval obligations imposed as a condition of approval, such as Phase IV clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

There also are continuing annual user fee requirements, as well as new application fees for certain applications. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register and/or self-identify their establishments with the FDA and certain state agencies and list their drug products. The distribution of prescription pharmaceutical product samples is also subject to the Prescription Drug Marketing Act ("PDMA").

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties, as well as liability under the civil False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, and refusal of government contracts among other consequences.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Specifically, manufacturers and product sponsors may not promote a product for off-label uses

and must also comply with FDA's other promotional requirements.

Manufacturing and Quality Regulations

The FDA established regulations to require that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs and medical devices conform to cGMPs and QSRs. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations, and require the conduct of investigations and FDA reporting under certain circumstances. The cGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design requirements and validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the FFDCA. Compliance with the regulations requires a continuous commitment of time, money and effort in all operational areas.

Concurrent with clinical trials, companies must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to NDAs and ANDAs. In addition, manufacturers of both

pharmaceutical products and active pharmaceutical ingredients (APIs) used to formulate the drug also ordinarily undergo a pre-approval inspection. Failure of any facility to pass a pre-approval inspection will result in delayed or non-approval and would have a material adverse effect on our business, results of operations, financial condition and cash flows.

The FDA also conducts periodic inspections of drug and device facilities to assess the cGMP/QSR status of marketed products. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance for a Warning Letter. FDA guidelines also provide for the issuance of Warning Letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. Finally, the FDA could issue a Form 483 Notice of Inspectional Observations, which could cause us to modify certain activities identified during the inspection. If the FDA were to find serious cGMP/QSR non-compliance during such an inspection, it could take other regulatory actions that could adversely affect our business, results of operations, financial condition and cash flows. Imported API and other components needed to manufacture our products could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or request or in some instances require product recalls and seek to enjoin or otherwise limit a product's manufacture and distribution. In certain circumstances, violations could support civil penalties, criminal prosecutions, and sanctions that include preventing that company from receiving the necessary licenses to export its products, among other consequences.

Controlled Substances Regulation

Certain of our drug products are considered "controlled substances" as defined in the Controlled Substances Act ("CSA") and implementing regulations, which establish certain registration, security, reporting, storage, distribution, importation, inventory, quota, record keeping, and other requirements administered by the Drug Enforcement Agency ("DEA"). The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. These requirements are directly applicable to us and also applicable to our contract manufacturers and to distributors, prescribers and dispensers of our products.

The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The active ingredient in our pending QST product, testosterone, is listed by the DEA as a Schedule III substance under the CSA. Consequently, if in the future QST is approved by the FDA, QST will be subject to certain regulations under the CSA. For example, certain prescription requirements must be met for the dispensing of Schedule III controlled substances both on the federal and state level.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule. Certain reports must also be made for controlled substances, such as reports for thefts or significant losses of any controlled substance. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states may also regulate controlled substances, and we, as well as our third-party suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of certain controlled substances.

Foreign Approval Process

In addition to regulations in the U.S., we (and, where appropriate, our partners marketing medicinal products incorporating our devices) are subject to various foreign regulations governing clinical trials, manufacturing, and the commercial sales and distribution of our medicinal products. We and/or our partners must obtain approval of a medicinal 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, manufacturing, 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.

In the European Union ("EU"), marketing authorizations for medicinal products can be obtained through several different procedures, principally the centralized mutual recognition procedure, and the decentralized procedure. The centralized procedure allows a company to submit a single application to the European Medicines Agency ("EMA"), which may provide a positive opinion regarding the application to the effect that it meets certain safety, quality and efficacy requirements. A centralized marketing authorization will be granted based on a positive opinion of the EMA as approved by the European Commission. It is valid in all EU member states and three of the four European Free Trade Association countries (Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and biologic products, and optional for certain other high technology products. The decentralized procedure allows companies to file identical applications for authorization to several EU member states simultaneously for medicinal products that have not yet been authorized in any EU member state. The competent authority of one EU member state, selected by the applicant (the Reference Member State), assesses the application for marketing authorization. The competent authorities of the other EU member states are subsequently required to grant marketing authorization for their territories on the basis of this assessment except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized by the competent authorities in other EU member states.

In so far as our products may be sold as medical devices outside of the U.S. (as opposed to a delivery system of a medicinal product) we are also subject to foreign legal and regulatory requirements. 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 primarily 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.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, marketing, sale and promotion of drug products and medical devices are subject to numerous regulations by various federal, state and local authorities.

We are subject to various U.S. federal and state laws restricting certain marketing practices in the pharmaceutical industry, including anti-kickback laws and false claims laws. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Liability under the federal anti-kickback statute may be established without a person or entity having actual knowledge of the statute or specific intent to violate it. Violations of the federal anti-kickback statute may be punished by civil and criminal fines, imprisonment, and/or exclusion from participation in federal healthcare programs. The federal civil False Claims Act, also known as the False Claims Act, prohibits, among other things, any person from

knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false statement to get a false claim paid. Violations of the False Claims Act may result in significant financial penalties and damages.

Various federal health care programs obligate us to report drug pricing information that is used as the basis for their reimbursement rates for pharmacies and other health care providers, prices charged certain federal agencies and non-federal purchasers, and rebates on prescriptions paid by Medicaid and other plans. Failure to comply with the rules for calculating and submitting pricing information or otherwise overcharging the government or its beneficiaries could expose us to sanctions, including False Claims Act liability.

In addition, the Physician Payment Sunshine Act provisions of the Healthcare Reform Act require extensive tracking of payments and transfers of value to physicians and teaching hospitals and public reporting of the data collected, and government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports. The Sunshine Act and similar state laws impose reporting requirements for various types of payments to

physicians and teaching hospitals. Failure to comply with required reporting requirements under these laws could subject manufacturers and others to substantial civil money penalties.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and the False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities. Some states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to implement compliance programs or marketing codes of conduct.

Medicare patients and documents concerning the provision of financial assistance to Medicare patients taking drugs sold by us. The OIG has established guidelines that permit pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor’s product. If we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Healthcare Reform Act, is broad legislation designed to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the “donut hole”), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service’s 340B drug pricing discount program, or 340B program, fraud and abuse and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. While the Affordable Care Act may be repealed and replaced by Congress, in whole or in part, which may greatly affect these government and third-party programs and their effect on our business, certain of the programs described above will remain and will require our continued compliance.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996 ("HIPPAA") and its implementing regulations established uniform standards for certain "covered entities," which are certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which expanded certain of HIPAA's privacy and security standards. Among other things, HITECH makes HIPAA's security standards and certain privacy standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, the U.S.

Third-Party Payor Coverage and Reimbursement

The commercial success of our product portfolio, if and when approved, will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the

associated healthcare costs. Sales of our product portfolio will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our product portfolio will be paid by health maintenance, managed care, pharmacy benefit, and/or similar healthcare management organizations, or are reimbursed by government health administration authorities, such as Medicare and Medicaid, private health coverage insurers and other third-party payors. The market for our product portfolio will depend significantly on access to third-party payors' formularies, or lists of treatments for which third-party payors provide coverage and reimbursement.

Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Further, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. The cost of pharmaceuticals and medical devices continues to generate substantial governmental and third-party payor scrutiny. We expect that the pharmaceutical industry will experience continued pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative and administrative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative and administrative reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product portfolio and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Reform

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that will likely affect our future operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs, improve access, and improve quality. The Affordable Care Act (“ACA”), passed in 2010, provided more Americans with health care coverage while attempting to curb the growth in healthcare spending in the United States. The legislation included reforms to patient rights and protections, rules for insurance companies, taxes, tax breaks, funding, spending, and amended other laws including the Food, Drug and Cosmetics Act. Some of the main provisions of the ACA that affected the pharmaceutical and biotechnology industry include, among others, included:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and inclusion of Medicaid managed care plan utilization in manufacturers’ rebate obligations;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated;

- a new Medicare Part D coverage gap discount program;
- expansion of eligibility criteria for Medicaid programs thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

We anticipate that the Affordable Care Act may be repealed and replaced by Congress, whether in whole or in part.

The Drug Supply Chain Security Act imposes on manufacturers of certain pharmaceutical products obligations related to product tracking and tracing, among others. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, near the end of 2017 will be required to label drug product with a product identifier, and are required to keep certain records regarding the drug product. The

transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers are also required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufacturers have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements are also imposed on other trading partners in the supply chain.

We expect that additional state and federal healthcare reform measures will be adopted in the future. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in January 2016, CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, revises the manner in which the “average manufacturer price” is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the ACA. Any additional healthcare reform measures could further constrain our business or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressures.

Other Regulatory Requirements

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. We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

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, 2017, we had 110 full-time employees. Of the 110 employees, 50 are primarily involved in research, development and manufacturing activities, 44 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 $24,338,804 and $20,658,846 in the years ended December 31, 2016 and 2015, respectively. In addition, we had an accumulated deficit at December 31, 2016 of $253,445,306. 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, 2016, we had cash and cash equivalents of $27,714,588 and no debt obligations. We believe the combination of our current cash and projected product sales, product development fees, license revenues, milestone payments and royalties should provide us with sufficient funds to meet our obligations and support operations through at least the first quarter of 2018. However, we have not historically generated, and do not currently generate, enough revenue or operating cash flow to support our operations, and continue to operate primarily by raising capital. We reported net losses of $24,338,804, $20,658,846 and $35,151,715 and negative cash flows from operations for each of the years ended December 31, 2016, 2015 and 2014, respectively. We have an accumulated deficit at December 31, 2016 of $253,445,306. We are exploring collaborations and potential financings to raise additional capital. If, however, we are not successful in raising additional cash, we may be required to defer or delay certain planned capital expenditures and other spending related to the potential approval and launch of QST, or curtail other controllable costs and discretionary spending for new research and development activities.

If we do obtain financing, we cannot assure that the amount or the terms of such financing will be as attractive as we may desire, and your equity interest in the company may be diluted. If we are unable to obtain 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 market and sell OTREXUP®;
- our ability to successfully develop and obtain regulatory approval for our own product candidates such as QST, and if approved, successfully commercialize the same;

- our and our partners' ability to obtain regulatory approval, and where applicable to obtain an AB-rating, of partnered products including VIBEX® epinephrine, multi dose pens for use with exenatide and teriparatide, the auto injector for AMAG's Makena®, and others;
- the success of our partners in launching and selling new products such as VIBEX® Sumatriptan and selling our existing products;
- our ability to successfully build commercial channels and sell future products if we choose not to partner the product;
- our ability to manufacture, or have manufactured, products efficiently, at the appropriate commercial scale, and with the required quality;
- timing of our and 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. Regardless of whether we commercialize our products ourselves or rely on third parties, we will be responsible for compliance with FDA's laws and regulations concerning marketing and promotion. Should our employees or the employees of a third party fail to comply with these requirements, we may face regulatory enforcement action. 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® requires 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 rely on third parties to perform many necessary services for OTREXUP®, including services related to the distribution, invoicing, rebates and contract administration, 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. We rely on third parties to administer our drug price reporting rebate payments, and contracting obligations under federal programs; however, we are responsible for compliance with the program requirements. If our employees or these third-party service providers fail to comply with applicable laws and regulations, we and/or they may face regulatory enforcement action. Moreover, if these third-party service providers 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 and/or they 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.

The increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products may adversely affect our revenues and profits.

Our ability to achieve continued growth and profitability through sales of generic pharmaceuticals is dependent on our and our partners' continued success in challenging patents, developing non-infringing products or developing products with increased complexity to provide opportunities with U.S. market exclusivity or limited competition.

To the extent that we or our partner succeed in being the first to market a generic version of a product, and particularly if we or our partner receives a 180-day period of exclusivity in the U.S. market, as a result of being the first applicant to submit a substantially complete ANDA with a paragraph IV certification and successfully launch the product as provided under the Hatch-Waxman Act, our and our partners' sales, profits and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of an equivalent product. Even after the exclusivity period ends, there is often continuing benefit for a time from having the first generic product in the market.

Similarly, to the extent we are able to receive exclusivity for our products approved through the 505(b)(2) pathway, our sales, profits, and profitability can be positively impacted. However, we may not be granted the periods of regulatory exclusivity that we anticipate, and if we do not receive such periods, we may be subject to ANDA and/or 505(b)(2) competition sooner than we anticipate.

Additionally, the number of generic manufacturers targeting significant new generic opportunities with Hatch-Waxman exclusivity, or which are complex to develop, continues to increase. Additionally, many of the smaller generic manufacturers have increased their capabilities, level of sophistication and development resources in recent

years. Other companies may also be developing drugs using the 505(b)(2) pathway that are substantially similar to our products and/or product candidates. The failure to successfully develop and commercialize highly complex generic and 505(b)(2) products could adversely affect our sales and profitability. For instance, if another company receives the 180-day exclusivity period, FDA may not make our application effective during the first-to-file company's exclusivity period. This may prevent us from establishing a sufficient market share for our product. Similarly, should another company obtain FDA approval for a pharmaceutically equivalent product to one of our product candidates, we may no longer be able to use the 505(b)(2) pathway. In that case, it is the FDA's policy that the appropriate submission would be an ANDA. We may, however, not be able to immediately submit an ANDA or have an ANDA approval made effective, as we could be blocked by others' periods of patent and regulatory exclusivity protection.

The 180-day market exclusivity period is triggered by commercial marketing of the generic product or, in certain cases, by a final court decision holding the applicable patents to be invalid, unenforceable or not infringed. 180-day exclusivity may also be triggered by a settlement order or consent decree, or the withdrawal of the patent information by the reference listed drug sponsor. However, the exclusivity period can be forfeited by our failure to obtain tentative approval of our product or to launch a product within a specified statutory period. The Hatch-Waxman Act also contains other forfeiture provisions that may deprive the first "Paragraph IV" filer of exclusivity if certain conditions are met, some of which may be outside our control. Accordingly, we may face

the risk that our exclusivity period is triggered or forfeited before we are able to commercialize a product and therefore may not be able to exploit a given exclusivity period for specific products.

We face intense competition from companies that have greater resources and capabilities.

Many of our competitors are larger and have substantially longer experience in the development and marketing of innovative and specialty consumer-oriented products. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development and marketing of new products and/or technologies than we can. As a result, any products and/or innovations that we develop may become obsolete or noncompetitive before we can recover the expenses incurred in connection with their development. In addition, for these product categories we must demonstrate to physicians, patients and third-party payors the benefits of our products relative to competing products that are often more familiar or otherwise better established. If competitors introduce new products or new variations on their existing products, our marketed products, even those protected by patents, may be replaced in the marketplace, we may never be able to establish a sufficient market share or we may be required to lower our prices.

In addition, our specialty pharmaceuticals business requires much greater use of a direct sales force than does our generic business. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. We may also need to enter into co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well-aligned to achieve maximum penetration in the market. Any failure to attract or retain qualified sales personnel or to enter into third-party arrangements on favorable terms could prevent us from successfully maintaining current sales levels or commercializing new innovative and specialty products.

