ANTARES PHARMA, INC.
Form 10-K
March 12, 2019

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, 2018

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018, was $374,318,627 (based upon the last reported sale price of $2.58 per share on June 29, 2018, on the NASDAQ Capital Market).

There were 160,532,311 shares of common stock outstanding as of March 1, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2019 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this annual report on Form 10-K are incorporated by reference into Part III of this annual report on Form 10-K.

ANTARES PHARMA, INC.

FORM 10-K

TABLE OF CONTENTS

PART I

Item 1	Business	4
Item 1A	Risk Factors	32
Item 1B	Unresolved Staff Comments	60
Item 2	Properties	60
Item 3	Legal Proceedings	60
Item 4	Mine Safety Disclosures	61

PART II

Item 5	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	62
Item 6	Selected Financial Data	63
Item 7	Management's Discussion and Analysis of Financial Condition and Results of Operations	64
Item 7A	Quantitative and Qualitative Disclosures About Market Risk	71
Item 8	Financial Statements and Supplementary Data	72
Item 9	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	98
Item 9A	Controls and Procedures	98
Item 9B	Other Information	98

PART III

Item 10	Directors, Executive Officers and Corporate Governance	99
Item 11	Executive Compensation	99
Item 12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	99
Item 13	Certain Relationships and Related Transactions, and Director Independence	99
Item 14	Principal Accounting Fees and Services	99

PART IV

Item 15	Exhibits and Financial Statement Schedules	100
	Signatures	103

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 the commercialization of XYOSTED™ (testosterone enanthate) injection for testosterone replacement therapy, including marketing and reimbursement strategies, and future revenues related thereto;
- our expectations regarding continued sales of OTREXUP® (methotrexate) injection;
- our expectations regarding sales of Sumatriptan Injection USP to our partner, Teva Pharmaceutical Industries, Ltd. ("Teva"), and Teva's ability to successfully distribute and sell Sumatriptan Injection USP;
- our expectations regarding the ability of our partner, AMAG Pharmaceuticals, Inc. ("AMAG"), to continue to successfully commercialize the Makena® subcutaneous auto injector, and any future revenue related thereto;
- our expectations regarding the ability of our partner, Teva, to successfully commercialize the generically equivalent version of Mylan's EpiPen® ("generic epinephrine injection"), and any future revenue related thereto;
- our expectations regarding continued product development with Teva of the teriparatide disposable pen injector and exenatide disposable pen injector, and Teva's ability to obtain FDA approval and AB-rating for each of those products;
- our plans to develop a rescue pen for an undisclosed drug and our intention to enter into a separate supply agreement with Pfizer, Inc. ("Pfizer") for the same;
- our expectations about the timing and successful completion of the sale of our worldwide rights, including the successful transfer of the CE Mark and completion of outstanding purchase orders, for the ZOMAJET™ needle-free auto injector device product line to Ferring International Center S.A. (together with Ferring Pharmaceuticals Inc. and Ferring B.V. individually and collectively referred to as "Ferring");
- our expectations about the timing and outcome of pending or potential claims and litigation, including without limitation, the pending securities class action and derivative actions;
- 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;
- timing and results of our research and development projects, including clinical trials, and our anticipated continued reliance on third parties in conducting studies, trials and other research and development activities;
- expectation about our future revenues, cash flows and our ability to support our operations;
- our estimates and expectations regarding the sufficiency of our cash resources, anticipated capital requirements and our need for and ability to obtain additional financing;
- our expectations and estimates with regard to current accounting practices and the potential impact of new accounting pronouncements and tax legislation; and
- other statements regarding matters that are not historical facts or statements of current condition.

2

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 or unsuccessful marketing and commercialization efforts by us or our partners;
- interruptions in supply or an inability to adequately manage third party contract manufacturers to meet customer supply requirements;
- our inability to obtain or maintain adequate third-party payer coverage of marketed products;
- the timing and results of our or our partners' research projects or clinical trials of product candidates in development including projects with Teva and Pfizer;
- actions by the FDA or other regulatory agencies with respect to our products or product candidates of our partners;
- our inability to generate continued growth in product, product development, licensing and royalties;
- the lack of market acceptance of our and our partners' products and future revenues from these products;
- 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 or our marketing capabilities;
- our inability to establish and maintain our sales and marketing capability, our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers;
- changes or delays in the regulatory review and approval process;
- 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;
- our inability to obtain additional financing, reduce expenses or generate funds when necessary; and
- adverse economic and political conditions.

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

Company Overview

Antares Pharma, Inc. (“Antares,” “we,” “our,” “us” or the “Company”) is a combination drug device company focused primarily 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 patented drug delivery technology to enhance the drug delivery methods. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems that are designed to provide commercial or functional advantages, such as improved safety and efficacy, reduced side effects, and enhanced patient comfort and adherence. Our intramuscular and subcutaneous injection technology platforms include the VIBEX® and VIBEX® QuickShot® pressure-assisted auto injector systems suitable for branded and generic injectable drugs in unit dose containers as well as disposable multi-dose pen injectors. We have a portfolio of proprietary and partnered commercial products and ongoing product development programs in various stages of development. We have formed significant strategic alliances and partnership arrangements with industry leading pharmaceutical companies including Teva, AMAG and Pfizer.

2018 Highlights

Antares Pharma, Inc. experienced several significant and transformative milestones in 2018. The following is a discussion of significant accomplishments:

- Approval and Launch of XYOSTED™ – We developed XYOSTED™ (testosterone enanthate) injection, indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, which was approved by the FDA on September 28, 2018 and launched for commercial sale in November 2018. XYOSTED™ is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration. In connection with the launch of XYOSTED™, we hired approximately 50 additional sales representatives and cross-trained the combined specialty sales force to leverage our existing resources and enhance our commercial organization. Our sales representatives started detailing XYOSTED™ to physicians in the second half of December 2018.
- Approval and Launch of Teva’s Generic Epipen® - In collaboration with Teva, we developed a version of our VIBEX® auto injector for use in a combination epinephrine auto injector product that was approved by the FDA in August 2018 and was commercially launched in limited quantities in late fourth quarter of 2018. Teva’s Epinephrine Injection USP is indicated for emergency treatment of severe allergic reactions including those that are life threatening (anaphylaxis) in adults and certain pediatric patients and was approved as a generic drug product with an AB rating, meaning that it is therapeutically equivalent to Mylan, Inc.’s branded products EpiPen® and EpiPen Jr® and therefore, subject to state law, substitutable at the pharmacy. We are the exclusive supplier of the device and Teva is responsible for commercialization and distribution of the finished product, for which we also receive royalties on net sales.
- Approval and Launch of AMAG’s Makena® subcutaneous auto injector – In collaboration with AMAG, we developed a variation of our VIBEX® QuickShot® subcutaneous auto injector for the Makena® (hydroxyprogesterone caproate injection) Subcutaneous Auto-Injector product, which was approved by the FDA in February 2018 and launched for commercial sale in March 2018. The Makena® subcutaneous auto injector is a ready-to-administer treatment indicated to reduce the risk of preterm birth in women pregnant with one baby and who spontaneously delivered one preterm baby in the past. We are the exclusive supplier of the devices and the final assembled and packaged commercial product, upon which we receive royalties on net sales made by AMAG.
- New Pipeline Development with Pfizer - In August 2018, we entered into a new collaboration agreement with Pfizer to jointly develop a combination drug device rescue pen that will utilize our QuickShot® auto injector and an

undisclosed Pfizer drug. Pfizer will pay us for design and development services and be responsible for obtaining FDA regulatory approval. We intend to enter into a separate supply agreement with Pfizer under which we will provide fully packaged commercial ready finished product to Pfizer. Pending FDA approval, Pfizer will then be responsible for commercialization and sale of the product, upon which we will receive royalties on net sales.