We depend on Teva to manufacture and supply the drug and to 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. In addition, if Teva is not able to produce sufficient supplies of the drug in accordance with cGMPs, we also will be unable to produce a finished product and we and/or Teva may be subject to regulatory enforcement action. 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 and product candidates according to government regulations. The future development and delivery of our and our partners' products and 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' products and 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. We and/or our partners must obtain FDA approval for a product's or product candidate's manufacturing process and facilities, which we and/or our partners may never obtain or may not be able to maintain. If we or our partners are not able to obtain or maintain this approval, we and/or they would not be able to receive product approval, and commercialize and/or sell the applicable products. Moreover, should any manufacturer fail to comply with the applicable regulatory requirements, we, our partners, and/or the manufacture may face regulatory consequences, including enforcement actions and/or product recalls. 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. We and/or our partners would be dependent on the contract manufacturer for the maintenance and right of reference to the drug master file. If the contract manufacture fails to maintain a drug master file or withdraws our or our partners' right of reference, we and/or our partners may no longer be able to manufacture, develop, market, and sell our or our partners' products or product candidates. FDA approval of the new manufacturer and manufacturing site, as well as certain changes to the manufacturing process, 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 and sumatriptan 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 product candidates or failure to supply product or product candidates 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 and our partners depend on these third-party manufacturers to comply with cGMPs/QSRs 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 site-specific, the FDA and other regulatory authorities will repeatedly inspect our and our partners' current and future third-party manufacturers' facilities for compliance with cGMPs/QSRs. If we, our partners, or 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, refuse to approve any marketing applications, or refuse to allow future or current development of product candidates, among other things. Our third-party manufacturers may also fail to pass the audits by our or our partners' internal quality and regulatory group. Any of these actions could delay or prevent our development of products, delay or prevent the submission of these products for regulatory approval, delay or prevent marketing approval, or result in insufficient product or product candidate quantity to support commercial demand or development. 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® and Sumatriptan Injection USP:

- 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® and Sumatriptan Injection USP;
- Cardinal for services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management; and
- ComDel for manufacturing services related to the sumatriptan auto injector.

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 or cGMP 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. Increasingly, payors are looking for metrics and performance-based pricing to justify increased cost of therapeutic advancements.

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 profit sharing on Sumatriptan Injection USP with Teva and 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 FFDCA 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 also 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" or otherwise not in accordance with the agency's promotional requirements, 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, among other enforcement requirements. 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 and/or government contracting, 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 scientific 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 their 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, and two pen products with exenatide and teriparatide. 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 in a timely manner or at all, or if FDA approved they will be a significant revenue source for us. Additionally, we are currently working with AMAG to develop an auto injector for the subcutaneous administration of Makena® and there is no assurance that development of this product will continue or that it will receive FDA approval or, if FDA approved, that such product will be a significant revenue source for us. There is no assurance that AMAG will be able to submit an sNDA for Makena in a timely fashion or at all, or that FDA will accept the sNDA filing mechanism or approve the sNDA.

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, 2016, we derived approximately 48% of our revenue from Teva and 12% from Ferring. 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 2016.

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, such as Sumatriptan Injection USP, 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 U.S. laws and regulations, such as 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 and/or they may also be subject to regulatory action should we or they fail to comply with the applicable laws and regulations.

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® and Sumatriptan Injection USP has involved high volume production of numerous complex parts as well as assembly of those parts. Our planned future device business may necessitate changes and additions to our contract manufacturing and assembly process or the use of a secondary manufacturer due to the anticipated larger scale of manufacturing in our business plan. Our devices must be manufactured in compliance with regulatory requirements, in a timely manner and in sufficient quantities while maintaining quality and acceptable manufacturing costs. In the course of these changes and additions to our manufacturing and production methods, we may encounter difficulties, including problems involving scale-up, yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment and component supplies, any of which could result in significant delays in production. We may also need to obtain FDA approval for any such changes, which may not be granted.

We rely on Nypro and Phillips to manufacture the pressure assisted auto injector device. 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 use ComDel Innovation, Inc. and other third parties to manufacture certain parts for Sumatriptan Injection USP. Any failure by ComDel to successfully manufacture the device for Vibex sumatriptan 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 use Sharp for final assembly and packaging of many of our and our partners' products. Any failure by Sharp to successfully perform final assembly and packaging of our or our partners' products, or be in compliance with regulatory requirements, may result in product shipment delays and may have a negative impact on our product availability and future revenue expectations.

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.

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 and may require regulatory approval. 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, or managed care organizations do not cover our products or disadvantage them on their formularies, 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 and perceived advantages/disadvantages;
- cost effectiveness;
- substitutability under state pharmacy laws, in the case of generic products;
- 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 other 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, and AMAG 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 and that a launch, if any, will not take place before late 2017 or early 2018. There can be no assurances that the ANDA for the epinephrine pen will be approved by the FDA, or that the product will ultimately be launched. While we assist our partners in some cases 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 may also 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, FDA, or other applicable regulatory authorities. We cannot assure you that we or our partners will not experience delays or undesired results in these or any other clinical trials. Clinical trials may also be suspended, placed on hold, or terminated by us, institutional review boards, FDA, or other applicable regulatory authorities for a number of reasons, including failure to comply with the applicable regulatory requirements, including GCPs, and issues involving subject safety.

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 or other costly and burdensome requirements. Such limits and requirements may include warnings, including black box warnings, limitations on the indicated use, including the applicable population, contraindications, Risk Evaluation and Mitigation Strategies, and post-approval studies and/or monitoring. 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 may face competition from generic products, 505(b)(2) products, full NDA products, biologics, and biosimilars. Competition from generic and/or biosimilar products could result in lower cost products, which could lower our value proposition relative to that of costlier branded products and decrease the revenue we receive for our products.

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, in 2016 Teva completed its acquisition of the generic business of Allergan (formerly Actavis). We are presently working with Teva on four products, VIBEX® with epinephrine, Sumatriptan Injection USP, a pen product with exenatide, and a pen product with teriparatide. 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. For instance, for any products approved via the NDA pathway, we will be required to submit certain patent information for inclusion in FDA's Orange Book. If third parties identify our products as reference listed drugs in any ANDA or 505(b)(2) applications, they will be required to provide patent certifications in their applications for our listed patents, and notifications to us. In the event such third parties make paragraph IV certifications, we would be entitled to file a patent infringement lawsuit, and if that is accomplished within 45 days after receiving the notification, it would trigger a 30-month stay against FDA making the approval of the third party's application effective. 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.

Additionally, we are developing and may develop other products in the future for ourselves and/or our partners using the ANDA and/or 505(b)(2) pathways. Our partners may also do the same. There can be no assurance that those products do not follow the same type of litigation process as the epinephrine case which could delay or prohibit the launch of those potential products. 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. Moreover, regardless of whether we and/or our partners are ultimately successful in defending a patent infringement suit, we and/or they may be significantly delayed by a 30 month stay in the event we and/or they make a paragraph IV certification.

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

Additionally, based on the written recommendations from the FDA related to our clinical development program for QST, we launched a supplemental safety study QST-15-005 with additional participants, which we completed in 2016 in support of our NDA submission for QST. We believe that QST-15-005 should satisfy the FDA's previous recommendation that we create a larger safety base of subjects exposed to QST. 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 often 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 and teriparatide pen products 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. Due to the major nature of the CRL, Teva expects that its epinephrine product will be substantially delayed from their previously anticipated launch date and that a launch, if any, will not take place before late 2017 or early 2018.

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.

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

QST and our other products and product candidates are subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act (FFDCA), and its implementing regulations. QST, as well as other of our products and product candidates are subject to regulation by the FDA as combination products, which means they are composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of QST and our other products and product candidates, the primary mode of action is attributable to the drug component of the product, which means that the Center of Drug Evaluation and Research (CDER) has primary jurisdiction over

its pre-market development and review. Following product approval, however, our products may be subject to regulation under FDA's drug and device requirements.

We are not permitted to market our product candidates, including QST, in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of a marketing application. We have historically used FDA's 505(b)(2) NDA and ANDA pathways as further described in the Government Regulation Section. A 505(b)(2) NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. An ANDA must be supported by studies demonstrating that the product candidate is bioequivalent to the reference listed drug, as well as extensive information regarding CMC. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the approval pathway, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate.

Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including, failure to receive FDA or IRB authorization to begin a trial, negative or inconclusive results, slow or insufficient subject enrollment, failure to obtain adequate clinical supply of product candidates, and failure by us, our partners, Contract Research Organizations, and clinical trial sites to follow the applicable regulatory requirements, including GCPs. The FDA and similar foreign authorities could also delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
    - may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may not agree with the pathway that we have chosen for our product candidates, requiring us to pursue more difficult approval pathways, including full NDAs;
- may find that our reliance on a reference listed drug for an ANDA or 505(b)(2) application or literature for a 505(b)(2) application is not appropriate;
- may not agree with the design and/or implementation of our clinical and/or pre-clinical studies;
- may require us to conduct additional clinical and/or pre-clinical studies;
- may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Significant delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow competitors, to bring products to market before we do.

Additionally, based on the written recommendations from the FDA related to our clinical development program for QST, we launched a supplemental safety study QST-15-005 with additional participants, which we completed in 2016 in support of our NDA submission for QST. We believe that QST-15-005 should satisfy the FDA's previous recommendation that we create a larger safety base of subjects exposed to QST. 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 may 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.

Undesirable side effects caused by any product candidate that we develop, a lack of bioequivalence for ANDA product candidates, and/or an inability to demonstrate product candidate efficacy could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs.

Undesirable side effects could also interrupt, delay, or halt clinical trials. The regulatory review and approval process is lengthy, expensive and inherently uncertain.

In December 2016, we submitted the QST NDA which was accepted for filing by FDA in February 2017. Failure to obtain, or delays in obtaining, regulatory approvals may:

- adversely affect the commercialization of the current version of QST or any products that we develop in the future;
- adversely affect the commercialization of the current version of QST or any products that we develop in the future;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We may never receive approval for certain of our product candidates, and even if our product candidates are approved, the approval may be subject to limitations on the indicated uses for which the products may be marketed, distribution restrictions, or to other conditions of approval; may contain significant safety warnings, including boxed warnings, contraindications, and precautions; may not be approved with label statements necessary or desirable for successful commercialization; or may contain requirements for costly post market testing and surveillance or other requirements, including REMS, to monitor the safety or efficacy of the products. Moreover, any future actions or inquiries by the FDA with respect to the reference listed drug may require that we make changes to our labeling or, possibly, withdraw the product from the market. Any of the foregoing may impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

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, provided 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 requirements will ultimately determine which regulatory approval route will be required.

Many of our and our partners' 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 or our partner 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 or our partners' NDA, we or our partner 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.

NDAs submitted under Section 505(b)(2) and ANDAs subjects us to the risk that we may be subject to a patent infringement lawsuit or regulatory actions that would delay or prevent the review or approval of our product candidate.

Applicants submitting NDAs under Section 505(b)(2) of the FFDCA and ANDA applicants must provide a patent certification with their applications. One such certification is known as a Paragraph IV certification, which certifies that any patents listed in the FDA's Orange Book are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the product that is the subject of the application. Under the Hatch Waxman Act, the holder of patents or the reference listed drug applications that the new application references may file a patent infringement lawsuit following a Paragraph IV certification, triggering a 30 month stay. In such a case, the FDA may not make the application approval effective until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent is favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) or ANDA application approval will not be made effective until any existing non patent exclusivity have expired or, if possible, are carved out from the label.

We are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense for our approved products. Failure to comply with these obligations could result in regulatory and/or legal consequences.

Our approved products are subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities, including requirements related to the manufacturing processes, post approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post marketing information, including manufacturing deviations and reports; registration and listing requirements; the payment of user fees; requirements regarding the distribution of samples to physicians and recordkeeping; and GCPs, for any clinical trials that we conduct post approval. The FDA's policies may also change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates or products, or that could impose additional regulatory obligations on us.

By example, we and our partners also must comply with FDA's promotional requirements, including FDA's prohibition on the promotion of products for unapproved uses. Promotional communications may receive significant attention and scrutiny from not only the FDA but also the Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public.

In addition, later discovery of previously unknown adverse events or that the drug is less effective than previously thought or other problems with our products, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various results, including manufacturing and distribution restrictions, changes to product labeling, post-marketing study or other requirements such as REMS, refusal to approve marketing applications or supplements, withdrawal of marketing application approvals, product recalls, fines, penalties, FDA debarment, debarment from government contracts, and exclusion from federal healthcare programs. Any of these events could have other material and adverse effects on our operations and business.

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 ("AKS"), 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, except for activities protected by narrowly-drawn statutory and regulatory safe harbors. Remuneration alleged to induce prescribing practices, reimbursement or recommendations may be subject to scrutiny if it does not qualify for a safe harbor. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, formulary managers, and beneficiaries. Actual knowledge of the statute or specific intent to violate it is not needed to establish liability, and a violation of the AKS may be grounds for a government or whistleblower claim under the federal civil False Claims Act;
- 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 FCA authorizes imposition of treble damages and a civil penalty for each false claim submitted;
- 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 For violations after November 2, 2015, the penalty has increased from a minimum of $5,500 to $10,781, and a maximum of $11,000 to $21,563;
- the Veterans Health Care Act ("VHCA") of 1992 that requires manufacturers of "covered drugs" to enter into a Master Agreement and Federal Supply Schedule contract with the Department of Veterans Affairs through which their covered drugs must be offered for sale at a mandatory ceiling price 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 VHCA also requires manufacturers to enter into pricing agreements with the Department of Health and Human Services to charge no more than a different ceiling price to covered entities, and failure to provide the mandatory discount may subject the manufacturer to specific civil monetary

penalties;

- 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 and reporting to CMS required by 90th day of each calendar year;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, changed by the PPACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts and failure to report accurate pricing information exposes us to federal False Claims Act liability;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects; and
- the Drug Supply Chain Security Act of 2013 imposes obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, and will be implemented over a 10-year period. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug products to individuals and entities to which product ownership is transferred, will be required to label drug product with a product identifier, and are required to keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers are also required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufactures have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of

fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements are also imposed on other trading partners in the supply chain.

Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and these changes could have a material adverse effect on our business and financial condition.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together "the Healthcare Reform Act"), is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Healthcare Reform Act, including the employer mandate. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

Moreover, legislative changes to the Healthcare Reform Act remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third party payors to keep healthcare costs down while expanding individual healthcare benefits.

To help patients afford our product OTREXUP®, we offer discount, rebate and co-pay coupon programs. Co-pay coupon programs have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives. In recent years, other pharmaceutical manufacturers have been named in class action lawsuits challenging the legality of their co-pay programs under a variety of federal and state laws. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar lawsuits or insurer actions. It is possible that the outcome of litigation against other manufacturers, changes in insurer policies regarding co-pay coupons, and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these programs.

We are dependent on third parties to decide to utilize our and our partners' products to make them readily available at the point of care throughout their networks of pharmacies.

In addition to extensive internal efforts, the successful commercialization of our and our partners' products require many third parties, over whom we have no control, to decide to utilize them, and to make them readily available at the point of care throughout their networks of pharmacies. These third parties include HMOs, long term care facilities, and pharmacy benefit managers, or PBMs, which use pharmacy and therapeutics committees, commonly referred to as P&T committees, to make purchasing and reimbursement decisions. Generally, before an HMO or long term care facility will acquire a product for its own pharmacies, or a PBM will pay retail network pharmacies on behalf of its health plans, the product must be approved for addition to that organization's list of approved drugs, or formulary list, by the organization's P&T committee. An institutional P&T committee typically governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations for the appropriate use of drugs within the institution to the medical staff. PBM P&T committees develop the criteria for plan beneficiaries to access prescription medication, including such cost control measures as step therapy and prior authorization. The frequency of P&T committee meetings varies considerably, and P&T committees often require additional information to aid in their decision making process, so we may experience substantial delays in obtaining formulary approvals. Additionally, P&T committees may be concerned that the cost of acquiring a product for use in their institutions or reimbursing retail pharmacies outweighs clinical benefits and will resist efforts to add the product to the formulary, or implement restrictions on the usage of the drug in order to

control costs. We cannot guarantee that we and/or our partners will be successful in getting the approvals we need from enough P&T committees quickly enough to maintain and grow sales of our or our partners' products.

Our products or product candidates may be subject to restrictive marketing and distribution requirements, which if applied to our product candidates would restrict their use and harm our ability to generate profits.