In addition to these significant achievements in 2018, we continue to market and sell our proprietary product OTREXUP® (methotrexate) injection and, through our partner Teva, Sumatriptan Injection USP, expand our commercial organization and our sales and marketing capabilities, meet the supply demands of our partners, devote significant resources to our research and development programs to further our development pipeline and maintain a disciplined approach to growth and expenditures.

Product Portfolio Overview

The following table provides an overview of our proprietary and partnered commercial products and product opportunities:

Approved Products	Drug	Partner	Indication	Territory
OTREXUP® (methotrexate) injection	Methotrexate	None	Rheumatoid Arthritis; pJIA, Psoriasis	U.S.
XYOSTED™ (testosterone enanthate) injection	Testosterone	None	Testosterone Replacement Therapy ("TRT")	U.S.
Sumatriptan Injection USP (generic equivalent to Imitrex® STATdose Pen®)	Sumatriptan succinate	Teva	Migraines	U.S.
Epinephrine Injection USP (generic equivalent to EpiPen® and EpiPen® Jr.)	Epinephrine	Teva	Anaphylaxis	U.S.
Makena® Subcutaneous Auto Injector	Hydroxy-progesterone caproate	AMAG	Reduced Risk of Pre-term Birth	U.S.
ZOMAJET™ Needle-free Injector(1)	hGH	Ferring	Growth Retardation	Worldwide
Twin-Jector® EZ II Needle-free Injector(1)	hGH	JCR	Growth Retardation	Japan
Products in Development	**Drug**	**Partner**	**Indication**	**Territory**
Disposable Pen Injector	Exenatide	Teva	Diabetes	U.S.
Disposable Pen Injector	Teriparatide	Teva	Osteoporosis	U.S., Europe(2)
QuickShot® Auto Injector	Undisclosed	Pfizer	Undisclosed	U.S.
Combination Product	ATRS-1701	None	Undisclosed	

(1) On October 10, 2017, we entered into an asset purchase agreement with Ferring to sell the worldwide rights, including certain assets, related to the needle-free auto injector device product line (the "Ferring Transaction"). We will continue to manufacture and supply needle-free devices under the existing license and supply agreements until the completion of the transaction, which is expected to occur in 2019.

(2)

Teva completed a decentralized procedure registration process in 17 countries in Europe and is awaiting patent clearance in the EU prior to launch.

For a detailed discussion of our proprietary and partnered approved and marketed products, and other products currently in development, see “Our Products” and “Research and Development” sections below.

Our Strategy and Market Opportunity

Our business strategy is to identify development and commercialization opportunities that apply our patented drug delivery injection technology to new or existing approved drug formulations in order to enhance the drug delivery methods and provide commercial and/or functional advantages. Our strategy is to pursue these opportunities both on our own or with industry leading partners. We believe this strategy offers a distinct value to patients, healthcare providers, 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. Our patented drug delivery technologies, such as the VIBEX® QuickShot®, enable the delivery of highly viscous drug compounds through fine gauge needles. We believe our technology platforms have potential in both the branded and generic marketplace, and that there are a number of existing approved drugs that may benefit from an alternate route of delivery such as subcutaneous injection.

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 and our partners have historically sought, and are in the process of seeking, FDA approval for certain product candidates primarily using the 505(b)(2) NDA (New Drug Application) or ANDA (Abbreviated New Drug Application) approval pathways, which are further described in the Government Regulation section below. Our technology platforms allows for device customization, which can provide multiple opportunities in both the 505(b)(2) NDA and generic market spaces. There are a number of injectable branded products that have recently lost patent protection in the U.S. that will be or have been subject to the ANDA approval pathway. By way of example, two of the products in development with our partner Teva (disposable pen injector products with teriparatide and exenatide) are being developed as generic versions of 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 may be substitutable at the pharmacy in lieu of the branded product affording a potentially low cost, high market penetration generic product.

Many pharmaceutical companies continue to focus on the development of important chronic care products and therapies that can be administered only by injection. We believe that many of these injectable drugs that are currently under development may eventually be administered by self-injection once they reach the market. Our belief is supported by 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 can result in improved safety and efficacy, reduced side effects, and enhanced patient comfort and adherence.

Continuing pressures to reduce physician visit costs 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.

According to a Market Research Engine report, it is estimated that the global injectable drug delivery market will grow to $624.5 billion by 2022, representing a compounded annual growth rate of 11.5% from 2016 - 2022. 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.

See also “Our Products and Products in Development” below for additional discussion of market size and opportunities relative to the current therapeutic areas associated with our existing portfolio of products and products in development.

Our Competitive Strengths

We have a proven business model of applying our patented drug delivery injection technology to new and existing therapeutic products. We believe our key competitive strengths are our proprietary injection technologies, and our ability to form significant strategic alliances with industry-leading pharmaceutical partners to develop and commercialize proprietary and partnered products. We believe our management team has unique knowledge of, and experience in the drug/device combination product space, and in identifying new product candidates that could potentially benefit from our device technology platforms, which creates opportunities for us and potential pharmaceutical partners that look to us for our unique capabilities and know-how. Our business model for developing and commercializing proprietary and partnered products has been validated, we believe, by the successive FDA approvals of our NDAs for XYOSTED™ and OTREXUP® and our ANDA for Sumatriptan Injection USP, as well as the FDA approval of

AMAG's sNDA for the Makena® auto injector utilizing our VIBEX® QuickShot® technology and the recent FDA approval of Teva's AB-rated generic version of the EpiPen® also utilizing our VIBEX® auto injector.

Intellectual Property, Patents, Trade Secrets and Proprietary Information

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 actively seek protection for our products and proprietary information by means of U.S. and international patents and trademarks. We currently hold a portfolio of patents with expirations dates ranging from 2019 to 2036, and numerous patent applications pending in the U.S. and other countries. These patents consist primarily of design, formulation and method-of-use patents.

In addition to our patents and patent applications, trade secrets play an important role in protecting our products and technologies and provide protection beyond patents and regulatory exclusivity. We strive to preserve the confidentiality of our trade secrets, proprietary know-how and inventions by maintaining physical security of our sites and electronic security of our information technology systems. We also require all employees, contractors and third-party 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. Partners with which we have entered into development agreements have the right to certain technology developed in connection with such agreements.

Our Technology and Product Platforms

Pressure assisted auto injection is a form of parenteral drug delivery that continues to gain acceptance and demand among the medical and patient community. Encompassing a wide variety of sizes and designs, our 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, testosterone deficiency and maternal health. Our current platforms includes the VIBEX® and the VIBEX® QuickShot® disposable pressure assisted auto injection systems, disposable pen injection systems and needle-free injectors.

Disposable VIBEX® Injectors

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. We believe the key competitive advantages of the VIBEX® system include:

- Reliable subcutaneous or intramuscular injection
- Designed around conventional pre-filled syringes
- Rapid injection with ability to deliver viscous solutions
- Ease of use in emergencies
- Reduced pain

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. Our proprietary product

OTREXUP® uses the VIBEX® auto injector system for delivery of methotrexate. We also have two license agreements with Teva for our VIBEX® system, one for Teva's generic epinephrine auto injector and the other for our Sumatriptan Injection USP.

VIBEX® QuickShot® Auto Injectors

An advancement of our proprietary line of VIBEX® auto injectors is the VIBEX® QuickShot® auto injector system, which offers a dose capacity of 1 mL or greater in a compact design. VIBEX® QuickShot® is designed to enhance performance on the attributes we believe most critical to patient acceptance, which are speed, comfort and discretion. VIBEX® QuickShot® 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 less-powerful conventional auto injectors are typically unable to

deliver. Many self-injectable drugs that are currently marketed or in clinical development are of higher viscosity and are formulated to be administered in a 1 mL dose volume. Our proprietary product XYOSTED™ was developed using the VIBEX® QuickShot® auto injector platform, which is also used in the Makena® subcutaneous auto injector that we developed with our partner AMAG. We also have a license agreement with Pfizer to develop a rescue pen utilizing our VIBEX® QuickShot® auto injector system with an undisclosed Pfizer drug.

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

Needle-Free Injectors

Needle-free devices administer injectable drugs by using a spring to push the active ingredient in solution or suspension through a micro-fine opening in the needle-free syringe. A fine liquid stream then penetrates the skin, and the dose is dispersed into the layer of fatty, subcutaneous tissue. 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. However, needle-free devices may be commercially limited due to the high cost of the product and the need for consumable disposables.

On October 10, 2017, we entered into the Ferring Transaction. We will continue to manufacture and supply needle-free devices under the existing license and supply agreements until the completion of the transaction, which is expected to occur in 2019.

Our Products

The following is a discussion of our approved and marketed commercial products, including proprietary and partnered products. For a discussion of other product candidates currently in development, see “Research and Development” section below.

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. We have FDA approval for eight dosage strengths 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. According to the American Academy of Dermatology, as many as 7.5 million Americans, or approximately 2.2% of the population suffer from psoriasis.

Methotrexate is considered the first-line disease modifying anti-rheumatic drug ("DMARD") prescribed to patients with RA according to the Johns Hopkins Arthritis Center. 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.

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 3,500 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.

Medac Pharma markets and sells Rasuvo®, a subcutaneous injectable methotrexate, which is a direct competitor to OTREXUP®. Competition in the methotrexate market also 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"), Hospira and Accord Healthcare. In several European countries, Canada, and South Korea, Medac International or its licensees market methotrexate in prefilled syringes (Metoject®) and have 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, 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.

XYOSTED™ (testosterone enanthate) injection

XYOSTED™ (testosterone enanthate) injection is our proprietary product for subcutaneous administration of testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency or absence of endogenous testosterone. XYOSTED™ was approved by the FDA on September 28, 2018 and was commercially launched in November 2018. Our sales representatives started detailing XYOSTED™ to physicians in the second half of December 2018. XYOSTED™ is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration and is approved in three dosage strengths, 50 mg, 75 mg and 100 mg.

According to an IQVIA National Sales Perspectives® ("NSP") report of nationally projected sales activities, the U.S. TRT market was approximately $2.15 billion in 2018 based on wholesale acquisition costs ("WAC"). The same report showed injectable TRT grew from $339.4 million in 2017 to $357.7 million in 2018, an increase of 5.4%. There is significant competition within the TRT market among many pharmaceutical companies including Abbvie, Inc. (formerly Abbott), Lilly, Endo, Pfizer, Sandoz, Mylan and Teva. We believe that XYOSTED™ provides several potential benefits over other TRT treatments such as topical gels and other forms of injectable testosterone administered via needle and syringe in healthcare settings. These benefits include easy and virtually pain-free administration, low risk of transfer as compared to topical gels and the ability to achieve and maintain more steady levels of testosterone.

Topical formulations of TRT are frequently prescribed in the U.S. Not all men are able to adequately absorb the gel formulations or otherwise find them unacceptable for reasons including risks of transferring the gel to spouses or children, dissatisfaction with the application process, or suboptimal clinical results due to variability in exposure and compliance. Injectable testosterone is an option for men with an inadequate response to transdermal therapies.

Currently, injectable testosterone is available and represents a majority 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.

Competition in the U.S. testosterone replacement market includes topical solutions such as Abbvie's Androgel® and Androgel® 1.62%, Perrigo's generic 1.62% testosterone topical gel, Lilly's Axiron®, Endo's Fortesta® and Testim® (and the authorized generic) and Allergan plc ("Allergan") Androderm®. Other forms of TRT include injectables, such as Endo's Aveed®, Pfizer's Depo®-Testosterone, and several generic testosterones in oil products sold by Actavis, Sandoz, Mylan, Teva and others, as well as Testopel® pellets by Endo. In addition, two additional oral treatments for low testosterone levels are 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, Tlando®. Acerus Pharmaceuticals markets Natesto,™ an intra-nasal testosterone.

Sumatriptan Injection USP

We, through our partner Teva, sell Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine headaches and cluster headache in adults. 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 complete assembly and packaging of the finished 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 $4.7 billion in 2018 according to IQVIA's National Prescription Audit® ("NPA") report based on TRx Pharmacy Dollars. The majority of patients who use triptans take oral tablets. Oral drugs accounted for $3.8 billion of the total, and injectable products accounted for approximately $391 million of the total market, measured in terms of TRx Pharmacy Dollars. 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 IQVIA's NPA, about 3% 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 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.

Makena® (hydroxyprogesterone caproate injection) Subcutaneous Auto Injector

We developed a variation of our VIBEX® QuickShot® subcutaneous auto injector for use with AMAG's progestin hormone drug Makena® (hydroxyprogesterone caproate injection) under an exclusive license and development agreement. The Makena® subcutaneous auto injector drug-device combination product is a ready-to-administer treatment indicated to reduce the risk of preterm birth in women pregnant with one baby and who spontaneously delivered one preterm baby in the past. The product was approved by the FDA in February 2018. We are the exclusive supplier of the devices and the final assembled and packaged commercial product, which was launched in the U.S. for commercial sale by AMAG in March 2018.

The Makena® subcutaneous auto injector provides an alternative to the existing intramuscular methods of administration, and was designed to enhance performance based on the attributes we believe are most critical to healthcare providers and patient acceptance, including decreased time to administer and reduced pain by using a shorter, thinner nonvisible needle for subcutaneous injection. The development of the subcutaneous auto-injector was part of AMAG's broader next-generation program exploring alternative injection methods, sites and formulations.

Makena® (hydroxyprogesterone caproate) is the only FDA approved drug indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. Makena® was approved by the FDA in February 2011 as a weekly intramuscular injection, and was granted orphan drug exclusivity through February 3, 2018. The Makena® intramuscular injection is administered weekly by a healthcare professional 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.

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, which were affirmed in 2014. Preterm birth is defined as a birth prior to 37 weeks of pregnancy. According to the National Center for Health Statistics Report, in 2016, preterm births affected nearly 400,000 babies, or one of every ten infants born in the U.S. According to AMAG, revenue from Makena® was $322.0 million in 2018, and the company estimates that approximately half of all eligible patients are currently treated with Makena®. The 7-year orphan drug exclusivity expired in February 2018, and there are now two generic versions of the intramuscular formulation of Makena®.

Epinephrine Injection USP

We developed and are the exclusive supplier of the device for Teva's generic Epinephrine Injection USP products, indicated for emergency treatment of severe allergic reactions including those that are life threatening (anaphylaxis) in adults and certain pediatric patients. Teva's Epinephrine Injection, utilizing our patented VIBEX® injection technology, was approved by the FDA in August 2018 as a generic drug product with an AB rating, meaning that it is therapeutically equivalent to Mylan, Inc.'s branded products EpiPen® and EpiPen Jr® and therefore, subject to state law, substitutable at the pharmacy. We supply the device and Teva is responsible for the drug, assembly and packaging, distribution and commercialization of the finished product, for which we also receive royalties on Teva's net sales. Teva announced a limited commercial launch of its generic epinephrine product in late fourth quarter of 2018 and have indicated they expect full availability and launch of the generic EpiPen Jr in 2019.

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. Mylan's EpiPen®, along with its own authorized generic of the product, continues to be the global market leader in the epinephrine auto injector market. In December 2016, Mylan announced the availability of its lower-priced authorized generic to EpiPen®, intended to address pricing concerns of the branded version. In the U.S., sales of epinephrine injection products were approximately $1.8 billion in 2018 based on WAC, according to the IQVIA NSP report. 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 announced FDA approval of SYMJEPI,™ an epinephrine pre-filled syringe, which will be marketed and distributed in the U.S. by Sandoz Inc.

Needle-Free Injectors with hGH

Our needle-free auto injector products, including the ZOMAJET™ and Twin-Ject® II, were designed to provide a needle-free means of administering human growth hormone to patients with growth retardation. We have historically sold needle-free injection devices to partners who manufacture and/or market human growth hormone directly. These

partners then market our device together with their growth hormone. The device is reusable and designed to last for approximately 3,000 injections (or approximately two years) while the needle-free syringe included in the device is disposable after approximately one week when used by a patient for injecting from multi-dose vials.