Some of the currently approved testosterone products are subject to a REMS program. REMS programs may require medication guides, special communication plans to healthcare professionals, or elements to assure safe use, such as restricted distribution methods, distribution only to certain medical professionals, training for medical professionals prescribing, patient registries, or other risk minimization tools. The FDA may determine that QST or other products or product candidates require a REMS program. We cannot predict whether REMS will be required as part of the FDA's approval of our product candidates or whether such REMS would be required following approval, and, if required, what those requirements might be. Any limitations on approval or marketing could restrict the commercial prospects of our products.

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

Once a drug product is approved by the FDA, including its labels and labeling, the Office of Prescription Drug Promotion ("OPDP"), the FDA's marketing surveillance department within the Center for Drug Evaluation and Research, will oversee and regulate marketing claims asserted by us and our pharmaceutical company partners. If we or a pharmaceutical company partner fails to use acceptable marketing claims for a product incorporating our drug technologies, our revenues from that product may be limited and we may be subject to enforcement actions. The claims the pharmaceutical company partners are asserting about our drug delivery technologies, or the drug product itself, may not be accepted by OPDP.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification, or FDA approval. This could delay completion of clinical trials; require the conduct of bridging clinical trials or studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay approval of our product candidates; and jeopardize our business prospects.

Risks Related to our Common Stock

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

As of March 1, 2017, we had options outstanding that are exercisable, at exercise prices ranging from $0.47 to $4.54 per share, for an aggregate of approximately 11,000,000 shares of our common stock. Purchasers of our common stock could therefore experience dilution of their investment upon exercise of the above options.

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

As of March 1, 2017, our officers and directors beneficially owned an aggregate of approximately 19,000,000 shares (or approximately 12%) of our outstanding common stock, including stock options exercisable within 60 days. If our officers and directors, or other stockholders, sell a substantial amount of our common stock, it could cause the market

price of our common stock to decrease.

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

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

Our failure to meet the continued listing requirements of the NASDAQ Capital Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of the NASDAQ Capital Market, such as the requirement that we maintain a minimum bid price of at least $1.00 per share, NASDAQ may take steps to de-list our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would expect to seek to take actions to restore our compliance with NASDAQ's listing requirements, but

we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock or prevent our common stock from dropping below the NASDAQ minimum bid price requirement in the future.

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us, our partners or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- fluctuations in our quarterly operating results or the operating results of our competitors;
- variance in our financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- changes in our pricing policies or the pricing policies of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- changes in legislation or regulatory policies, practices or actions;
- the commencement or outcome of litigation involving our company, our general industry or both;
- recruitment or departure of key personnel;
- changes in our capital structure, such as future issuances of securities or the incurrence of debt;
- actual or expected sales of our common stock by our stockholders; and
- the trading volume of our common stock.

In addition, the stock markets, in general, the NASDAQ Capital Market and the market for specialty pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

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

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

all or any of our bylaws, subject to the power of the stockholders to change or repeal the bylaws. In addition, our bylaws limit who may call meetings of our stockholders.

Item 1B. UNRESOLVED STAFF COMMENTS
None.

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

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

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

Item 3. LEGAL PROCEEDINGS
None.

Item 4. MINE SAFETY DISCLOSURES
Not applicable.

PART II

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

Market Information

Our common stock trades on the NASDAQ Capital Market under the symbol "ATRS". The following table sets forth the per share high and low closing sales prices of our common stock for each quarterly period during the two most recent fiscal years.

	High	Low
2016:		
First Quarter	$1.23	$0.71
Second Quarter	$1.17	$0.81
Third Quarter	$1.77	$0.99
Fourth Quarter	$2.38	$1.50
2015:		
First Quarter	$2.76	$2.27
Second Quarter	$2.97	$2.08
Third Quarter	$2.29	$1.64
Fourth Quarter	$1.67	$1.21

Common Shareholders

As of March 1, 2017, we had 75 shareholders of record of our common stock as well as approximately 15,517 shareholders in street name.

For information on securities authorized for issuance under our equity compensation plans see "Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Dividends

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

Performance Graph

The graph below provides an indication of cumulative total stockholder returns ("Total Return") for the Company as compared with the NASDAQ Composite Index, the NASDAQ Biotechnology Stock Index, the Amex Composite Index, the NYSE Arca Biotechnology Index (formerly Amex Biotechnology Index) and the NYSE Arca Pharmaceutical Index weighted by market value at each measurement point. Our common stock began trading on the NASDAQ Capital Market on June 15, 2012 and prior to that time was traded on NYSE Amex. For this reason, we are comparing Total Returns for the Company to indexes from both NASDAQ and NYSE Amex. The graph covers the period beginning December 31, 2011, through December 31, 2016. The graph assumes $100 was invested in each of our common stock, the NASDAQ Composite Index, the NASDAQ Biotechnology Stock Index, the Amex Composite Index, the NYSE Arca Biotechnology Index and the NYSE Arca Pharmaceutical Index on December 31, 2011 (based upon the closing price of each). Total Return assumes reinvestment of dividends.

	December 31,					
	2011	2012	2013	2014	2015	2016
Antares Pharma, Inc.	$100.00	$173.18	$203.18	$116.82	$55.00	$105.91
NASDAQ Composite Index	100.00	115.91	160.32	181.80	192.21	206.63
NASDAQ Biotechnology Stock Index	100.00	131.91	218.45	292.93	326.39	255.62
Amex Composite Index	100.00	103.39	106.49	107.29	94.33	101.30
NYSE Arca Biotechnology Index	100.00	141.74	213.52	315.10	349.45	281.74
NYSE Arca Pharmaceutical Index	100.00	111.00	140.59	160.03	162.62	144.63

Item 6. SELECTED FINANCIAL DATA

The following table summarizes certain selected financial data. The selected financial data is derived from, and is qualified by reference to, our audited consolidated financial statements as of and for the years ended December 31, 2016, 2015, 2014, 2013, and 2012 and should be read in conjunction with those statements (amounts expressed in thousands, except per share amounts).

	At December 31,				
	2016	2015	2014	2013	2012
Balance Sheet Data:					
Cash and cash equivalents	$27,715	$32,899	$34,029	$39,067	$52,097
Investments	—	15,012	6,002	30,022	33,129
Total assets	66,325	84,562	68,773	88,932	95,527
Accumulated deficit	(253,445)	(229,107)	(208,448)	(173,296)	(152,789)
Total stockholders' equity	45,219	67,043	41,196	70,714	86,551

	Year Ended December 31,				
	2016	2015	2014	2013	2012
Statement of Operations Data:					
Product sales	$40,318	$27,533	$13,196	$10,958	$9,138
Development revenue	10,234	8,892	7,246	4,139	7,422
Licensing fees	166	7,242	3,709	849	2,141
Royalties	1,503	1,991	2,351	4,672	3,874
Total revenues	52,222	45,658	26,502	20,618	22,575
Cost of product sales	23,909	12,925	9,360	6,990	6,117
Cost of development revenue	4,908	6,533	1,877	2,207	3,403
Gross profit	23,405	26,200	15,265	11,421	13,055
Research and development	21,127	19,732	18,638	15,263	14,921
Selling, general and administrative	26,395	26,931	31,740	17,008	9,585
Total operating expenses	47,522	46,662	50,378	32,271	24,506
Operating loss	(24,116)	(20,462)	(35,113)	(20,850)	(11,451)
Other income (expense)	(122)	(22)	(14)	43	24
Net loss before income taxes	(24,239)	(20,484)	(35,127)	(20,807)	(11,427)
Income tax provision (benefit)	100	175	25	(300)	—
Net loss	$(24,339)	$(20,659)	$(35,152)	$(20,507)	$(11,427)
Net loss per common share [1] [2]	$(0.16)	$(0.14)	$(0.27)	$(0.16)	$(0.10)
Weighted average common shares outstanding	154,992	146,594	130,550	126,897	110,185

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

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

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

Overview

Company and Product 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 strategy is to identify new or existing approved drug formulations and apply our drug delivery technology to enhance the drug compounds and delivery methods. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems for improved safety and efficacy, reduced side effects, and enhanced patient comfort and adherence. Our subcutaneous injection technology platforms include the VIBEX® pressure-assisted auto injector system suitable for branded and generic injectable drugs in unit dose containers, reusable needle-free spring-action injector devices, and disposable multi-dose pen injectors for use with standard cartridges. We have a portfolio of proprietary and partnered products, including several approved commercial products and five product candidates in advanced stages of development and under active FDA review. We have formed significant strategic alliances and partnership arrangements with industry leading pharmaceutical companies including Teva, AMAG, and Ferring.

We launched our proprietary product OTREXUP® (methotrexate) injection, which utilizes our VIBEX® auto injector, in the U.S. in February 2014. OTREXUP® is the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector, indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. To date, we have received FDA approval for dosage strengths of 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg and 25 mg of OTREXUP®.

We, with our partner Teva, launched Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine and cluster headache in adults, in June 2016. We received FDA approval of our ANDA for 4 mg/0.5 mL and 6 mg/0.5 mL single-dose prefilled syringe auto-injectors, a generic equivalent to Imitrex® STATdose Pen®, in December 2015. Sumatriptan Injection USP represents the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform and is distributed by Teva under the terms of a license, supply and distribution arrangement.

We also make reusable, needle-free injection devices that administer injectable drugs, which are currently marketed primarily through our partner Ferring for use with human growth hormone. In addition, we have two gel-based products that are commercialized through partners under licensing arrangements.

Overview of Clinical and Regulatory Developments

We are developing QuickShot® Testosterone ("QST") for testosterone replacement therapy and submitted a 505 (b) (2) NDA with the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a PDUFA target date for completion of its review by October 20, 2017. We conducted a 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, and we previously announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved. Based upon

a written response we received from the FDA related to our clinical development program for QST, we conducted an additional supplemental safety study QST-15-005. The study included 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. In September 2016, we announced the successful completion of the QST-15-005 study. The results of these two studies formed the clinical basis of our NDA submission for QST.

We are collaborating with Teva on a VIBEX® auto injector pen containing epinephrine used for the treatment of severe allergic reactions (anaphylaxis). 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 has advised us that they submitted a response to the CRL and expects that any approval or launch will not take place before the end of 2017 or beginning of 2018.

Our other combination product development projects in collaboration with Teva include a multi-dose pen for a generic form of BYETTA® (exenatide injection) for the treatment of diabetes, and another multi-dose pen for a generic form of Forteo® (teriparatide [rDNA origin] injection) for the treatment of osteoporosis. Teva filed an ANDA for exenatide, which was accepted by the FDA in

October 2014 and is currently under FDA review. In 2016, we announced that Teva had settled the patent litigation with AstraZeneca relating to certain AstraZeneca U.S. patents and their drug, BYETTA® (exenatide). AstraZeneca and Teva entered into a settlement and license agreement pursuant to which AstraZeneca granted Teva a license to manufacture and commercialize the generic version of BYETTA® described in Teva's ANDA. The settlement allows Teva to commercialize their exenatide product in the U.S. beginning October 15, 2017 or earlier under certain circumstances. Teva also filed an ANDA for a generic version of Forteo® (teriparatide [rDNA origin] injection), which was accepted by the FDA in February 2016 and is currently under review. In response to Teva's paragraph IV certification contained in Teva's ANDA for teriparatide, Lilly filed a lawsuit against Teva alleging infringement of six U.S. patents related to Forteo® (teriparatide [rDNA origin] injection) resulting in a 30-month stay in FDA approval of the ANDA. The stay will expire in August 2018 unless the litigation is resolved sooner.

In partnership with AMAG, we are currently developing a variation of our VIBEX® QuickShot® subcutaneous 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, the manufacture and supply of the drug, and to market, sell and distribute the product. We are responsible for the design and development of the auto-injection device, the manufacturing and supply of the device, and assembly and packaging of the final product. AMAG initiated a PK study in October 2016 and disclosed positive top line results of the study in February 2017. According to AMAG, the study successfully demonstrated comparable bioavailability between subcutaneous injection of Makena® compared to intra muscular injection. AMAG anticipates submitting its sNDA for the subcutaneous auto injector for use with Makena® in the second quarter of 2017 and expects a six-month review by the FDA.

Critical Accounting Policies and Use of Estimates

The following discussion and analysis of our results of operations and financial condition is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP".) The preparation of these financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results could differ from our estimates, and significant variances could materially impact our financial condition and results of operations.

Our significant accounting policies are more fully described in the notes to our consolidated financial statements included in this Annual Report on Form 10-K. We believe the following accounting policies to be the most critical to understanding our results of operations and financial condition because they require the most subjective and complex judgments.

Revenue Recognition

We generate revenue from the sale of products, research and development projects, license fees and royalties. Revenue is recognized when all of the following criteria are met: persuasive evidence of the arrangement exists; delivery has occurred and we have no remaining obligations; the fee is fixed or determinable; and collectability is reasonably assured.

We enter into contracts with customers and partners that often contain multiple elements such as licensing, development, manufacturing and commercialization components. These arrangements are often complex and we may receive various types of consideration, including: up-front fees, reimbursements for research and development services, milestone payments, payments on product shipments, license fees and royalties.

In assessing our revenue arrangements, we must identify each deliverable and evaluate whether or not each deliverable has stand-alone value to our customer. Based on this evaluation, deliverables are separated into units of accounting and contract consideration is allocated to each unit of accounting in the arrangement at the inception of the contract based on the relative selling price of each of the deliverables. The preferred hierarchy for establishing the stand alone selling price of a deliverable is vendor specific objective evidence (VSOE), or third-party evidence (TPE) if VSOE is not available. However, management must often make its best estimate of the standalone selling price when neither VSOE nor TPE is available. The estimate of selling price is established considering multiple factors including, but not limited to, historical pricing on similar contracts.

Our contracts with customers often include refundable or non-refundable cash payments we receive in the form of upfront or milestone payments. Revenue may not be immediately recognizable due to the nature, term and future deliverables of the respective arrangement, and certain portions may be deferred over an extended period. Subsequent factors could affect the initial estimate of the effective terms of agreements and could either increase or decrease the amount and timing of the deferred revenue to be recognized.

Revenue Recognition - OTREXUP®

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

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

Product Sales Allowances

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

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

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

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

Rebates. We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two

to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue for these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

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

Inventory Valuation

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

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

Valuation of Long-Lived and Intangible Assets

Long-lived assets, including patent rights, are reviewed for impairment on a periodic basis or whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset or asset group. This analysis can be very subjective; however, we utilize the expected future undiscounted cash flows from signed contracts with customers to substantiate the recoverability of our long-lived assets. If the sum of the undiscounted cash flows is less than the carrying amount of the assets, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Management's estimates of fair value of long-lived and intangible assets are based upon assumptions believed to be reasonable. Unanticipated events and circumstances may occur which may affect the accuracy or validity of such assumptions, estimates or actual results.

Share-Based Compensation

The Company grants share based compensation awards to employees, directors and officers in the form of stock options, restricted stock units (“RSUs”) and performance-based restricted stock units (“PSUs”). Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee’s requisite service period on a straight line basis. The fair value of the stock options is estimated using the Black-Scholes valuation model. The fair values of RSU and PSU grants containing service or performance conditions are equal to the market value of the Company’s Common Stock on the date of grant. The fair value of PSUs containing a market condition are estimated using a Monte Carlo simulation and compensation expense is recognized over the requisite service period on a straight-line basis.

The determination of fair value of share-based payment awards and related compensation expense on the grant date requires significant judgment. Stock compensation expense is based on awards ultimately expected to vest, and accordingly, it has been reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Judgment is also involved in determining when performance based awards become probable of achievement, which affects the timing and amount of expense recognition. Assumptions concerning the Company’s stock price volatility and projected employee exercise behavior over the contractual life of the award could significantly impact the estimated fair value of an award.