On October 10, 2017 we entered into the Ferring Transaction. We will continue to manufacture and supply needle-free devices under existing license and supply agreements until the completion of the transaction, which is expected to occur in 2019.

Research and Development

We are committed to a strong research and development program, recognizing that the development of new product offerings is critical to our future success. Our research and development efforts are focused primarily on leveraging our existing product and technology platforms by broadening their applications for use in other drug/device combination products, as well as exploring new pharmaceutical products, technologies and drug delivery methods.

Our research and development programs consist primarily of clinical, regulatory, formulation development, engineering, device development and commercial development activities for our current products, next generation versions of current products, and new proprietary and partnered products and technologies in development. Our internal research and development team works with external consultants, industry experts, physicians and other medical personnel in an effort to drive a robust product development pipeline. We also have a business development team that actively seeks and evaluates product opportunities and business alliances. In addition, our clinical, quality and regulatory teams are committed to verifying and maintaining the safety and efficacy of our products according to regulatory standards enforced by the FDA and other international regulatory bodies. The following is a discussion of our significant research and development activities.

ATRS-1701

We are currently developing a proprietary drug device combination product for the neurology market, identified as ATRS-1701. In the fourth quarter of 2018, we conducted in man studies with two formulations of ATRS-1701 and did not achieve the optimal pharmacokinetic levels we expect to see in our products. Based on the results of the study data, we are reformulating the drug and anticipate advancing the product to clinical trials.

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 pen injector devices for use with generic versions of Forteo® (teriparatide) and BYETTA® (exenatide), and a collaboration arrangement with Pfizer for the development of a rescue pen utilizing our QuickShot® platform. 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 partnered products in development.

Disposable Pen Injector with Teriparatide

We are developing with Teva, under a license, development and supply agreement, a multi-dose disposable pen injector device with teriparatide for the treatment of osteoporosis. Teva is actively working toward a regulatory approval with the FDA for a generic version of Forteo® (teriparatide [rDNA origin] injection) using the ANDA pathway. Teva and Eli Lilly and Company (“Lilly”) settled their Paragraph IV patent litigation, the terms of which have not been disclosed. Teva also successfully completed a decentralized procedure registration process in 17 countries in Europe for teriparatide, and is awaiting patent clearance in the EU prior to launch.

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 2018 annual report on Form 10-K, 2018 global sales of Forteo® grew to $1.58 billion, of which $758.0 million was recorded in the U.S. and $818.0 million in the rest of the world.

Disposable Pen Injector with Exenatide

We are also developing with Teva a multi-dose pen injector device for use with a generic form of BYETTA® (exenatide injection) for the treatment of diabetes. Teva is working through the U.S. regulatory approval process for its exenatide pen using the ANDA pathway.

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 gross U.S. sales of BYETTA® (exenatide) by AstraZeneca in 2018 were approximately $216 million according to IQVIA NSP. BYDUREON®, a long acting form of the medication BYETTA®, had approximately $1.2 billion in gross sales in the U.S. in 2018 based on WAC, according to IQVIA NSP.

Rescue Pen (drug undisclosed)

In August 2018, we entered into a collaboration agreement with Pfizer and began developing a combination drug device rescue pen. This rescue pen will utilize the Antares QuickShot® auto injector and an undisclosed Pfizer drug. We will develop the product and Pfizer will be responsible for obtaining FDA approval of the combination product. We intend to enter into a separate supply

agreement with Pfizer pursuant to which we will provide fully packaged commercial ready finished product to Pfizer and Pfizer will then be responsible for commercializing the product in the U.S., pending FDA approval, for which the Company will receive royalties on net sales. We have begun design work, feasibility testing and Human Factor studies.

Manufacturing

We do not own any manufacturing facilities; we use third parties to manufacture our products and product candidates. To the extent that we are the sponsor of a drug/device combination product or product candidate or to the extent that we are responsible for drug and device operations with regard to products or product candidates sponsored by our partners, we must ensure that the product or product candidate is manufactured in accordance with FDA's current Good Manufacturing Practices ("cGMPs") for drug products and FDA's current Quality System Regulations ("QSRs") for medical devices and equivalent provisions in the EU and elsewhere which are required as part of the overall obligations necessary, in the EU for instance, to obtain a CE-mark . To the extent that we are only supplying the device component to one of our partners, we are responsible for compliance with QSRs. We believe that our third party manufacturers are currently in compliance with cGMPs and QSRs, to the extent applicable. Assembly and packaging of all of our products is performed by third-party service providers 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 range of third party manufacturers to manufacture and supply certain components, drugs, final assembly and finished product. Below is a summary of our production, manufacturing, assembly and packaging arrangements with third parties:

- We have contracted with 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 have contracted with Phillips-Medisize Corporation ("Phillips"), an international outsource provider of design and manufacturing services, to produce clinical and commercial quantities of our VIBEX® QuickShot® auto injector device for XYOSTED™, our VIBEX® QuickShot® device for the Makena® auto injector product with AMAG and our VIBEX® epinephrine auto injector.
- 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 and for the teriparatide and exenatide pen products with Teva.
- We have contracted with Nypro Inc. ("Nypro"), an international manufacturing development company to supply commercial quantities of our VIBEX® pressure assisted auto injector device for our OTREXUP® and VIBEX® epinephrine products.
- We have contracted with Pharmascience Inc. to supply commercial quantities of methotrexate pre-filled syringes for the U.S and Canadian markets for OTREXUP®.
- We utilize Sharp Corporation ("Sharp"), an international contract packaging company, to assemble and package OTREXUP®, XYOSTED™, Sumatriptan Injection USP, and the Makena® auto injector.
- We purchase commercial quantities of pre-filled syringes of testosterone for XYOSTED™ from Fresenius Kabi.
- We utilize various pharmaceutical companies to supply the active pharmaceutical ingredient ("API") for OTREXUP®, XYOSTED™ and Sumatriptan Injection USP.
- Our partner Teva supplies the pre-filled syringes for Sumatriptan Injection USP.

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

matters.

Sales & Marketing

We have built a robust internal commercial organization, consisting of specialty sales representatives, management and support staff, to market and sell our proprietary products OTREXUP® and XYOSTED™ in the U.S. We have entered into agreements with vendors for certain commercialization services such as third-party logistics, distribution, data analytics and claims processing. We may enter into licensing and or additional distribution arrangements for commercialization of our products outside the U.S.

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. We also utilize a division of Cardinal for sample administration. In addition, we utilize third parties to perform various other services for us relating to regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services.

Trade – We have contracted with numerous wholesale distributors, including Cardinal, McKesson Corporation ("McKesson") and Amerisource Bergen Corporation, to distribute our OTREXUP® and XYOSTED™ products to the retail pharmacies as well as the Veterans Administration and other governmental agencies. In addition to shipping our product, these distributors 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 to consumers depend to a significant degree on the availability of coverage and reimbursement by third-party payers, such as government and private insurance plans. Third-party payers 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 for our products from Medicaid, Medicare and private payers. 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 payers.

Third-party payers often utilize a tiered reimbursement system, which may adversely affect demand for our products by placing them in a more expensive patient co-payment tier. Additionally, third party payers may require step edits or prior authorization. We cannot be certain that our products will successfully be placed on the list of drugs covered by particular health plan formularies or in a more preferential position on their formularies. Third-party payers are currently demanding, and will most likely continue to demand more aggressive pricing and rebates from Antares for favorable formulary placement. 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 our products not included on these preferred drug lists, they may be subject to prior authorization. Physicians may not be inclined to prescribe OTREXUP® or XYOSTED™ to their Medicaid patients, and even if they do prescribe it, Medicaid may not authorize payment, thereby diminishing the potential market for our products in this market segment.