Results of Operations

Years Ended December 31, 2016, 2015 and 2014

We are a growing, revenue generating company focused on the development of complex drug device combination products and providing customized pressure-assisted auto injectors and disposable multi-dose pen injector technology. We reported consecutive year-over-year increases in our revenue for the years ended December 31, 2016, 2015 and 2014, respectively. We reported a net loss of $24,338,804 ($0.16 per share) for the year ended December 31, 2016 as compared to $20,658,846 ($0.14 per share) and $35,151,715 ($0.27 per share) for the years ended December 31, 2015 and 2014, respectively. The following is a discussion of our results of operations on a comparative basis.

Revenues

	For the Years Ended December 31,		
	2016	2015	2014
OTREXUP®	$15,145,214	$13,249,715	$7,309,603
Auto injector and pen injector devices	19,712,591	10,079,955	1,476,816
Needle-free injector devices and components	5,460,534	4,203,372	4,409,158
Total product sales	40,318,339	27,533,042	13,195,577
Development revenue	10,234,486	8,892,121	7,246,080
Licensing revenue	166,188	7,242,030	3,708,938
Royalties	1,503,033	1,990,907	2,351,070
Total revenue	$52,222,046	$45,658,100	$26,501,665

Total revenues for the year ended December 31, 2016 grew to $52,222,046, as compared to $45,658,100 for the year ended December 31, 2015, an increase of $6,563,946 or 14% on a year-over-year basis. Total revenue for the year ended December 31, 2015 increased by $19,156,435 or 72% as compared to $26,501,665 for the year ended December 31, 2014. The following is a detailed discussion of the components of revenue.

OTREXUP®

We launched OTREXUP® and began recognizing product revenues based on patient prescriptions beginning in the first quarter of 2014. We sell OTREXUP® in a package of four pre-filled, single-dose disposable auto injectors to wholesale pharmaceutical distributors, our customers. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of OTREXUP® to our customers until the right of return no longer exists, which occurs at the earlier of the time OTREXUP® units are dispensed through patient prescriptions or expiration of the right of return. Patient prescriptions dispensed are estimated using third-party market prescription data. These third-party sources poll pharmacies, hospitals, mail order and other retail outlets for OTREXUP® prescriptions and project this sample on a national level. We use this third party prescription data, among other information, as a basis for revenue recognition in each reporting period.

We have achieved a relatively steady growth rate in prescriptions and sales of OTREXUP® from the time of our launch in February 2014 through the year ended December 31, 2016. For the years ended December 31, 2016 and 2015, we recognized $15,145,214 and $13,249,715, respectively, related to the sale of OTREXUP® based on prescription data, representing an increase of 14% on a year-over-year basis. We believe the increase is primarily attributable to an increase in, and broadening of, our sales and marketing efforts, including the expansion and penetration of our sales force in 2015, and a continuing increase in prescriber education and acceptance. We recognized $7,309,603 for OTREXUP® sales for the year ended December 31, 2014. Due to the timing of our launch of OTREXUP® in February 2014, the 2014 revenue included approximately ten months of prescription sales as compared to a full year of prescription sales in 2016 and 2015.

At December 31, 2016 and 2015, we had deferred revenue of $1,670,220 and $1,064,874, respectively, for OTREXUP® product shipments sold to wholesalers, which is net of estimated wholesaler fees, stocking allowances, prompt pay discounts, rebates and patient discount programs. We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred.

Auto injector and pen injector devices

Product sales of auto injector and pen injector devices generated $19,712,591, $10,079,955 and $1,476,816 in revenues for the years ended December 31, 2016, 2015 and 2014, respectively. The 2016 revenue included approximately $9,104,000 from sales of sumatriptan product to Teva, $1,687,000 in pre-commercial device sales to AMAG, and $8,922,000 in sales of pre-launch quantities of auto injector devices sold to Teva for use with their generic epinephrine product in anticipation of a potential launch. Teva's ANDA for the epinephrine auto injector is under active FDA review, however, as discussed above, Teva received a CRL from the FDA citing certain major deficiencies. As a result, Teva expects that any approval or launch will not take place before the end of 2017 or beginning of 2018, which may impact our future sales of epinephrine devices to Teva. Principally all of the 2015 revenue from auto injector and pen injector devices, and approximately $400,000 of the 2014 revenue from auto injector and pen injector devices is attributable to sales of pre-launch quantities of auto injector devices to Teva for their generic epinephrine auto injector product. Revenues in 2014 also included sales of pre-commercial pen injector devices to Teva for use with exenatide and teriparatide pen products.

Needle-free injector devices and components

Our revenue from reusable needle-free injector devices and disposable components totaled $5,460,534, $4,203,372 and $4,409,158 for the years ended December 31, 2016, 2015 and 2014, respectively. The 2016 revenues were generated primarily from sales to Ferring, which sells our needle-free injector device for use with its hGH product. Prior to 2015, we also sold needle-free devices to Teva for use with an hGH branded product; however, Teva sold its rights to Ferring in the fourth quarter of 2014. In March 2015, Ferring received FDA approval of a name change enabling its newly acquired recombinant hGH to be marketed in the U.S. as ZOMACTON™ (somatropin [rDNA origin]) for injection, and the needle-free delivery system to be marketed in the U.S. as ZOMA-Jet.™ Ferring launched ZOMACTON™ in the U.S. in the second quarter of 2015 and the 5mg ZOMA-Jet™ needle-free devices became available in early 2016.

We do not control our partners' sales volume or inventory levels of our injectors and components, which can cause fluctuations in our product sales in comparative periods.

Development Revenue

Development revenues typically represent amounts earned under arrangements with partners in which we develop new products jointly or on their behalf. Frequently, we receive upfront payments from our partners that are initially deferred and recognized as revenue over the development period or upon completion of defined deliverables. Development revenue totaled $10,234,486, $8,892,121 and $7,246,080 for the years ended December 31, 2016, 2015 and 2014, respectively. For the year ended December 31, 2016, development revenue included amounts from Teva for the ongoing development of the epinephrine auto injector and the exenatide and teriparatide pen injectors, all of which have an ANDA under active FDA review. In 2016 we also performed significant development activities, including engineering, design, testing and final assembly readiness for AMAG related to the Makena® auto injector for use in clinical trials, and recognized development revenue upon completion of the defined project deliverables. Development revenue recognized for the years ended December 31, 2015 and 2014 was principally attributable to development activities for Teva of the epinephrine auto injector.

Licensing Revenue

Licensing revenues represent the amounts recognized from up-front or milestone payments received from partners under licensing arrangements that are generally deferred and recognized over the licensing period. Licensing revenue was $166,188, $7,242,030, and $3,708,938 for the years ended December 31, 2016, 2015 and 2014, respectively. The significant decline in licensing revenue for the year ended December 31, 2016 as compared to 2015 was primarily due to revenue recognized in connection with the termination of our license and promotion agreement with LEO Pharma in June 2015, as discussed below.

Licensing revenue recognized in 2015 and 2014 was primarily attributable to the license and promotion agreement with LEO Pharma, which began in November of 2013 for certain rights related to our OTREXUP® product. The upfront and milestone payments received from LEO totaled $10.0 million and were being recognized into revenue over a 35-month period. Effective June 23, 2015, our agreement with LEO Pharma was terminated and, as a result, we recognized the remaining unamortized balance of the deferred revenue of $5,142,857 as licensing revenue in the second quarter of 2015, resulting in total revenue of $6,000,000 recognized in 2015 under this arrangement. We have not recognized, and do not expect to recognize, any additional revenue related to this agreement in subsequent periods. In addition, we recognized a $1,000,000 milestone payment from Ferring in 2015, which was earned under the terms of a licensing agreement and triggered by Ferring filing a NDA related to our patents and licensed technology.

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

Royalties

Royalty revenue was $1,503,033, $1,990,907 and $2,351,070 for the years ended December 31, 2016, 2015, and 2014, respectively. We currently receive royalties from Ferring related to needle-free injector device sales and sales of ZOMACTON™ in the U.S. We also receive royalties from Meda Pharmaceuticals, Inc., which was acquired by Mylan in 2016, on sales of Elestrin® and from Allergan plc on sales of Gelnique®. In 2014, we also received royalties from Teva on Teva's sales of their hGH drug, Tev-Tropin®. However, Teva initiated a recall of the drug product, Tev-Tropin® (not the device which we supply), at the end of April 2014 and had halted sales of the drug earlier in the year. Accordingly, the decline in royalties earned in 2016 and 2015 was primarily the result of receiving no royalties from Teva after the first quarter of 2014.

Cost of Revenues and Gross Profit

The following table summarizes our total cost of revenue and gross profit:

	2016	2015	2014
Total revenue	$52,222,046	$45,658,100	$26,501,665
Total cost of revenue	28,816,766	19,457,683	11,236,695
Gross profit	$23,405,280	$26,200,417	$15,264,970
Gross profit percentage	45 %	57 %	58 %

Our gross profit was $23,405,280 for the year ended December 31, 2016 as compared to $26,200,417 and $15,264,970 for the years ended December 31, 2015 and 2014, respectively. The decrease in our gross profit in 2016 compared to 2015 is primarily attributable to the additional licensing revenues recognized in 2015, including the $6,000,000 from the LEO agreement and $1,000,000 milestone from Ferring, both of which had no associated costs. In addition, the 2016 revenues include approximately $9,104,000 in sales of Sumatriptan Injection USP sold at cost to Teva subject to a profit sharing arrangement on sales by Teva. Other variations in revenue, cost of revenue and gross profit are attributable to our development activities, which fluctuate depending on the mix of development projects in progress and stages of completion in each period, as discussed in more detail below.

The following table summarizes the revenue, cost of sales and gross margin associated with our product sales:

	2016	2015	2014
Product sales	$40,318,339	$27,533,042	$13,195,577
Cost of product sales	23,908,659	12,925,129	9,359,457
Product gross margin	$16,409,680	$14,607,913	$3,836,120
Gross margin percentage	41 %	53 %	29 %

The cost of product sales includes product acquisition costs from third-party manufacturers and internal manufacturing overhead expenses. The decrease in product gross margin for the year ended December 31, 2016 as compared to 2015 is primarily attributable to approximately $9,000,000 in sales of Sumatriptan Injection USP sold at cost to Teva subject to a profit sharing arrangement on sales by Teva. The increase in margin for the year ended December 31, 2015 compared to 2014 is primarily attributable to OTREXUP®, for which we receive a higher gross margin than our partnered device products. This gross margin increase was partially offset by the gross margin impact of the increased sales to Teva of pre-launch quantities of our VIBEX® auto injector for Teva's generic epinephrine auto injector product, which has a lower gross margin than OTREXUP®. The 2014 gross margin was also impacted by the establishment of and increases to the reserves for potential excess or dated OTREXUP® inventory.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. Development gross profits can vary significantly from period to period depending on the mix of development projects in progress and stages of completion in each period. Cost of development revenue was $4,908,107, $6,532,554 and $1,877,238 for the years ended December 31, 2016, 2015 and 2014, respectively. The cost of development revenue recognized in each of the years presented was principally related to revenue recognized under the Teva auto injector and pen injector programs, with the addition of development activities related to the

Makena® auto injector in 2016.

Operating Expenses

Research and Development

Research and development expenses consist of external costs for studies and analysis activities, design work and prototype development, FDA fees, and internal salaries and overhead costs and were $21,126,936, $19,731,564 and $18,638,016 for the years ended December 31, 2016, 2015 and 2014, respectively. The increase in research and development costs in 2016 as compared to 2015 is principally attributable to the $2.0 million FDA fee paid in connection with our NDA submission for QST in December 2016. In each of the years ended December 31, 2016, 2015 and 2014, approximately half of our research and development expenses were driven by external expenses incurred in connection with the development of QST for testosterone replacement therapy.

Selling, General and Administrative

Selling, general and administrative expenses were $26,394,804, $26,930,832 and $31,740,249 for the years ended December 31, 2016, 2015 and 2014, respectively. Our selling, general and administrative expenses decreased in 2016 as compared to 2015 primarily as a result of a reduction in legal fees related to the Medac litigation settled in 2015 and a reduction in certain personnel costs in

connection with the CEO and CFO transitions. The decrease was partially offset by additional sales and marketing costs related primarily to the OTREXUP® sales force and our on-going marketing efforts.

The decrease in total selling, general and administrative expenses in 2015 as compared to 2014 was primarily due to a reduction in market research, product branding, commercialization and pre-commercialization activities related to the OTREXUP® product launch in 2014, as well as a reduction in litigation fees incurred in 2015 as compared to 2014 in connection with the Medac litigation settled in early 2015. In 2015, personnel costs increased as a result of hiring new employees to build our sales and marketing organization in connection with commercialization of OTREXUP®. In 2014 we used a third-party contract sales organization, Quintiles, Inc. ("Quintiles"), to commercialize OTREXUP® in the U.S. In January 2015, we hired our own internal sales force to replace Quintiles.

Liquidity and Capital Resources

At December 31, 2016 we had cash and cash equivalents of $27,714,588 and no debt obligations. We believe that the combination of our current cash and cash equivalents, and projected product sales, product development revenue, license revenues, milestone payments and royalties will provide us with sufficient funds to meet our obligations and support operations through the first quarter of 2018. However, we reported net losses of $24,338,804, $20,658,846 and $35,151,715 and negative cash flows from operations for each of the years ended December 31, 2016, 2015 and 2014, respectively. We have an accumulated deficit at December 31, 2016 of $253,445,306. We have not historically generated, and do not currently generate, enough revenue or operating cash flow to support our operations, and continue to operate primarily by raising capital. We are exploring collaborations and potential financings to raise additional capital. If, however, we are not successful in raising additional cash, we may be required to defer or delay certain planned capital expenditures and other spending related to the potential approval and launch of QST, or curtail other controllable costs and discretionary spending for new research and development activities.

On May 11, 2015, we completed an underwritten offering of 23,000,000 shares of our common stock at a price to the public of $2.00 per share. We received net proceeds of $42.9 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We have used and will continue to use the net proceeds from the offering for general corporate purposes including research and development activities.

If additional capital is needed to support our operations or growth in the future, we may need to raise additional funds through financings, such as the issuance of debt, equity or notes convertible into our common stock. However, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

Net Cash Used in Operating Activities

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, research and development projects including clinical studies, sales and marketing activities, and general and administrative costs. Net cash used in operating activities was $15,194,942, $28,198,841 and $26,333,301 for the years ended December 31, 2016, 2015 and 2014, respectively. Net operating cash used in operations is a function of the net losses incurred of $24,338,804, $20,658,846 and $35,151,715 for the years ended December 31, 2016, 2015 and 2014, respectively, adjusted by noncash expenses and changes in operating assets and liabilities. Our reconciliation of net loss to operating cash flow is significantly affected by the timing of operating expenditures and cash receipts.

Cash used in operating activities for the year ended December 31, 2016 as compared to 2015 decreased primarily due to a growth in accounts payable, which conserved cash, an increase in deferred revenue, and a reduction in prepaid

expenses, offset by an increase in accounts receivable and a decrease in accrued expenses. For the year ended December 31, 2015, the increase in net cash used in operating activities as compared to 2014 is primarily the result of changes in operating assets and liabilities including the use of additional cash to pay down accounts payable combined with a growth in accounts receivable and a reduction in deferred revenue related to cash payments received from LEO and Teva in prior periods that were recognized in income in 2015.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the year ended December 31, 2016 was $9,993,335 as compared to net cash used in investing activities of $15,724,346 for the year ended December 31, 2015 and net cash provided by investing activities of $18,346,897 in 2014. The changes are primarily attributable to timing of purchases and maturities of investment securities as well as timing and amount of capital expenditures. In 2016, we made capital expenditures and additions to patent rights of $5,006,665 offset by proceeds from investment maturities of $15,000,000. In 2015, we made capital expenditures and additions to patent rights of $6,686,671 and purchased investments, net of proceeds from maturities, of $9,037,675. In 2014, we received $24,000,000 in connection with the

maturities of investments offset by capital expenditures and additions to patent rights of $5,653,103. Capital expenditures were primarily for QST and Sumatriptan Injection USP commercial molds and assembly equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $17,461, $42,793,707 and $2,950,705 for the years ended December 31, 2016, 2015 and 2014, respectively. In 2016, the net cash provided by financing activities was a result of cash proceeds from stock option exercises partially offset by cash remitted to taxing authorities in connection with net-share settled awards for which we withheld shares equivalent to the value of the employees' minimum statutory obligation for the applicable income and other employment taxes. In 2015, we completed an underwritten offering of 23,000,000 shares of our common stock at a price to the public of $2.00 per share. We received net proceeds of $42,850,677 after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Cash provided by financing activities in 2014 was primarily attributable to proceeds from the exercise of stock options offset by taxes paid to taxing authorities for net-share settled employee equity awards.

Contractual Obligations

Our contractual cash obligations at December 31, 2016 are associated with operating leases and are as follows:

	Payment Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	After 5 years
Total contractual cash obligations	$2,340,146	$620,482	$1,188,671	$471,097	$59,896

Off Balance Sheet Arrangements

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

Research and Development Programs

Our research and development activities are integral to our operations. For a complete discussion of our current complex combination drug device development programs and other device development projects see the "Research and Development" section in Part I, Item I. "Business" of this annual report on Form 10-K.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The standard creates a five-step model that requires a company to identify customer contracts, identify the separate performance obligations, determine the transaction price, allocate the transaction price to the separate performance obligations and recognize revenue when each performance obligation is satisfied. Applying the standard requires management to exercise significant judgment when considering the terms of the contracts and all relevant facts and circumstances. This

guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about contract balances and remaining performance obligations, significant judgments made in determining the timing of satisfaction of performance obligations (over time or at a point in time), and estimates made in determining the transaction price and amounts allocated to performance obligations.

We are in the process of evaluating the impact the adoption of this standard will have on our consolidated financial statements and have performed an initial review of all of our major contracts with customers. Based on the initial reviews, we believe the adoption of the new standard may accelerate the timing of revenue recognition for product sales and development revenue under certain license, development and supply agreements, and will require us to estimate and potentially recognize certain variable revenue streams such as royalties and profit sharing arrangements earlier at an amount we believe will not be subject to significant reversal.

We anticipate adopting the new revenue recognition standard on the effective date of January 1, 2018 utilizing the modified retrospective method of adoption, under which the cumulative effect of the change is recognized as an adjustment to the opening

balance of the accumulated deficit within the consolidated balance sheet, and prior reporting periods are not retrospectively adjusted. No significant changes to business processes or systems are currently expected to be necessary.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory. The new standard changes the measurement principle for inventory from the lower of cost or market to lower of cost and net realizable value. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. Entities are required to disclose the nature and reason for the change in accounting principle in the first interim and annual period of adoption. The adoption of this standard is not expected to have a significant impact on our consolidated results of operations and financial position.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). This new standard requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This new standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. We are currently evaluating the impact of ASU 2016-02 in our consolidated financial statements and currently expect that most of our operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon our adoption of ASU 2016-02.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective on January 1, 2017. The adoption of ASU 2016-09 is not expected to have a significant impact on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-04"). This new standard eliminates Step 2 from the goodwill impairment test. ASU 2017-04 requires an entity to perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. ASU 2017-04 still allows the option to perform a qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. ASU 2017-04 is effective for any annual or interim goodwill impairment tests in the fiscal years beginning after December 15, 2019 and must be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. Adoption of ASU 2017-04 is not expected to have a significant impact on our consolidated financial statements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with a licensing agreement with Ferring, under which certain products sold to Ferring and royalties are denominated in Euros. Most of our product sales, including a portion of our product sales to Ferring, and our development and licensing fees and royalties are denominated in U.S. dollars, thereby significantly mitigating the

risk of exchange rate fluctuations on trade receivables. We do not currently use derivative financial instruments to hedge against exchange rate risk. The effect of foreign exchange rate fluctuations on our financial results for the years ended December 31, 2016, 2015, and 2014 was not material.

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
ANTARES PHARMA, INC.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Antares Pharma, Inc.:

We have audited the accompanying consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2016. We also have audited the Company's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

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

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

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Antares Pharma, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also in our opinion, Antares Pharma Inc. and subsidiaries

maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ KPMG LLP

Minneapolis, Minnesota

March 14, 2017

ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2016	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$27,714,588	$32,898,676
Short-term investments	—	15,012,225
Accounts receivable	9,073,173	7,952,478
Inventories	5,326,962	5,724,397
Deferred costs	1,773,446	1,199,217
Prepaid expenses and other current assets	1,376,299	3,274,254
Total current assets	45,264,468	66,061,247
Equipment, molds, furniture and fixtures, net	17,867,412	14,793,084
Patent rights, net	2,044,608	2,434,542
Goodwill	1,095,355	1,095,355
Other assets	53,607	177,943
Total Assets	$66,325,450	$84,562,171
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$7,884,983	$5,187,703
Accrued expenses and other liabilities	5,872,846	6,488,032
Deferred revenue	6,149,087	5,143,825
Total current liabilities	19,906,916	16,819,560
Deferred revenue – long term	1,200,000	700,000
Total liabilities	21,106,916	17,519,560
Stockholders' Equity:		
Preferred Stock: $0.01 par, authorized 3,000,000 shares, none outstanding	—	—
Common Stock: $0.01 par; authorized 300,000,000 shares; 155,167,677 and 154,848,512 issued and outstanding at December 31, 2016 and 2015, respectively	1,551,677	1,548,485
Additional paid-in capital	297,826,433	295,292,414
Accumulated deficit	(253,445,306)	(229,106,502)
Accumulated other comprehensive loss	(714,270)	(691,786)
	45,218,534	67,042,611
Total Liabilities and Stockholders' Equity	$66,325,450	$84,562,171

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2016	2015	2014
Revenue:			
Product sales	$40,318,339	$27,533,042	$13,195,577
Development revenue	10,234,486	8,892,121	7,246,080
Licensing revenue	166,188	7,242,030	3,708,938
Royalties	1,503,033	1,990,907	2,351,070
Total revenue	52,222,046	45,658,100	26,501,665
Cost of revenue:			
Cost of product sales	23,908,659	12,925,129	9,359,457
Cost of development revenue	4,908,107	6,532,554	1,877,238
Total cost of revenue	28,816,766	19,457,683	11,236,695
Gross profit	23,405,280	26,200,417	15,264,970
Operating expenses:			
Research and development	21,126,936	19,731,564	18,638,016
Selling, general and administrative	26,394,804	26,930,832	31,740,249
Total operating expenses	47,521,740	46,662,396	50,378,265
Operating loss	(24,116,460)	(20,461,979)	(35,113,295)
Other income (expense):			
Interest income	79,783	60,469	76,661
Foreign exchange gain (loss)	(2,691)	(47,951)	156
Other, net	(199,436)	(34,385)	(90,237)
Total other expense	(122,344)	(21,867)	(13,420)
Net loss before income taxes	(24,238,804)	(20,483,846)	(35,126,715)
Income tax provision	100,000	175,000	25,000
Net loss	$(24,338,804)	$(20,658,846)	$(35,151,715)
Basic and diluted net loss per common share	$(0.16)	$(0.14)	$(0.27)
Basic and diluted weighted average common shares outstanding	154,992,124	146,594,079	130,549,701

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,		
	2016	2015	2014
Net loss	$(24,338,804)	$(20,658,846)	$(35,151,715)
Foreign currency translation adjustment	(22,484)	13,901	(52,485)
Comprehensive loss	$(24,361,288)	$(20,644,945)	$(35,204,200)

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years Ended December 31, 2014, 2015 and 2016

	Common Stock					
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
December 31, 2013	128,740,604	$1,287,406	$243,375,465	$(173,295,941)	$ (653,202)	$70,713,728
Exercise of warrants and options	2,669,223	26,692	3,078,410	—	—	3,105,102
Common stock issued under equity compensation plan, net of shares withheld for taxes	333,538	3,335	(46,551)			(43,216)
Share-based compensation	—	—	2,624,742	—	—	2,624,742
Net loss	—	—	—	(35,151,715)	—	(35,151,715)
Other comprehensive loss	—	—	—	—	(52,485)	(52,485)
December 31, 2014	131,743,365	1,317,433	249,032,066	(208,447,656)	(705,687)	41,196,156
Issuance of common stock	23,000,000	230,000	42,620,677	—	—	42,850,677
Common stock issued under equity compensation plan, net of shares withheld for taxes	85,147	852	(49,803)	—	—	(48,951)
Exercise of options	20,000	200	30,600	—	—	30,800
Share-based compensation	—	—	3,658,874	—	—	3,658,874
Net loss	—	—	—	(20,658,846)	—	(20,658,846)
Other comprehensive income	—	—	—	—	13,901	13,901
December 31, 2015	154,848,512	1,548,485	295,292,414	(229,106,502)	(691,786)	67,042,611

Common stock issued under equity compensation plan, net of shares withheld for taxes	216,389	2,164	(85,795)	—	—	(83,631)
Exercise of options	102,776	1,028	100,064	—	—	101,092
Share-based compensation	—	—	2,519,750	—	—	2,519,750
Net loss	—	—	—	(24,338,804)	—	(24,338,804)
Other comprehensive loss	—	—	—	—	(22,484)	(22,484)
December 31, 2016	155,167,677	$1,551,677	$297,826,433	$(253,445,306)	$ (714,270)	$45,218,534

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$(24,338,804)	$(20,658,846)	$(35,151,715)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation expense	2,519,750	3,658,874	2,624,742
Depreciation and amortization	1,860,682	1,569,848	1,224,217
Loss on disposal of equipment	261,814	167,097	39,983
Write-off of capitalized patent costs	—	31,501	—
Increase in inventory reserve	748,378	700,000	3,550,000
Amortization of premiums and discounts	12,225	10,313	20,036
Changes in operating assets and liabilities:			
Accounts receivable	(1,137,543)	(4,422,689)	(2,478,494)
Inventories	(350,943)	(564,473)	(2,948,873)
Prepaid expenses and other current assets	1,921,937	(934,356)	(617,121)
Deferred costs	(574,229)	714,704	(1,538,148)
Other assets	100,000	148,000	545,059
Accounts payable	2,858,884	(3,494,536)	2,688,054
Accrued expenses and other liabilities	(582,295)	905,882	221,086
Deferred revenue	1,505,202	(6,030,160)	5,487,873
Net cash used in operating activities	(15,194,942)	(28,198,841)	(26,333,301)
Cash flows from investing activities:			
Purchases of equipment, molds, furniture and fixtures	(4,879,509)	(5,643,043)	(4,663,313)
Additions to patent rights	(127,156)	(1,043,628)	(989,790)
Proceeds from maturities of investment securities	15,000,000	6,000,000	24,000,000
Purchases of investment securities	—	(15,037,675)	—
Net cash provided by (used in) investing activities	9,993,335	(15,724,346)	18,346,897
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	—	42,850,677	—
Proceeds from exercise of stock options and warrants	101,092	30,800	3,105,102
Taxes paid related to net share settlement of equity awards	(83,631)	(87,770)	(154,397)
Net cash provided by financing activities	17,461	42,793,707	2,950,705
Effect of exchange rate changes on cash	58	(733)	(2,648)
Net decrease in cash and cash equivalents	(5,184,088)	(1,130,213)	(5,038,347)
Cash and cash equivalents:			
Beginning of year	32,898,676	34,028,889	39,067,236
End of year	$27,714,588	$32,898,676	$34,028,889
Supplemental disclosure of non-cash investing activities:			
Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	$424,389	$641,379	$1,118,925
Additions to patent rights recorded in accounts payable and accrued	$44,589	$21,027	$949,631

expenses

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Antares Pharma, Inc. ("Antares" or the "Company") is an emerging, specialty pharmaceutical company focused on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. The Company develops and manufactures, for itself or with partners, novel therapeutic products using its advanced drug delivery technology to enhance the existing drug compounds and delivery methods. The subcutaneous injection technology platforms include the VIBEX® pressure-assisted auto injector system suitable for branded and generic injectable drugs in unit dose containers, reusable needle-free spring-action injector devices, and disposable multi-dose pen injectors for use with standard cartridges. The Company has a portfolio of several approved commercial products and five product candidates in advanced stages of development and/or currently under review for approval by the U.S. Food and Drug Administration ("FDA"). The Company has formed significant strategic alliances with Teva Pharmaceutical Industries, Ltd. ("Teva"), AMAG Pharmaceuticals, Inc. ("AMAG"), Ferring Pharmaceuticals Inc. and Ferring B.V. (together "Ferring").

The Company launched its proprietary product OTREXUP® (methotrexate) injection, which is the first subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector approved by the FDA, in February 2014. OTREXUP® is indicated for adults with severe active rheumatoid arthritis ("RA"), children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis.

The Company, with its partner Teva, launched Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine and cluster headache in adults, in June 2016. In December 2015, the Company received FDA approval for an Abbreviated New Drug Application (ANDA) for 4 mg/0.5 mL and 6 mg/0.5 mL single-dose prefilled syringe auto-injectors, a generic equivalent to Imitrex® STATdose Pen®. 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 Company is developing VIBEX® QuickShot® Testosterone ("QST"), for testosterone replacement therapy, and submitted a 505 (b) (2) New Drug Application ("NDA") with the FDA in December 2016 that is currently under review. The Company also has multiple ongoing product development programs with its partners Teva and AMAG.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Antares Pharma, Inc. and its two wholly-owned foreign subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's significant accounting estimates relate to the revenue recognition periods for license revenues, OTREXUP® revenue recognition based on estimated patient prescriptions dispensed, inventory valuation, valuation of equity instruments used in stock-based compensation, and determination of the fair value and recoverability of patent rights. Actual results could differ from these estimates.

Foreign Currency Translation

The majority of the foreign subsidiaries' revenues are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the U.S. parent. Nearly all operating expenses of the foreign subsidiaries are denominated in Swiss Francs. Additionally, bank accounts held by foreign subsidiaries are denominated in Swiss Francs, there is a low volume of intercompany transactions and there is not an extensive interrelationship between the operations of the subsidiaries and the parent company. As such, the Company has determined that the Swiss Franc is the functional currency for its foreign subsidiaries. The reporting currency for the Company is the United States Dollar ("USD"). The financial statements of the Company's foreign subsidiaries are translated into USD for consolidation purposes. All assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a separate component

of stockholders' equity, comprising all of the accumulated other comprehensive income (loss). Sales to certain customers by the U.S. parent are in currencies other than the U.S. dollar and are subject to foreign currency exchange rate fluctuations. Foreign currency transaction gains and losses are included in foreign exchange gain (loss) in the consolidated statements of operations.

Cash and Cash Equivalents

Cash consists of demand deposits at commercial banks. The Company also invests in cash equivalents consisting of highly liquid investments in money market funds with original maturities of three months or less.

Allowance for Doubtful Accounts

Trade accounts receivable are stated at the amount the Company expects to collect. The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. The Company considers the following factors when determining the collectability of specific customer accounts: customer credit-worthiness, past transaction history with the customer, current economic industry trends, and changes in customer payment terms. At December 31, 2016, the Company's accounts receivable balance is due primarily from Teva and distributors of OTREXUP®. Each of these companies has historically paid timely and have been financially stable organizations. Due to the nature of the accounts receivable balance, the Company believes the risk of doubtful accounts is minimal. If the financial condition of the Company's customers were to deteriorate, adversely affecting their ability to make payments, additional allowances would be required. The Company provides for estimated uncollectible amounts through a charge to earnings and a credit to a valuation allowance. Balances that remain outstanding after the Company has used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. The Company had no bad debt expense in 2016 and 2015, and recorded bad debt expense of $37,000 in 2014. The allowance for doubtful accounts was $10,000 at December 31, 2016 and 2015, respectively.