We offer discount card programs and co-pay assistance to patients for OTREXUP® and XYOSTED™ in which patients covered by commercial pharmacy benefit plans receive discounts on their prescriptions. Our XYOSTED™ STEADYCare Co-pay Assistance Program provides financial support to most commercially insured patients to assist with out-of-pocket costs of XYOSTED™. We utilize a contract service provider to process and pay claims to patients for actual usage.

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 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, including discounts mandated by the Veterans Health Care Act, discounted prescriptions to DoD's Tricare retail pharmacy program, 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 the 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.

Sales, Marketing & Distribution of Partnered Products

Our partnered products may encounter some of the same reimbursement issues described above, and although we do not control the reimbursement rate or discounts contracted with third-party payers by our partners, it ultimately affects our royalty payments we receive on net sales. The industry has experienced an increasingly widening gap between gross sales and net sales after discounts.

Makena® subcutaneous auto injector – Pursuant to our exclusive license, development and supply agreements with AMAG, AMAG is responsible for the commercialization and distribution of the Makena® subcutaneous auto injector. AMAG supplies the pre-filled syringe of the drug to Antares, and Antares manufactures the device and oversees the assembly and packaging of the final product, which is sold to AMAG at cost plus margin. Antares receives high single digit to low double digit royalties on net sales of the Makena® subcutaneous auto injector as well as sales based milestones. AMAG primarily sells Makena® to specialty pharmacies, specialty distributors, home infusion companies and pharmacies which, in turn, sell Makena® to healthcare providers, hospitals, government agencies and integrated delivery systems. AMAG plans to continue to offer the intramuscular formulation of Makena®.

Sumatriptan Injection USP – Under 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.

Epinephrine Injection USP – We are the exclusive supplier of the device used in Teva's epinephrine injection product. We receive payment for each device sold to Teva and royalties on Teva's commercial sales of the product. Teva's epinephrine injection was approved as a generic drug product with an AB rating, meaning that it is therapeutically equivalent to Mylan, Inc.'s branded products EpiPen® and EpiPen Jr® and therefore, subject to state law, is substitutable at the pharmacy. Teva is solely responsible for commercialization and distribution of the finished product.

Information about Revenues and Customer Concentrations

The Company derived 10% or more of its total revenue, in each of the years in the three-year period ended December 31, 2018, from the sale of its proprietary product OTREXUP® and certain partnered products. Any disruption in sales or supply of these products could have a material adverse effect on our business. For more detail, please see Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations.

Significant customers, from which the Company derived 10% or more of its total revenue in each or any of the years in the three-year period ended December 31, 2018 include: Teva, AMAG, McKesson, AmerisourceBergen and Ferring. For more detail, please refer to Note 11 – Significant Customers and Concentrations of Risk in the Notes to Consolidated Financial Statements in Part II, Item 8.

Collaborative Arrangements and License Agreements

We have entered into significant partnering arrangements and licensing agreements with Teva, AMAG, Pfizer 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 for an epinephrine auto injector product to be marketed in the U.S. and Canada. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from us. We received an upfront cash payment and a milestone payment upon FDA product approval. We also receive a negotiated purchase price for each device sold, as well as royalties on Teva's future sales of the product. This agreement has been amended to provide for payment of capital equipment and other ongoing 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 that 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, we received an upfront payment and development milestones, and may receive royalties on future

product sales. 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. 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 2035.

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. Teva is responsible for the manufacture and supply of the drug, and we are responsible for the manufacture and supply of the device and assembly and packaging of the finished 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 continues seven years from commercial launch, which was in June 2016, with automatic one-year renewals unless terminated sooner by either party in accordance with the terms of the agreement.

AMAG Agreements

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 to reduce the risk of preterm birth. 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 amounts of net sales of the product.

AMAG was responsible for the clinical development and preparation, submission and maintenance of all regulatory applications, and is responsible for the manufacture and supply of 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 AMAG's 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.

In March 2018, we entered into a manufacturing agreement with AMAG for the exclusive supply of the devices and fully assembled and packaged final finished product of the Makena® subcutaneous auto injector. The term of the agreement is concurrent with the term of the development and license agreement, and will continue until such time AMAG halts commercialization of the product. We receive a contracted price per unit on product manufactured for AMAG.

Pfizer Agreement

In August 2018, we entered into a collaboration agreement with Pfizer to jointly develop a combination drug device rescue pen. This rescue pen will utilize the Antares QuickShot® auto injector and an undisclosed Pfizer drug. Pfizer will pay us for design and development services and be responsible for obtaining FDA approval of the combination product. We intend to enter into a separate supply agreement with Pfizer pursuant to which we will provide fully packaged commercial ready finished product to Pfizer and Pfizer will then be responsible for commercializing the product in the U.S., pending FDA approval, for which the Company will receive royalties on net sales and other sales-based milestone payments.

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. This agreement will remain in effect until the completion of the Ferring Transaction, as described in Part I, Item 1. Business "Overview" section above.

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. This agreement will remain in effect until the completion of the Ferring Transaction, as described in Part I, Item 1. Business "Overview" section above.

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.

Other Agreements

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

Seasonality of Business

We do not believe seasonality has a significant impact on our business.

Competition

The pharmaceutical, medical device and biotechnology industries are intensely competitive and subject to rapid and significant technological change. 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 include established biotechnology development companies, specialty pharmaceutical companies, major brand name and generic manufacturers of pharmaceuticals such as Teva, Mylan, Lilly and Endo, as well as a wide range of medical device companies that sell a single or limited number of competitive products or participate in only a specific market segment. 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. Recent trends in the pharmaceutical industry include merger and acquisition activity leading to further market consolidation. In many cases, the resulting combined pharmaceutical companies are bigger and have more financial, technical and market strength and greater resources, which increases competitive pressure in the industry.

There is ongoing effort by public and private payers 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 continue 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, controlled substance security, export, import, storage, record keeping, safety and other reporting, sampling, advertising, marketing, 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 recalls, seizures, manufacturing shut downs, quarantines, refusal of the government to approve NDAs or ANDAs, or supplements to the same, clinical holds, injunctive actions, withdrawal of approvals, civil or criminal actions or penalties, disgorgement, adverse publicity, labeling revisions, dear healthcare provider letters, FDA debarment, exclusion from Federal healthcare programs, contract debarment or refusal of future orders under existing government contracts, consent decrees, and corporate integrity agreements. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Drug Approval Process

FDA approval of our own and our partners' products is required before the products may be commercialized in the U.S. 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 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 reference 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. The 505(b)(2) product, may have some or all of the same warnings and precautions in its label as the reference product.
- 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 pharmaceutical 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, pursuant to state laws.

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	505(b)(1) 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 a substantially complete application containing a paragraph IV certification that is lawfully maintained.	Potential for 30-month stay if ANDA or 505(b)(2) applicant citing our or our partners' product as a reference listed drug includes a paragraph IV certification.	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. Potential for 30-month stay if ANDA or 505(b)(2) applicant citing our or our partners' product as a reference listed drug includes a paragraph IV certification.
Patent Certification Required	Yes	Yes	No
Potential orphan drug designation Drug Status	No	Yes	Yes

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 a 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 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. In the case of drug product candidates for which the sponsor will seek marketing approval via a 505(b)(2) NDA application, some of the above information may be abbreviated or omitted.

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. If the FDA places a trial on clinical hold, the sponsor must address the issue to the FDA's satisfaction before the trial may begin. 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 protocols 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. Failure to submit the required information to ClinicalTrials.gov can result in monetary penalties. Investigators must also provide certain information to the clinical trial sponsors to enable sponsors to make certain financial disclosures to the FDA. 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 I trials may also be used to gain an initial indication of product effectiveness.
- Phase II - Phase II involves controlled 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.
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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 the case of 505(b)(2) NDAs, the above studies may be abbreviated. In addition to the above traditional kinds of data required for the approval of a 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 for previously approved products, and, for appropriate indications sought through supplemental marketing applications, data summaries.

In addition, under the Pediatric Research Equity Act, or PREA, a NDA or supplement to a NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the

applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

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 a 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 a NDA.