Inventories

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

The Company provides reserves for potentially excess, dated or obsolete inventories based on estimates of forecasted product demand and the likelihood of consumption in the normal course of business, considering the expiration dates of the inventories on hand, planned production volumes and lead times required for restocking of customer inventories. Although every effort is made to ensure that forecasts and assessments are reasonable, changes to these assumptions are possible. In such cases, estimates may prove inaccurate and result in an understatement or overstatement of the reserves required to fairly state such inventories. The Company's established reserve for excess, dated or obsolete inventory was $900,000 and $800,000 at December 31, 2016 and 2015, respectively. In 2016, the Company wrote off inventory totaling $650,000 and increased the reserve for excess, dated or obsolete inventory by approximately $750,000. In 2015, the Company wrote off $3,500,000 of inventory and increased the reserve for excess, dated or obsolete inventory by approximately $700,000.

Equipment, Molds, Furniture, and Fixtures

Equipment, molds, furniture, and fixtures are stated at cost and are depreciated using the straight-line method over their estimated useful lives ranging from three to ten years. Depreciation expense was $1,326,378, $1,034,057 and $880,400 for the years ended December 31, 2016, 2015 and 2014, respectively.

Patent Rights

The Company capitalizes the costs of obtaining patent rights when there are projected future cash flows for marketed or partnered products associated with the patent. These capitalized costs are being amortized on a straight-line basis over the shorter of the life of the patent or the estimated useful life of the patent, which typically is over periods ranging from five to fifteen years beginning on the earlier of the date the patent is issued or the first commercial sale of product utilizing such patent rights. The Company periodically reviews capitalized patent costs to identify any amounts to be charged to expense for patents that are no longer being pursued or for which there are no future revenues or cash flows anticipated.

The Company capitalizes external legal patent defense costs and costs for pursuing patent infringements when it determines that a successful outcome is probable and will lead to an increase in the value of the patent. The capitalized costs are amortized over the remaining life of the related patent. If changes in the anticipated outcome were to occur that reduce the likelihood of a successful

outcome of the entire action to less than probable, the capitalized costs would be charged to expense in the period in which the change is determined.

The gross carrying amount and accumulated amortization of patents, which are the only intangible assets of the Company subject to amortization, was $4,659,103 and $2,614,495, respectively at December 31, 2016, and $4,533,439 and $2,098,897, respectively, at December 31, 2015. The Company's estimated aggregate patent amortization expense for the next five years is approximately $541,000, $541,000, $311,000, $92,000 and $71,000 in 2017, 2018, 2019, 2020 and 2021, respectively. Patent amortization expense for the years ended December 31, 2016, 2015 and 2014 was $534,304, $535,791 and $343,817, respectively, and is recorded in selling, general and administrative expenses in the consolidated statements of operations. In 2015, the Company expensed $31,501 of capitalized patent costs for abandoned patents or patents no longer connected with current products. There was no write-off of patent costs in 2016 and 2014, respectively.

Impairment of Long-Lived Assets and Intangibles

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

Goodwill

Goodwill is evaluated for impairment annually at December 31, or more frequently if an event occurs or circumstances change that indicate that the carrying value may not be recoverable. Such circumstances could include, but are not limited to: (1) a significant adverse change in legal factors or in business climate, (2) unanticipated competition, (3) an adverse action or assessment by a regulator, or (4) a sustained significant drop in the Company's stock price. When evaluating whether goodwill is potentially impaired, the Company compares the fair value of the reporting unit to the carrying amount, including goodwill. If the carrying amount is found to be greater, then the Company would determine the implied fair value of goodwill by subtracting the fair value of all the identifiable net assets other than goodwill from the fair value of the reporting unit and record an impairment loss, if any, for the excess of the carrying value of goodwill over the implied fair value.

At December 31, 2016, the Company had goodwill with a carrying value of $1,095,355 attributable to its single reporting unit. Based on the results of its evaluations, the Company determined that goodwill was not impaired, and no impairment losses were recognized in the years ended December 31, 2016, 2015, and 2014, respectively.

Fair Value of Financial Instruments

The carrying value of certain of the Company's financial instruments, including accounts receivable and accounts payable, approximate fair value due to the short-term nature of the instruments. From time to time, the Company invests in U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The investment securities are carried at amortized cost and fair value is determined by quoted market prices, which is a Level 1 fair value measurement. At December 31, 2015, the fair value of the Company's short-term investments approximated the carrying values and no short-term

investments were held at December 31, 2016.

Revenue Recognition

The Company recognizes revenue from the sale of products, development project milestones, license fees and royalties. Revenue is recognized when all of the following criteria are met: persuasive evidence of the arrangement exists; delivery has occurred and we have no remaining obligations; the fee is fixed or determinable; and collectability is reasonably assured.

OTREXUP® Revenue Recognition

The Company began detailing OTREXUP® to health care professionals in the U.S. in February 2014, and began shipping to wholesale pharmaceutical distributors, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Given the limited sales history of OTREXUP®, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, recognition of revenue is deferred on product shipments of

OTREXUP® until the right of return no longer exists, which occurs at the earlier of the time OTREXUP® units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. Patient prescriptions dispensed are estimated using third-party market prescription data. These third-party sources poll pharmacies, hospitals, mail order and other retail outlets for OTREXUP® prescriptions and project this sample on a national level. If patient prescriptions dispensed for a given period are underestimated or overestimated, adjustments to revenue may be necessary in future periods.

The Company recognized $15,145,214, $13,249,715 and $7,309,603 in OTREXUP® product revenue for the years ended December 31, 2016, 2015 and 2014, respectively, presented net of estimated product sales allowances, which include wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs, as more fully described below. A deferred revenue balance of $1,670,220 and $1,064,874 was recorded at December 31, 2016 and 2015, respectively for OTREXUP® product shipments, net of product sales allowances discussed below.

The Company will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until there has been sufficient history to estimate product returns. When it becomes possible to reasonably estimate product returns, a one-time increase in net revenue will be recorded to recognize revenue previously deferred. In addition, the costs of manufacturing OTREXUP® associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized.

Product Sales Allowances

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

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

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

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

Rebates. The Company participates in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, the Company will pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. The Company estimates and accrues for these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

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

Sumatriptan Revenue Recognition

Under a license, supply and distribution agreement with Teva for an auto-injector product containing sumatriptan, the Company produces devices and assembles final product for shipment to Teva, and Teva is responsible for commercial distribution and sale of the product. The Company is compensated, and recognizes revenue, at cost for shipments of product delivered to Teva. The Company is also entitled to receive 50 percent of the future net profits from commercial sales made by Teva. Given the relatively short time period since product launch and limited historical sales data, management is not currently able to estimate the profit margin the Company expects to receive from commercial sales made by Teva. Therefore, revenue from the profit sharing arrangement is currently recognized in the period following the commercial sale by Teva when amounts become fixed and determinable and payable to the Company, which is within 45 days after the end of each fiscal quarter in which commercial sales are made. In future periods, management may be able to reasonably estimate and recognize revenue from the profit sharing arrangement when product is sold by Teva.

Other Revenue Recognition

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

Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the deliverable has stand-alone value to the customer, the customer has a general right of return relative to the delivered item and delivery or performance of the undelivered item is probable and substantially within the vendor's control. Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price. The selling price for each deliverable is determined using: (i) vendor-specific objective evidence of selling price ("VSOE"), if it exists, (ii) third-party evidence of selling price ("TPE") if VSOE does not exist, and (iii) the Company's best estimate of the selling price if neither VSOE nor TPE exists. Revenue, excluding variable consideration, is recognized upon completion of deliverables based on the relative selling price of each deliverable that was assigned at inception of the arrangement.

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

Share-Based Compensation

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

Company’s stock price volatility and projected employee exercise behavior over the contractual life of the award can significantly impact the estimated fair value of an award.

Product Warranty

The Company provides a warranty on its reusable needle-free injector devices. The warranty period on a needle-free injector device is typically 24 months from either the date of retail sale of the device by a dealer or distributor or the date of shipment to a customer if specified by contract. The Company recognizes the estimated cost of warranty obligations at the time the products are shipped based on historical claims incurred by the Company. Actual warranty claim costs could differ from these estimates. At December 31, 2016 and 2015, the Company had $100,000 in warranty liability reserves.

Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs including personnel costs, materials and supplies associated with design work and prototype development, FDA fees and the cost of services provided by outside contractors such as expenses related to clinical trials. All costs associated with research and development activities are expensed as incurred.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Net Loss Per Share

Basic net loss per share is computed by dividing net income or loss available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed similar to basic net loss per share except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of stock options and warrants, if dilutive. The number of additional shares is calculated by assuming that outstanding stock options or warrants were exercised and that the proceeds from such exercise were used to acquire shares of common stock at the average market price during the reporting period. All potentially dilutive common shares were excluded from the calculation because they were anti-dilutive for all periods presented. Potentially dilutive securities excluded from dilutive loss per share were 11,313,909, 9,480,497 and 7,245,485 at December 31, 2016, 2015 and 2014, respectively.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company’s chief operating decision maker currently evaluates the Company’s operations as a whole from a number of different operational perspectives, including but not limited to, on a product-by-product, customer and partner basis. The Company derives all significant revenues from self-administered parenteral pharmaceutical products and technologies, and has a single reportable operating segment of business. Accordingly, the Company does not report more than one segment; nevertheless, management periodically evaluates whether the Company continues to have one single reportable segment of business.

Going Concern

The Company adopted Auditing Standard Update (“ASU”) No. 2014-15, Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern, which defines management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures, if required. As of December 31, 2016, the Company had cash and cash equivalents of $27,714,588 and no debt obligations. Based on management’s evaluation, management concluded there is not substantial doubt about the Company’s ability to meet its obligations within one year from the date the financial statements were issued. The Company is currently exploring collaborations and potential financings to raise additional capital. If, however, the Company is not successful in raising additional cash, the Company may be

required to defer or delay certain planned capital expenditures and other spending related to the potential approval and launch of QST, or curtail other controllable costs and discretionary spending for new research and development activities.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU No. 2014-09"). This guidance requires an entity to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard creates a five-step model that requires a company to identify customer contracts, identify the separate performance obligations, determine the transaction price, allocate the transaction price to the separate performance obligations and recognize revenue when each performance obligation is satisfied. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows

arising from contracts with customers. Qualitative and quantitative information is required about contract balances and remaining performance obligations, significant judgments made in determining the timing of satisfaction of performance obligations (over time or at a point in time), and estimates made in determining the transaction price and amounts allocated to performance obligations.

The Company is in the process of evaluating the impact the adoption of this standard will have on its consolidated financial statements and has performed an initial review of its major contracts with customers. Based on the initial reviews, the Company believes the adoption of the new standard may accelerate the timing of revenue recognition for product sales and development revenue under certain license, development and supply agreements, and will require management to estimate and potentially recognize certain variable revenue streams such as royalties and profit sharing arrangements earlier at an amount it believes will not be subject to significant reversal.

The Company anticipates adopting the new revenue recognition standard on the effective date of January 1, 2018 utilizing the modified retrospective method of adoption, under which the cumulative effect of the change is recognized as an adjustment to the opening balance of the accumulated deficit within the consolidated balance sheet, and prior reporting periods are not retrospectively adjusted. No significant changes to business processes or systems are currently expected to be necessary.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory. The new standard changes the measurement principle for inventory from the lower of cost or market to lower of cost and net realizable value. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016 and entities are required to disclose the nature and reason for the change in accounting principle in the first interim and annual period of adoption. The adoption of this standard is not expected to have a significant impact on the consolidated results of operations and financial position of the Company.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”). This new standard requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This new standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements and currently expects that most of its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets in the statement of financial position upon adoption of ASU 2016-02.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“ASU 2016-09”). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective on January 1, 2017. The adoption of ASU 2016-09 is not expected to have a significant impact on the Company’s consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment (“ASU 2017-04”). This new standard eliminates Step 2 from the goodwill impairment test. ASU 2017-04 requires an entity to perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. ASU 2017-04 still allows the option to perform a qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. ASU 2017-04 is effective for any annual or interim goodwill impairment tests in the fiscal years beginning after December 15, 2019 and must be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. Adoption of ASU 2017-04 is not expected to have a significant

impact on the Company’s consolidated financial statements.

3. Composition of Certain Financial Statement Captions

	December 31, 2016	December 31, 2015
Inventories:		
Raw material	$142,491	$305,149
Work in process	2,429,075	1,539,319
Finished goods	2,755,396	3,879,929
	$5,326,962	$5,724,397
Equipment, molds, furniture and fixtures:		
Furniture, fixtures and office equipment	$2,234,222	$2,058,146
Production molds and equipment	10,582,575	8,481,005
Molds and tooling in process	10,149,596	8,169,543
Less accumulated depreciation	(5,098,981)	(3,915,610)
	$17,867,412	$14,793,084
Patent rights:		
Patent rights	$4,659,103	$4,533,439
Less accumulated amortization	(2,614,495)	(2,098,897)
	$2,044,608	$2,434,542
Accrued expenses and other liabilities:		
Accrued employee compensation and benefits	$2,703,470	$3,018,987
OTREXUP® product sales allowances	1,483,699	751,318
Other liabilities	1,685,677	2,717,727
	$5,872,846	$6,488,032

4. Stockholders' Equity

The Company amended its certificate of incorporation to increase the total number of authorized shares of capital stock from 203,000,000 to 303,000,000 and to increase the number of authorized shares of common stock, par value $0.01 per share, of the Company from 200,000,000 shares to 300,000,000 shares. The amendment was approved and adopted by a vote of the stockholders at the Company's annual meeting of stockholders on June 2, 2016.

On May 11, 2015, the Company completed an underwritten offering of 23,000,000 shares of its common stock at a price to the public of $2.00 per share. The Company received net proceeds of approximately $42.9 million after deducting underwriting discounts, commissions and offering expenses paid by the Company. The Company has used the net proceeds from the offering for general corporate purposes including research and development activities.

5. Share-Based Compensation

The Company's 2008 Equity Compensation Plan (the "Plan") was amended and restated pursuant to stockholder approval in June 2016 in order to increase the number of shares available for issuance under the Plan, extend the term of the Plan, impose a one-year minimum vesting requirement and provide for double trigger accelerated vesting for

certain awards in the event of a change in control. The Plan allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company's officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. Under the Plan, the maximum number of shares authorized for issuance is 32,200,000 and the maximum number of shares of stock that may be granted to any one participant during a calendar year is 4,000,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair market value on the dates of grant. The term of each option is 10 years and the options typically vest in quarterly installments over a three-year period. As of December 31, 2016, the Plan had approximately 9,400,000 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

Stock Options

Stock option activity under the Plan as of and for the three years ended December 31, 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($)
Outstanding at December 31, 2013	7,697,892	1.89		
Granted/Issued	2,596,201	2.89		
Exercised	(2,124,123)	1.21		3,585,453
Cancelled/Forfeited	(924,485)	3.41		
Outstanding at December 31, 2014	7,245,485	2.25		
Granted/Issued	2,984,010	2.23		
Exercised	(20,000)	1.54		—
Cancelled/Forfeited	(728,998)	2.92		
Outstanding at December 31, 2015	9,480,497	2.19		
Granted/Issued	4,029,500	1.14		
Exercised	(142,493)	1.23		121,782
Cancelled/Forfeited	(2,053,595)	2.13		
Outstanding at December 31, 2016	11,313,909	1.84	7.0	7,741,133
Exercisable at December 31, 2016	7,789,081	2.04	6.1	513,003

As of December 31, 2016, there was $2,067,000 of total unrecognized compensation costs related to nonvested outstanding stock options that are expected to be recognized over a weighted average period of approximately 1.9 years.

Stock option expense recognized in 2016, 2015 and 2014 was approximately $2,039,000, $2,883,000 and $2,060,000, respectively. The per share weighted average fair value of options granted during 2016, 2015 and 2014 was estimated as $0.57, $1.13 and $1.64, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock. The weighted average expected life is based on both historical and anticipated employee behavior.

	December 31,		
	2016	2015	2014
Risk-free interest rate	1.3 %	1.3 %	1.6 %
Annualized volatility	51.7%	53.5%	60.7%
Weighted average expected life, in years	6.0	6.0	6.0
Expected dividend yield	0.0 %	0.0 %	0.0 %

Option exercises during 2016, 2015 and 2014 resulted in proceeds of $101,092, $30,800 and $2,564,987, respectively, and in the issuance of shares of common stock of 102,776 in 2016, 20,000 in 2015 and 2,124,123 in 2014. In 2016, certain options were net exercised, whereby the Company withheld 39,717 shares, the fair value of which was equivalent to the aggregate exercise price and tax withholding on the date of exercise.

Long Term Incentive Program

The Company's Board of Directors has approved a long term incentive program ("LTIP") for the benefit of the Company's senior executives. Pursuant to the LTIP, the Company's senior executives have been awarded stock options, restricted stock units ("RSU") and performance stock units ("PSU") with targeted values based on similar award structures granted by the Company's peer group. The stock options have a ten-year term, have an exercise price equal to the closing price of the Company's common stock on the date of grant, vest in quarterly installments over three years, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the stock options table above. The RSUs vest in three equal annual installments, and the PSU awards vest and convert into shares of the Company's common stock based on the Company's attainment of certain performance goals over a performance period, which is typically three to five years. In 2016 and 2015, the value of the annual award for each senior executive was delivered 33% in the form of PSUs, 33% in the form of RSUs and 34% in the form of stock options. In 2014, the value of the annual award for each senior executive was delivered 50% in the form of PSUs, 25% in the form of shares of RSUs and 25% in the form of stock options.

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

	Performance Stock Units		Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value ($)	Number of Shares	Weighted Average Grant Date Fair Value ($)
Outstanding at December 31, 2013	406,663	3.19	155,724	3.96
Granted	651,980	3.02	325,991	3.02
Vested/settled	(87,519)	2.03	(51,907)	3.96
Forfeited/expired	(507,582)	3.26	(198,684)	3.45
Outstanding at December 31, 2014	463,542	3.08	231,124	3.07
Granted	664,391	2.09	664,391	2.18
Vested/settled	—		(112,285)	2.92
Forfeited/expired	(171,755)	2.69	(68,402)	2.47
Outstanding at December 31, 2015	956,178	2.40	714,828	2.32
Granted	750,500	1.15	750,500	1.12
Vested/settled	(16,835)	3.96	(264,001)	2.41
Forfeited/expired	(342,554)	2.17	(378,669)	1.91
Outstanding at December 31, 2016	1,347,289	1.50	822,658	1.39

In each of the years in the three-year period ended December 31, 2016, the LTIP awards include PSUs that will be earned based on the Company's total shareholder return ("TSR") as compared to the Nasdaq Biotechnology Index ("NBI") at the end of the respective annual performance periods. Depending on the outcome of the performance goal, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 150% of the PSUs granted. The fair values of the TSR PSUs granted were determined using a Monte Carlo simulation and utilized the following inputs and assumptions:

	2016 Award	2015 Award	2014 Award
Closing stock price on grant date	$ 1.12	$ 2.18	$ 3.09
Performance period starting price	$ 1.29	$ 2.52	$ 4.08
Term of award (in years)	2.58	2.59	2.59
Volatility	70.1 %	60.5 %	50.9 %
Risk-free interest rate	0.97 %	0.83 %	0.60 %
Expected dividend yield	0.00 %	0.00 %	0.00 %
Fair value per TSR PSU	$ 1.25	$ 1.71	$ 2.64

The performance period starting price is measured as the average closing price over the last 20 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of the Company's common stock and the common stocks of the NBI companies and stock price volatilities of the NBI companies. The fair value of the target number of shares that can be earned under the TSR PSUs is being recognized as compensation expense over the term of the award.

In connection with PSU awards, including both TSR based awards and awards with defined performance goals considered probable of achievement, the Company recognized total compensation expense of approximately $68,000 and $250,000 in 2016 and 2015, respectively, and a net expense reduction of $3,000 in 2014. The net expense reduction was primarily the result of award forfeitures and the reversal of expense associated with awards previously granted to senior executives who left the Company in 2014. Compensation expense recognized in 2016, 2015 and 2014 in connection with the RSUs was $413,000, $526,000 and $212,000, respectively.

In 2016, 2015 and 2014, a portion of the LTIP awards were net-share settled such that the Company withheld shares with value equivalent to the employees' minimum statutory obligation for the applicable income and other employment taxes, and remitted the cash to the appropriate taxing authorities. The total shares withheld were 73,888, 39,665 and 38,768 in 2016, 2015 and 2014, respectively, and were based on the value of the shares on their vesting date as determined by the Company's closing stock price. Total payments for the employees' tax obligations to the taxing authorities were $83,631, $87,770 and $154,397 in 2016, 2015 and 2014, respectively, and are reflected as a financing activity within the Consolidated Statements of Cash Flows. These net-share

settlements reduced the number of shares that would have otherwise been issued as a result of the vesting and did not represent an expense to the Company.

Warrants

There were no outstanding warrants or warrant activity in 2016 or 2015. In 2014, warrants were exercised at $1.00 per share, resulting in proceeds of $545,115 to the Company and the issuance of 545,100 shares of common stock.

6. Employee 401(k) Savings Plan

The Company sponsors a 401(k) defined contribution retirement savings plan that covers all U.S. employees who have met minimum age and service requirements. Under the plan, eligible employees may contribute up to 50% of their annual compensation into the plan up to the IRS annual limits. The Company makes elective contributions to the plan allocated in proportion to employee contributions. For the years ended December 31, 2016, 2015 and 2014, the Company elected to make contributions to the plan totaling approximately $519,000, $392,000 and $373,000, respectively.

7. Leases

The Company has non-cancellable operating leases for its corporate headquarters facility in Ewing, New Jersey, and its office, research and development facility in Plymouth, Minnesota, a suburb of Minneapolis. The leases require payment of all executory costs such as maintenance and property taxes. Rent expense incurred for the years ended December 31, 2016, 2015 and 2014 was $679,693, $672,210 and $611,818, respectively. Future minimum lease payments under operating leases with remaining terms in excess of one year as of December 31, 2016 were as follows:

	Amount
2017	$611,067
2018	622,716
2019	565,955
2020	232,865
2021	238,232
Thereafter	59,896
Total future minimum lease payments	$2,330,731

8. Income Taxes

The Company was subject to taxes in both the U.S. and Switzerland in each of the years in the three-year period ended December 31, 2016. In the U.S., the Company incurred losses for both book and tax purposes for the year ended December 31, 2016, and, accordingly, no income taxes were provided. In Switzerland, net operating loss

carryforwards were used to fully offset taxable income of approximately $13,000, $1,127,000 and $177,000 in the years ended December 31, 2016, 2015 and 2014, respectively.

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

	2016	2015	2014
U.S.	$(24,228,608)	$(21,831,232)	$(35,359,378)
Switzerland	(10,196)	1,347,386	232,663
	$(24,238,804)	$(20,483,846)	$(35,126,715)

Effective tax rates differ from statutory income tax rates in the years ended December 31, 2016, 2015 and 2014 are as follows:

	2016	2015	2014
Statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State income taxes	(6.8)	(5.7)	(3.7)
Valuation allowance increase	35.9	35.2	37.8
Effect of foreign operations	—	(1.3)	(0.2)
Change in unused net operating loss and credit carryforwards	3.7	2.8	(0.2)
Nondeductible items	1.6	3.9	0.4
	0.4 %	0.9 %	0.1 %

Deferred tax assets (liabilities) as of December 31, 2016 and 2015 consist of the following:

	2016	2015
Gross deferred tax assets:		
Net operating loss carryforward – U.S.	$58,206,000	$49,450,000
Net operating loss carryforward – Switzerland	65,000	1,526,000
Research and development tax credit carryforward	5,477,000	4,707,000
Deferred revenue	438,000	301,000
Stock-based compensation	2,678,000	2,201,000
Inventory reserve	364,000	315,000
Compensation accruals	996,000	1,006,000
Other	378,000	241,000
	68,602,000	59,747,000
Gross deferred tax liabilities – depreciation and amortization	(844,000)	(753,000)
Less valuation allowance	(67,758,000)	(58,894,000)
Net deferred tax asset	$—	$100,000

The valuation allowance for deferred tax assets as of December 31, 2016 and 2015 was $67,758,000 and $58,894,000, respectively. The total valuation allowance increased $8,864,000 for the year ended December 31, 2016 and increased $7,853,000 for the year ended December 31, 2015.

At December 31, 2016 and 2015, the Company had deferred tax assets, net of valuation allowances, of zero and $100,000, respectively. In assessing the realizability of deferred tax assets, management considered whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences become deductible or in which net operating loss or tax credit carryforwards can be utilized. Both positive and negative evidence is considered in assessing the realizability of deferred tax assets and determining whether or not to record a valuation allowance. In 2015 and 2014, the Switzerland entities generated taxable income of $1,127,000 and $177,000, respectively, and the Company recognized tax expense of $175,000 and $25,000, respectively, realizing the benefit of $175,000 and $25,000, respectively of deferred tax assets associated with NOL carryforwards in Switzerland. However, in 2016, the Swiss entities only generated taxable income of $13,000. Management

determined it was more likely than not that the deferred tax assets associated with NOL carryforwards in Switzerland will not be realized and has recorded a full valuation allowance as of December 31, 2016.

After considering the evidence with respect to the U.S. deferred tax assets, management determined that as of December 31, 2016, it continues to be more likely than not that the U.S. deferred tax assets will not be realized and has recorded a valuation allowance against all U.S. deferred tax assets.

The Company has a U.S. federal net operating loss carryforward at December 31, 2016, of $156,343,000, which, subject to limitations of Internal Revenue Code (“IRC”) Section 382, is available to reduce income taxes payable in future years. If not used, this carryforward will expire in years 2018 through 2036. Included in the federal net operating loss is $5,075,000 of loss generated by deductions related to equity-based compensation, the tax effect of which will be recorded to additional paid in capital when utilized. Additionally, the Company has research credit carryforwards of $5,051,000. These credits expire in years 2018 through 2036.

Utilization of U.S. net operating losses and tax credits of the Company may be subject to annual limitations under IRC Sections 382 and 383, respectively. The annual limitations, if any, have not yet been determined. When a review is performed and if any

annual limitations are determined, then the gross deferred tax assets for the net operating losses and tax credits would be reduced with a reduction in the valuation allowance of a like amount.

The Company also has a Swiss net operating loss carryforward at December 31, 2016, of $437,000, which is available to reduce income taxes payable in future years. If not used, this carryforward will expire in 2018.

As of December 31, 2016 and 2015, there were no unrecognized tax benefits. Accordingly, a tabular reconciliation from beginning to ending periods is not provided. The Company will classify any future interest and penalties as a component of income tax expense if incurred. To date, there have been no interest or penalties charged or accrued in relation to unrecognized tax benefits.

The Company does not anticipate that the total amount of unrecognized tax benefits will change significantly in the next twelve months. The Company is subject to federal and state examinations for the years 2011 and thereafter. There are no tax examinations currently in progress.

9. Revenue Arrangements
Teva License, Development and Supply Agreements

In November 2012, the Company entered into a license, supply and distribution agreement with Teva for an auto injector product containing sumatriptan for the treatment of migraines. The Company manufactures the device and assembles the final product for shipment to Teva for distribution. Teva supplies sumatriptan in prefilled syringes and is responsible for commercial distribution of the product in the U.S. Under the agreement, the Company received an upfront payment and a milestone payment upon commercial launch in June 2016. In addition, the Company is compensated for devices it delivers to Teva, and shares in net profits from product sales made by Teva, which are split 50/50 between the Company and Teva. The term of the agreement continues seven years from commercial launch, with automatic one year renewals.

In December 2007, the Company entered into a license, development and supply agreement with Teva under which the Company is developing two disposable pen injector devices for use with the patient-administered pharmaceutical products exenatide and teriparatide. Under the agreement, an upfront payment, development milestones, and royalties on Teva's product sales, as well as a purchase price for each device sold are to be received by the Company. In January 2011, this agreement was amended such that Teva pays for all development work and tooling associated with device development. This agreement will continue until the later of December 2017 or the expiration date of the last to expire patent covering the device or product that is filed no later than 12 months after FDA approval, and will be automatically renewed for successive periods of two years each.

In July 2006, the Company entered into an exclusive license, development and supply agreement with Teva for an epinephrine auto injector product. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements to be marketed in the U.S. and Canada from the Company. The Company was entitled to an upfront cash payment, milestone fees, a negotiated purchase price for each device sold, as well as royalties on sales of product. This agreement will continue until 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.

Under a separate agreement, Teva agreed to provide the Company with device orders of an undisclosed amount, to make a milestone payment to the Company upon FDA approval of epinephrine auto injector, and to assume all

litigation costs related to a patent litigation between Teva and Meridian Medical, a Pfizer subsidiary.

AMAG Development and License Agreement

In September 2014 the Company entered into a development and license agreement with Lumara Health, Inc., which was later acquired by AMAG Pharmaceuticals, Inc. (AMAG) in November 2014. Under the agreement, the Company granted an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export an auto-injection system for use with 17-alpha hydroxyprogesterone caproate, a progestin drug indicated to reduce the risk of preterm birth. The Company received an upfront payment for its license and development work, and is entitled to receive milestones payments, payment of purchase price for each device sold, and royalties on net product sales.

Under the arrangement, AMAG is responsible for the clinical development and preparation, submission and maintenance of all regulatory applications, supply of the drug to be used in the product, and to market and sell the product. The Company is the exclusive supplier of the auto-injection system devices for the product and is responsible for the manufacture and supply of the devices and final assembly and packaging of the product. The Company is entitled to receive royalties on 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.

The Company identified and evaluated a number of deliverables in the agreement and concluded that the manufacturing deliverable has stand-alone value but the license and development work do not have value on a stand-alone basis. As a result, the license and development deliverables do not qualify for treatment as separate units of accounting, and accordingly, are accounted for as a single unit of accounting and will be recognized as revenue during the estimated development period.

LEO Pharma Promotion and License Agreement

In November 2013, the Company entered into a promotion and license agreement with LEO Pharma. Under this agreement the Company granted LEO Pharma the exclusive right to promote OTREXUP® to dermatologists for symptomatic control of severe recalcitrant psoriasis in adults in the U.S. LEO Pharma is responsible for promotion and marketing activities in dermatology and the Company is responsible for the supply of OTREXUP® product and samples. The Company received from LEO Pharma a non-refundable upfront payment of $5.0 million, a milestone payment of $5.0 million, and was entitiled to a milestone payment of $10.0 million upon realizing a defined level of net sales in a calendar year. The Company agreed to pay LEO Pharma a percentage of net sales generated in dermatology and recorded the payments to LEO Pharma as sales and marketing expense.

The Company identified and evaluated a number of deliverables in the agreement and concluded that none of the deliverables had value on a stand-alone basis. As a result, these deliverables did not qualify for treatment as separate units of accounting, and accordingly, were accounted for as a single unit of accounting with each of the milestone payments deferred and allocated to the deliverables and recognized as revenue over the 35 month estimated life of the agreement.

Effective June 23, 2015, the agreement with LEO was terminated and the Company regained the exclusive U.S. marketing rights to OTREXUP®. As a result, the Company recognized the remaining unamortized balance of the deferred revenues related to this arrangement in the second quarter of 2015. In total, the Company recognized revenue of $6,000,000 and $3,429,000 in the years ended December 31, 2015 and 2014, respectively, pursuant to this agreement.