The results of drug development, pre-clinical studies and clinical trials are submitted to the FDA as part of a NDA. NDAs also must contain extensive chemistry, manufacturing and control information. In most cases, the submission of a 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 a 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. These timeframes, however, are only goals, which FDA may not meet. Moreover, 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.

The FDA may also refer drugs to advisory committees when it is determined that an advisory committee's expertise would be beneficial to the regulatory decision-making process, including the evaluation of new technology. An advisory committee is a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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 Complete Response Letter ("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. 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. A pharmaceutical company seeking to market a generic version of a branded drug must file a ANDA with the FDA. For ANDAs, applicants are not required to conduct complete clinical studies. Such applications, though, normally require bioavailability and/or bioequivalence studies. “Bioavailability” indicates the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action. “Bioequivalence” indicates that there are no significant differences in the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action, when administered at the same molar dose and under similar conditions in an appropriately designed study. Generic drug products must be bioequivalent to a drug product approved by the FDA under a NDA application, referred to as a reference listed drug. While an IND, in many cases, is not required for bioavailability and bioequivalence testing, such studies must still be conducted in accordance with Good Clinical Practices (“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, program fees and fees for 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. As part of this substantive review, the FDA will determine whether or not the generic version submitted by the company meets the necessary approval standards, including bioequivalence to the reference listed drug, adequate chemistry, manufacturing, and controls, and manufacturing facilities and clinical study sites passing pre-approval inspections. Under FDA's Generic Drug User Fee Act performance goals, the FDA has the goal of reviewing and acting on 90% of standard original ANDAs within ten months of submission. Certain factors, such as the availability of other approved drug products, certain patent certifications, and certain exclusivities, may result in an ANDA being considered to be a priority ANDA, which can result in this review time being shortened to eight months, provided that a sufficiently complete and accurate pre-submission facility correspondence is submitted to FDA two months before the ANDA submission, and information provided in this correspondence remains unchanged.

Following its completion of the review of a ANDA, the FDA will either issue an approval letter or a CRL. If a CRL is issued, the applicant may either respond to FDA, 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 applicants' CRL responses within eight or ten months, depending on whether a preapproval inspection is required. This timeframe may be shortened to six or eight months, respectively, for priority responses and provided that certain criteria are met. Even with the applicant's 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.

Upon approval, the FDA will rate generic drug products in the Orange Book. Products meeting bioequivalence standards will typically receive an AB rating. Under state law, such generic drug products may be able to be substituted at the pharmacy for the brand-name drug, without the intervention of the prescribing physician, unless otherwise specified by the patient or physician, Many third party payers of prescription drugs (e.g., health insurance plans, Medicare and Medicaid programs) have adopted policies to encourage the substitution of the lower-priced AB-rated generic drugs for the higher-priced branded drugs, when an AB-rated generic drug is available, as generic drugs are sold generally at prices below those of the corresponding branded products. Generic drugs may provide a cost-effective alternative for consumers, while maintaining the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as the branded product.

Generally Applicable Requirements

Clinical trials for all product candidates must be conducted in accordance with GCPs, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial as well as review and approval of the study by an IRB. 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 U.S. are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the U.S. 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.

The Hatch-Waxman Amendments, Regulatory Exclusivity, and Patent Term Extension

Orange Book Patent Listing

When a 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 or method of use with the FDA. Upon approval of a 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 or 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 a 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 or modified versions of the original, unmodified drug product. Instead, three year exclusivity prohibits the FDA making the approval of 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 effective. 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. An ANDA for a product designated as competitive generic therapy that does not otherwise have patent or exclusivity protections listed in the Orange Book and that is the first approved applicant, is also eligible for a period of 180 days of regulatory exclusivity with respect to other ANDAs.

These ANDA exclusivity periods, however, can be lost under certain circumstances. Competitive generic therapies are products for which there is not more than one approved drug included in the Orange Book.

Pediatric exclusivity is another type of non patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory and statutory exclusivity for NDA products, including the non patent exclusivity period described above and patent protections. This six month exclusivity may be granted if a NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the required time frames, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. Moreover, pediatric exclusivity attaches to all formulations, dosage forms, and indications for products with existing marketing exclusivity or patent life that contain the same active moiety as that which was studied.

If approved, drug products may also be eligible for periods of U.S. patent term restoration. If granted, patent term restoration extends the patent life of a single unexpired patent, that has not previously been extended, for a maximum of five years. The total patent life of the product with the extension also cannot exceed fourteen years from the product' approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a marketing application, and all of the time between the submission of the marketing application and its approval. This period may be reduced by any time that the applicant did not act with due diligence. Whether any of our product candidates will be eligible for patent term restoration is currently unknown. Later, the applicable regulatory authorities may determine that we are not eligible for such restoration periods.

Depending on the drug product, other periods of regulatory exclusivity, such as orphan drug product exclusivity, may also block subsequent applicants.

Orphan Drug Designation

Some jurisdictions, including the U.S., 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 U.S., or affecting more than 200,000 in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. will be recovered from U.S. sales. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a product already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same as the already approved product. This plausible hypothesis must be demonstrated to receive orphan exclusivity. This hypothesis must be demonstrated to obtain orphan exclusivity. Orphan drug designation provides certain benefits, such as the opportunity for grants, tax credits, application user fee waivers, and exemption from program user fees under certain circumstances. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. 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. FDA may, however, approve a product with the same principal molecular features for the same orphan indication during this time period, if such product is able to demonstrate clinical superiority. Orphan exclusivity can also be lost under certain circumstances, such as the inability of the application holder to ensure sufficient quantities of the product. Orphan drugs are also exempt from the above discussed PREA requirements.

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. To date, our and our partners’ combination products have been regulated as 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”). MAF is not an FDA approval submission, but is a filing that can be used to provide supporting data for our partners’ drug approval submissions. A MAF will be reviewed by the FDA only when referenced in an approval submission. By filing a MAF, we are able to provide information directly to the FDA, which can then be referenced by our partners in their drug approval submissions, without having to share our proprietary information directly with our partners.

Where common data elements may be part of several submissions for regulatory approval, as in the case of information supporting an injection system, a MAF filing with the FDA may be the preferred route. A delivery device that is applicable to a variety of drug/device combination products, represents another opportunity for such a filing. Another option would be to obtain a 510(k) premarket clearance from FDA for our delivery device as a stand-alone product. 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 specific drug likely will be handled as part of the marketing application for the drug product, which may be a NDA, ANDA, or supplemental application. Under these circumstances, the device component is only approved if the drug component is approved.

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 and other reporting requirements, and all of the restrictions that apply to drug labeling and advertising. Additionally, such products will also be subject to certain device requirements, including QSRs and certain device reporting requirements. These requirements necessitate additional expenditures of time and resources, which 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. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register and, in the case of generic drug products, self-identify their establishments with the FDA and certain state agencies and list their drug products. Device manufacturers must also register their facilities and list the devices that they design, develop, manufacture, or import, except those subject to a drug approval. These facilities must also pay annual registration fees. 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 and devices, 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, Untitled 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 and QSR requirements. The FDA conducts pre-approval inspections of facilities engaged in the development, design, import, manufacture, processing, packing, testing and holding of the drugs and devices 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. Moreover, depending on the violation, the FDA could take more significant enforcement actions as a result of inspectional findings. Any of the foregoing 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, depending on the controlled substance Schedule, 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 product XYOSTED™, testosterone, is listed by the DEA as a Schedule III substance under the CSA. Consequently, XYOSTED™ is 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 procedure, the decentralized procedure and the mutual recognition 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 an 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 93/42/EC (to be replaced in 2020 by the EU Medical Devices Regulation 2017/745), 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 U.S., 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, directly or indirectly, in cash or in kind, 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, except for activities protected by narrowly-drawn statutory and regulatory safe harbors. 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, and a violation of the anti-kickback statute may be grounds for a government or whistleblower claim under the federal False Claims Act. 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 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. Claims may be pursued by whistleblowers through qui tam actions, even if the government declines to intervene. Intent to deceive is not necessary to establish civil liability, which may be predicated on reckless disregard for the truth. The civil False Claims Act authorizes imposition of treble damages and a civil penalty for each false claim, such as an invoice, submitted for payment and may result in significant financial penalties and damages. The criminal federal False Claims Act 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. Conviction or civil judgment for violation of the False Claims Act can also result in debarment from government contracting and exclusion from participation in federal healthcare programs.

Various federal and state 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. States, such as California, have also enacted transparency laws that require manufacturers to report price increases and related information. Some government health care programs impose penalties if drug price increases exceed specified percentages or inflation rates, and these penalties can result in mandatory penny prices for certain federal and 340B program customers. 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 payer. 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, some states require pharmaceutical companies to implement compliance programs or marketing codes of conduct.

Although we may not provide 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.

Federal price reporting laws require manufacturers to calculate and report complex pricing metrics used to determine prescription rebates paid under the Medicaid Drug Rebate Program and amounts reimbursed pharmacies and other providers by the Medicaid and Medicare programs. Payment for a manufacturer’s drugs by these programs is conditioned on submission of this pricing information. Failure to report accurate pricing information may result in criminal, civil, or administrative sanctions or enforcement actions.

The Veterans Health Care Act of 1992 requires, as a condition of payment by certain federal agencies and the Medicaid program, that manufacturers of “covered drugs” enter into a Master Agreement and Federal Supply Schedule (FSS) 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 the VA and Department of Defense. FSS contracts

require compliance with applicable federal procurement laws and regulations, including disclosure of commercial prices during contract negotiations and maintenance of price relationships during the term of the contract, and subject manufacturers to contractual remedies as well as administrative, civil, and criminal sanctions. The Veterans Health Care Act 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 (derived from the Medicaid rebate percentage) to covered entities participating in the 340B drug discount program. Failure to provide the mandatory discount may subject the manufacturer to specific civil monetary penalties. Termination of either of these agreements also jeopardizes payment by Medicaid for the manufacturer's drugs.

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, expanded healthcare coverage within the U.S., primarily through establishment of state insurance exchanges and expansion of the Medicaid program. This law substantially changed 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, payment of an annual fee by

manufacturers of branded drugs and biological products based on their share of the federal market, 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. The Affordable Care Act has since been amended to repeal the individual health insurance mandate and increase manufacturers’ share of Medicare Part D prescription costs in the donut hole, and other provisions of the law may be repealed and replaced by Congress, which may greatly affect these government and third-party programs and their effect on our business.

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. One such statute is the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations. HIPAA 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.

The Foreign Corrupt Practices Act (“FCPA”) further prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the U.S., can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

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. In particular, in the EU the data privacy regime is regarded as stricter than in the US and the coming into force of the General Data Protection Regulation on 25 May 2018 is in broad terms more restrictive than the current EU data protection laws. EU laws restrict the export of personal data outside the EU, for instance to the US, unless certain safeguards are in place.

Third-Party Payer Coverage and Reimbursement

The commercial success of the approved products in our portfolio depends, in part, upon the availability of coverage and adequate reimbursement from third-party payers 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 payers 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 payers. The market for our product portfolio will depend significantly on access to third-party payers' formularies, or lists of treatments for which third-party payers provide coverage and reimbursement.

Also, third-party payers are developing increasingly sophisticated methods of controlling healthcare costs. For example, for high cost specialty drugs, third party payers have begun demanding value-based pricing in which price is linked to performance metrics. Further, coverage and reimbursement for therapeutic products can differ significantly from payer to payer. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer 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 payer 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 payer policies as well as healthcare legislative and administrative reforms.

Some third-party payers 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, there are health technology assessment regimes with price ceilings and supply and demand side restraints on specific products and therapies and profit controls in certain countries including the UK. 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 payers, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Reform

In the U.S. 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 U.S. 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 U.S.. 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, the following:

- 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;

Since enactment of the ACA, some of its provisions have been repealed or amended, and other provisions may be repealed and replaced by Congress.

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, are 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 is 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. Legislators and regulators at both the federal and state level are increasingly focused on containing the cost of drugs, and there has been increasing legislative

and enforcement interest in the U.S. 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, California recently enacted a transparency law requiring manufacturers to report drug price increases and related information, and CMS reduced the payment rate for certain hospitals purchasing outpatient drugs at the 340B program discounted price. In 2016, CMS issued a final rule regarding the Medicaid drug rebate program, which 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. However, certain aspects of the proposed rule have yet to be finalized. Similarly, 340B program regulations on civil monetary penalties for statutory violations, which had been finalized in early 2017, went into effect in 2018. In October 2018, CMS issued an advance notice of proposed rulemaking paving the way for a proposed rule in 2019 that would significantly reduce the price of drugs paid by Medicare Part B by basing reimbursement on the average prices among other industrialized countries, and in January 2019, CMS proposed eliminating the Anti-Kickback Act safe harbor for rebates typically provided to PBMs and health plans that are included in their cost effectiveness determinations. These and 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.

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. We were incorporated as a Delaware corporation on April 29, 2005.

Segment and Geographic Information

We have a single reportable operating segment, 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.

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, 2019, we had 165 full-time employees. Of the 165 employees, 44 are primarily involved in research, development and

manufacturing activities, 102 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 U.S. 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 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 $6.5 million, $16.7 million and $24.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. In addition, we had an accumulated deficit at December 31, 2018 of $276.8 million. 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, 2018, we had cash and cash equivalents of $27.9 million. 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 2020. 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 through equity and debt financing arrangements. We reported net losses of $6.5 million, $16.7 million and $24.3 million, and negative cash flows from operations for each of the years ended December 31, and 2018, 2017 and 2016, respectively. To the extent additional financing is needed, the failure to raise necessary cash may require the Company to defer or delay spending for research and development, or cause us to curtail other controllable costs and discretionary spending.

We have funded our operations with proceeds from borrowings under a long-term debt financing arrangement. On June 6, 2017 we entered into a loan and security agreement with Hercules Capital, Inc. for a term loan of $25.0 million. Payments under the loan are interest only until the first principal payment is due on August 1, 2019. The loan is secured by substantially all of the Company's assets, excluding intellectual property, and will mature on July 1, 2022.

We have also funded operations with proceeds from sales of our common stock through an "at the market offering" (the "ATM"), under which we may raise up to $30.0 million. As of December 31, 2018, we had generated $7.6 million in gross proceeds from the sale of 2.1 million shares of common stock.

If we do obtain additional financing or sell additional shares under the ATM, 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 commercialize, market and sell XYOSTED™ and OTREXUP®;
- the success of our partners in commercializing and selling products such as AMAG's Makena® auto injector, Teva's generic epinephrine injection, and our product Sumatriptan Injection USP;
- our ability to successfully develop and receive marketing approval for any product candidates;
- our and our partners' ability to successfully develop and obtain regulatory approval, and where applicable to obtain an AB-rating, of partnered products including multi dose pens for use with exenatide and teriparatide, a rescue pen and others;

- 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 and success 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;
- product and 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 have significant outstanding indebtedness under a loan and security agreement. If we do not have sufficient cash available to repay the outstanding indebtedness as it becomes due, or if an event of default were to occur providing Hercules Capital, Inc. the right to accelerate the outstanding balance of the loan and to take possession of some or all of our collateral securing the loan, either situation could have a materially adverse effect on our business.

We entered into a loan and security agreement, referred to herein as the Hercules Loan Agreement, with Hercules Capital, Inc., or Hercules, for a term loan, of $25.0 million, which was funded to us upon the execution of the loan agreement on June 6, 2017. Proceeds from the loan have been and will be used for working capital and general corporate purposes. The term loan accrues interest at a calculated prime-based variable rate with a maximum interest rate of 9.50% and requires the payment of an additional end of term charge equal to 4.25% of the total principal amount of all advances under the loan. The Hercules Loan Agreement requires payments of interest only until the first principal payment is due on August 1, 2019. The loan is secured by substantially all of the Company's assets, excluding intellectual property, and will mature on July 1, 2022.