Ferring Agreements

In November 2009, the Company entered into an Exclusive License Agreement with Ferring, under which the Company licensed certain of its patents and agreed to transfer know-how for its transdermal gel technology for certain pharmaceutical products. The agreement will remain in effect until the last applicable patent under the agreement expires. Under the terms of the agreement, the Company is entitled to receive milestone payments as certain defined milestones are achieved. In 2015, the Company received and recognized a $1.0 million milestone under this arrangement, which was earned in connection with Ferring filing a NDA related to the patented licensed technology.

The Company entered into a License Agreement with Ferring in 2003 under which the Company licensed certain of its intellectual property and extended the territories available to Ferring for use of certain of the Company’s reusable needle-free injector devices. Specifically, the Company granted to Ferring an exclusive, perpetual, irrevocable, royalty-bearing license, within a prescribed manufacturing territory, to manufacture certain of the Company’s reusable needle-free injector devices for the field of human growth hormone. The Company granted to Ferring similar non-exclusive rights outside of the prescribed manufacturing territory.

As consideration for the license grants, Ferring paid the Company an upfront payment upon execution of the License Agreement, and an additional milestone in 2003. Ferring also pays the Company royalties for each device manufactured by or on behalf of Ferring, including devices manufactured by the Company. These royalty obligations expire, on a country-by-country basis, when the respective patents for the products expire, despite the fact that the License Agreement does not itself expire until the last of such patents expires. The license fees were initially deferred and are being recognized in income over the period from 2003 through 2016. In March 2007, the Company amended the agreement increasing the royalty rate and device pricing, included a next generation device and provided for payment principally in U.S. dollars rather than Euros.

In the fourth quarter of 2014, Ferring purchased the U.S. rights to Teva's hGH drug Tev-Tropin® and assumed the terms of an existing licensing and supply agreement with the Company. In 2015, Ferring received FDA approval for a name change of the drug to ZOMACTON™ and FDA approval for the 10mg needle-free device ZOMA-Jet™ to be marketed in the U.S. Under the terms of the agreement, the Company receives payment for product shipments on each device sold and royalty payments on Ferring's net sales, which are recognized as revenue when received. The agreement, as amended, provides for one-year automatic renewals unless terminated by either party six months ahead of the expiring term.

10. Significant Customers and Concentrations of Risk

Revenues by customer location are summarized as follows:

	For the Years Ended December 31,		
	2016	2015	2014
United States of America	$45,531,470	$39,228,615	$21,409,371
Europe	6,116,865	6,025,899	4,761,684
Other	573,711	403,586	330,610
	$52,222,046	$45,658,100	$26,501,665

The following summarizes significant customers comprising 10% or more of total revenue:

	For the Years Ended December 31,		
	2016	2015	2014
Teva	$24,941,371	$17,714,823	$8,682,384
Ferring	6,282,974	6,116,642	4,760,084
McKesson [1]	7,599,905	6,837,047	3,460,000
LEO Pharma	—	6,000,000	3,428,571

[1] Represents estimated revenue, net of deferrals, based on OTREXUP® shipments to the distributor.

11. Legal Proceedings

In the first quarter of 2014, Medac Pharma, Inc. ("Medac Pharma") announced that it submitted a NDA to the FDA for an auto-pen containing methotrexate. On February 28, 2014, Antares filed a complaint against Medac Pharma and medac GmbH, the parent company of Medac Pharma, (medac GmbH, together with Medac Pharma, "Medac") in the U.S. 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. On March 14, 2014, Antares filed a motion for preliminary injunction seeking to enjoin Medac from selling its methotrexate auto-pen product if and when such product is approved for sale in the United States, pending the final resolution of the litigation. On April 18, 2014 an amended complaint was filed asserting four Antares patents, and the motion for preliminary injunction was updated. On July 10, 2014, the District Court denied Antares' motion for preliminary injunction. Antares filed an appeal of the denial of the motion for preliminary injunction with the U.S. Court of Appeals for the Federal Circuit, and in February 2015, that motion was denied.

On March 7, 2014, Medac filed suit against Antares, LEO Pharma, Inc. and its parent company, LEO Pharma A/S (LEO Pharma, Inc. together with LEO Pharma A/S, the "LEO Entities") in the U.S. District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac Pharma's U.S. Patent 8,664,231 (the "231

patent") that was issued by the U.S. Patent and Trademark Office on March 4, 2014. Under the terms of the promotion and license agreement between the Company and the LEO Entities, the Company agreed to indemnify the LEO Entities from claims that OTREXUP® infringes the intellectual property rights of any third party. On July 1, 2014, Antares filed a petition with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office seeking an inter partes review of the 231 patent, and in January 2015, the PTAB decided to institute review of the 231 patent. Legal costs in connection with this suit and the inter partes review were expensed as incurred.

In April 2015, Antares, Medac and the LEO Entities entered into a settlement agreement pursuant to which all of the proceedings related to Antares' and Medac's respective patents mentioned above and the proceeding pending before the Technical Board of Appeal of the European Patent Office were dismissed. The settlement agreement also 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.

12. Quarterly Financial Data (unaudited)

	First	Second	Third	Fourth
2016:				
Total revenues	$12,318,772	$12,228,390	$13,478,763	$14,196,121
Gross profit	5,543,031	4,910,292	5,445,042	7,506,915
Net loss	(7,656,110)	(6,061,463)	(6,120,983)	(4,500,248)
Net loss per common share [1]	(0.05)	(0.04)	(0.04)	(0.03)
Weighted average shares	154,858,079	154,936,096	155,060,811	155,111,435
2015:				
Total revenues	$8,348,037	$14,420,391	$11,085,752	$11,803,920
Gross profit	4,673,308	9,712,297	5,985,989	5,828,823
Net loss	(6,787,674)	(1,506,646)	(5,738,041)	(6,626,485)
Net loss per common share [1]	(0.05)	(0.01)	(0.04)	(0.04)
Weighted average shares	131,744,741	144,650,269	154,808,641	154,828,729

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

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's management evaluated, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, the effectiveness of its disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based upon this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2016, the Company's disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended). Under the supervision and with the participation of the Chief Executive Officer and the Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting as of December 31, 2016. This assessment was based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework (2013).

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

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

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

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

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

Based on the Company's assessment using the COSO Internal Control-Integrated Framework (2013) criteria, management has concluded that its internal control over financial reporting was effective as of December 31, 2016 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles.

The Company's independent registered public accounting firm, KPMG LLP, has issued an audit report on the Company's internal control over financial reporting, which appears in Item 8 of this Annual Report on Form 10-K.

Changes in internal control over financial reporting.

There was no change in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. OTHER INFORMATION
None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item concerning our directors will be set forth under the caption “Election of Directors” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

Information required by this item concerning our executive officers will be set forth under the caption “Executive Officers of the Company” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

Information required by this item concerning the audit committee of the Company, the audit committee financial expert of the Company and any material changes to the way in which security holders may recommend nominees to the Company’s Board of Directors will be set forth under the caption “Corporate Governance” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

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

Item 11. EXECUTIVE COMPENSATION

Information required by this item will be set forth under the caption “Executive Compensation” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

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

Information required by this item concerning ownership will be set forth under the caption “Security Ownership of Certain Beneficial Owners” and “Security Ownership of Directors and Executive Officers” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

The following table provides information for our equity compensation plans as of December 31, 2016:

Plan Category	Number of securities to be issued upon exercise of outstanding options,	Weighted-average exercise price of outstanding	Number of securities remaining available for future issuance under equity

	warrants and rights	options, warrants and rights	compensation plans (excluding shares reflected in the first column)
Equity compensation plans approved by security holders	11,313,909	$ 1.84	9,400,000

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE
Information required by this item will be set forth under the captions “Certain Relationships and Related Transactions” and “Corporate Governance” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES
Information required by this item will be set forth under the caption “Ratification of Selection of Independent Registered Public Accountants” in our definitive proxy statement for our 2017 annual meeting, and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements - see Part II

(2) Financial Statement Schedules

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

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

(b) Exhibits

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

Exhibit No.	Description
3.1	Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 4.1 to Form S-3 on April 12, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 19, 2008 and incorporated herein by reference.)
3.3	Amended and Restated By-laws of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 15, 2007 and incorporated herein by reference.)
3.4	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 3.1 to Form 8-K on May 28, 2013 and incorporated herein by reference.)
3.5	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as exhibit 10.3 to Form 10-Q on August 9, 2016 and incorporated herein by reference.)
4.1	Form of Certificate for Common Stock (Filed as an exhibit to Form S-1/A on August 15, 1996 and incorporated herein by reference.)
4.2	Registration Rights Agreement with Permatec Holding AG dated January 31, 2001 (Filed as Exhibit 10.2 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
4.3	Stock Purchase Agreement with Sicor Pharmaceuticals, Inc., dated November 23, 2005 (Filed as exhibit 10.55 to Form 10-K for the year ended December 31, 2005 and incorporated herein by reference.)
4.4	Form of Subscription Agreement, by and between Antares Pharma, Inc. and the investor party thereto (Filed as Exhibit 10.1 to Form 8-K filed on September 18, 2009 and incorporated herein by reference).
4.5+	Antares Pharma, Inc. 2008 Equity Compensation Plan, as amended and restated (Filed as Exhibit 4.1 to the Company’s Form S-8 filed with the Commission on June 2, 2016 and incorporated herein by reference.)

10.0	Stock Purchase Agreement with Permatec Holding AG, Permatec Pharma AG, Permatec Technologie AG and Permatec NV with First and Second Amendments dated July 14, 2000 (Filed as an exhibit to Schedule 14A on December 28, 2000 and incorporated herein by reference.)
10.1	Third Amendment to Stock Purchase Agreement, dated January 31, 2001 (Filed as exhibit 10.1 to Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.)
10.2*	License Agreement between Antares Pharma, Inc. and Ferring, dated January 21, 2003 (Filed as exhibit 10.47 to Form 8-K on February 20, 2003 and incorporated herein by reference.)
10.3	Lease Agreement between Princeton South Investors, LLC and Antares Pharma, Inc., dated February 3, 2012 (Filed as exhibit 10.21 to Form 10-K for the year ended December 31, 2011 and incorporated herein by reference.)
10.4	First Amendment to Lease between Princeton South Investors, LLC and Antares Pharma, Inc., dated January 28, 2013. (Filed as Exhibit 10.22 to Form 10-K for the year ended December 31, 2012 and incorporated herein by reference.)

Exhibit No.	Description
10.5	Second Amendment to Lease between Princeton South Investors, LLC and Antares Pharma, Inc., dated December 4, 2013. (Filed as Exhibit 10.22 to Form 10-K for the year ended December 31, 2013 and incorporated herein by reference.)
10.6	Lease Agreement between St. Paul Fire and Marine Insurance Company and Antares Pharma, Inc., dated December 20, 2013. (Filed as Exhibit 10.23 to Form 10-K for the year ended December 31, 2013 and incorporated herein by reference.)
10.7+	Employment Agreement, dated April 25, 2014, by and between Antares Pharma, Inc. and Jennifer Evans Stacey. (Filed as Exhibit 10.1 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.8+	Separation and Consulting Services Agreement, dated July 13, 2015, by and between Antares Pharma, Inc. and Jennifer Evans Stacey. (Filed as Exhibit 99.1 to Form 8-K on July 15, 2015 and incorporated herein by reference.)
10.9+	Employment Agreement, dated June 23, 2014, by and between Antares Pharma, Inc. and Eamonn P. Hobbs. (Filed as Exhibit 10.2 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.10+#	Separation Agreement, dated February 4, 2016, by and between Antares Pharma, Inc. and Eamonn P. Hobbs. (Filed as Exhibit 10.20 to Form 10-K on March 8, 2016 and incorporated herein by reference.)
10.11+	Antares Pharma, Inc. Severance Plan, dated May 29, 2014. (Filed as Exhibit 10.4 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.12+*	Form of Performance Stock Unit Grant. (Filed as Exhibit 10.5 to Form 10-Q on August 7, 2014 and incorporated herein by reference.)
10.13	Form of Indemnification Agreement between Antares Pharma, Inc. and each of its directors and executive officers. (Filed as Exhibit 10.1 to Form 10-Q on August 10, 2015 and incorporated herein by reference.)
10.14+	Employment Agreement, dated July 8, 2015, by and between Antares Pharma, Inc. and Peter J. Graham (Filed as Exhibit 10.2 to Form 10-Q on August 10, 2015 and incorporated herein by reference.)
10.15+	Form of Restricted Stock unit Grant Agreement delivered by Antares Pharma, Inc. to each of its grantees (Filed as Exhibit 10.3 to Form 10-Q on August 10, 2015 and incorporated herein by reference.)
10.16+	Special Cash Bonus Plan of Antares Pharma, Inc. for named executive officers in connection with achievement of certain milestones regarding the approval by the U.S. Food and Drug Administration of the Abbreviated New Drug Application for the VIBEX® epinephrine pen (Incorporated herein by reference to the disclosure under Item 5.02 of the Form 8-K filed on June 3, 2015.)
10.17+	Antares Pharma, Inc. Annual Incentive Plan, effective December 2, 2015 (Filed as Exhibit 99.1 to Form 8-K on December 8, 2015 and incorporated herein by reference.)
10.18+	

Employment Agreement dated March 4, 2016 between Antares Pharma, Inc. and Robert F. Apple (Filed as exhibit 10.1 to Form 10-Q on May 9, 2016 and incorporated herein by reference.)

10.19+ Amended and Restated Employment Agreement dated June 30, 2016 between Antares Pharma, Inc. and James Fickenscher (Filed as exhibit 10.1 to Form 10-Q on August 9, 2016 and incorporated herein by reference.)

10.20+ Amended and Restated Employment Agreement dated June 30, 2016 between Antares Pharma, Inc. and Peter J. Graham (Filed as exhibit 10.2 to Form 10-Q on August 9, 2016 and incorporated herein by reference.)

10.21+ Form of Nonqualified Stock Option Grant Agreement (Filed as exhibit 10.4 to Form 10-Q on August 9, 2016 and incorporated herein by reference.)

10.22+ Form of Restricted Stock Unit Grant (Filed as exhibit 10.5 to Form 10-Q on August 9, 2016 and incorporated herein by reference.)

10.23+ Form of Restricted Stock Grant Agreement (Filed as exhibit 10.6 to Form 10-Q on August 9, 2016 and incorporated herein by reference.)

10.24+ Employment Agreement effective October 31, 2016 between Antares Pharma, Inc. and Fred M. Powell (Filed as exhibit 10.1 to Form 10-Q on November 9, 2016 and incorporated herein by reference.)

23.1 # Consent of KPMG LLP, Independent Registered Public Accounting Firm.

Exhibit No.	Description
31.1 #	Certification of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
31.2 #	Certification of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
32.1 ##	Certification of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.
32.2 ##	Certification of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.
101.INS #	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase
101.LAB#	XBRL Taxonomy Extension Label Linkbase
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase
101.DEF#	XBRL Taxonomy Extension Definition Linkbase

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report to be signed on its behalf by the undersigned thereunto duly authorized, on the 14th day of March 2017.

ANTARES PHARMA, INC.

/s/ Robert F. Apple
Robert F. Apple
President and Chief Executive Officer

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this annual report has been signed by the following persons on behalf of the registrant in the capacities indicated on March 14, 2017.

Signature	Title
/s/ Robert F. Apple Robert F. Apple	President and Chief Executive Officer, Director (Principal Executive Officer)
/s/ Fred M. Powell Fred M. Powell	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
/s/Leonard S. Jacob Dr. Leonard S. Jacob	Director, Chairman of the Board
/s/Thomas J. Garrity Thomas J. Garrity	Director
/s/Jacques Gonella Dr. Jacques Gonella	Director
/s/Anton G. Gueth Anton G. Gueth	Director
/s/Robert P. Roche, Jr. Robert P. Roche, Jr.	Director
/s/Marvin Samson Marvin Samson	Director

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