The Hercules Loan Agreement contains customary affirmative and restrictive covenants and representations and warranties, including financial reporting obligations and limitations on dividends, indebtedness, liens, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. Our business may be adversely affected by the restrictions on our ability to operate our business. The Hercules Loan Agreement also contains other customary provisions, such as expense reimbursement, non-disclosure obligations, as well as indemnification rights for the benefit of the lenders. Upon the occurrence of an event of default and following any applicable cure periods, if any, a default interest rate of an additional 4.00% may be applied to the outstanding loan balances, and the lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Hercules Loan Agreement.

Additionally, we may be required to repay the outstanding indebtedness plus penalties immediately under the term loan if an event of default occurs under the Hercules Loan Agreement. Under the Hercules Loan Agreement, an event of default will occur if, among other things, we fail to make payments as required under the Hercules Loan Agreement, we breach or default in the performance of any covenant or secured obligation under the Hercules Loan Agreement, a circumstance occurs that would reasonably be expected to have a material adverse effect on the Company, we become unable to pay our debts as they come due or are otherwise insolvent, we or our assets become subject to certain legal proceedings such as bankruptcy proceedings, a cross default to other indebtedness obligations of the Company in excess of $500,000, or a stop order is issued with respect to our common stock.

We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce

or terminate our product candidate development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Hercules could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes all of our property other than our intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

We have limited sales and marketing experience and limited experience working with payers on coverage issues, and we can provide no assurance on the successful launch and commercialization of our products.

The launch and successful commercialization of a new product requires substantial dedication of financial and other resources and include steps related to manufacturing, logistics, sales and marketing, and establishing insurance coverage and reimbursement. We launched OTREXUP® in February 2014, and XYOSTED™ in November 2018. Although we have hired and expect to continue to hire highly qualified personnel with specialized expertise, as a company, we have limited experience commercializing pharmaceutical products on our own. In order to commercialize our products, we have built and expect to continue to build our sales, marketing, distribution, managerial and other non-technical capabilities and have made and expect to continue to make arrangements with third parties to perform these services when needed.

If we are unable to successfully implement our sales and marketing plans and drive adoption by patients and physicians of our products through our sales, marketing and commercialization efforts, then we may not be able to generate sustainable revenue growth 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 and medical affairs. Developing and enhancing our commercial capabilities to market our products has been and will continue to be expensive and time-consuming. As we continue to develop, maintain and grow 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 our drug products may be adversely affected.

There is no guarantee that patients and healthcare providers will adopt our or our partners' products, and that we and our partners will be able to receive adequate payer coverage and reimbursement. New information concerning our or our partners' products learned through required post-approval studies and product use may also result in changes to our or our partners' products. Should any of these events occur, they could have a material and adverse effect on our operations and business.

There is no guarantee that patients and healthcare providers will adopt any newly approved products, or that insurers will provide adequate coverage and reimbursement, or will not disadvantage our products through imposition of prior authorization, step therapy, high co-payments, or similar formulary management techniques. Any labeled limitations on the use of a product or warnings could discourage adoption of the product by patients, healthcare providers, and insurers.

Moreover, we and our partners may experience a delay in receiving coverage and reimbursement for any new products or may not receive adequate levels of coverage or reimbursement at all. By way of example, we are in the process of obtaining payer coverage for our recently approved testosterone replacement treatment product, XYOSTED™. The process for obtaining payer coverage is time consuming and uncertain. If the time to obtain coverage is lengthy, or if we are unable to obtain adequate coverage or if the rebates we negotiate are higher than anticipated, it may negatively impact our revenue from product sales.

Additionally, if patients and healthcare providers do not adopt any new product, or if insurers restrict patient access or disadvantage our or our partners' products in their formularies or otherwise do not provide adequate coverage and reimbursement, we and our partners may not be able to generate sustainable revenue growth from product sales and royalties which will have a material adverse effect on our business and future product opportunities.

Product labeling restrictions and warnings may also discourage payers from providing adequate levels of coverage and reimbursement. We and our partners, accordingly, may need to take steps to assist patients to afford our products, such as offering bridge programs, free-trial, discounts, rebates and co-pay coupon programs. These programs, however, may not ultimately be successful.

Any post-approval requirements, including phase IV studies and Risk Evaluation and Mitigation Strategies, or REMS, may also require the dedication of substantial time and resources. By example, as a post-marketing requirement for XYOSTED™, the FDA has asked us to conduct a label comprehension study that assesses patients' understanding of key risk messages in the Medication Guide for XYOSTED™ and a study of testosterone replacement therapy in pediatric males ages 14 years and older for conditions associated with a deficiency or absence of endogenous testosterone. The label comprehension study findings may result in revisions to the Medication Guide to optimize patients' understanding of important risks of XYOSTED™ and potentially other label restrictions or changes. Additionally, the outcome of any post-approval studies, including the pediatric study, is uncertain and may not result in an expanded label indication or could result in additional labeling requirements or other post-approval restrictions or regulatory actions.

The label comprehension study must be completed by 2020 and the pediatric study by the end of 2026. The conduct of these studies will require dedication of funds and resources.

Additionally, use of our or our partners' products by patients and in phase IV and post-marketing studies may result in the discovery of new information concerning the products. By example, the products may be found to be less effective than initially demonstrated, or new, more severe, or more frequent adverse events or side effects may be reported. This may result in regulatory or other actions, including, product liability actions, enforcement actions, distribution and manufacturing restrictions, changes to product labeling and promotional materials, the imposition of post-market requirements, such as REMS or additional phase IV studies, withdrawal of marketing application approvals, withdrawal of the product from the market, refusal to approve new marketing applications or supplements, product recalls, clinical holds and suspension of clinical studies, safety alerts, dear healthcare provider letters, adverse publicity, and reimbursement and insurance coverage consequences, among others. Should any of these events occur, they could have a material and adverse effect on our operations and business.

If we or our partners are unable to achieve and maintain adequate levels of coverage and reimbursement for our or our partners' products or any of our or our partners' future products for which we or our partners receive regulatory approval, their commercial success may be severely hindered.

Successful sales of our products, such as OTREXUP® and XYOSTED™, depend on the availability of adequate coverage and reimbursement from third-party payers. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers 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 payers 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 payers' drug formularies, or lists of medications for which third-party payers provide coverage and reimbursement. Health plans often use tiered formularies that prefer one branded product in a therapeutic class over another through different patient co-payment amounts, and disadvantaging some products through techniques such as step therapy and prior authorization. Many states use formularies and preferred drug lists to obtain supplemental Medicaid rebates in excess of those required for Medicaid coverage. The industry competition to be included in such formularies and not disadvantaged often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers 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. Additionally, certain third-party payers restrict or block access to patients for new products until a clinical review has occurred or clinical evidence is provided to support the benefits for covered patients. These restrictions may be imposed for months or longer and some third-party payers may refuse to add new products to their formularies or otherwise restrict patient access. To ensure sales, manufacturers often must provide multiple discounts on the same drug in the chain of distribution to the health care provider and the payer. Further, manufacturers are required to assume responsibility for Medicare Part D prescription costs for innovator drugs and biologics and authorized generics while the beneficiary is in the coverage gap. Increasingly, payers are looking for metrics and performance-based pricing to justify increased cost of therapeutic advancements. Even if coverage is obtained, the net realization from price concessions may negatively impact our profitability. Government health programs also impose inflation penalties which may have adverse consequences if

we increase prices in the future.

Our partnered products encounter similar issues in obtaining reimbursement from third-party payers. While we are unable to control the reimbursement rate or discounts contracted with third-party payers by our partners, these rates ultimately affect our profit sharing on Sumatriptan Injection USP and royalties on products such as the Makena® Subcutaneous Auto-Injector and the Teva epinephrine auto injector.

Third-party payers, 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 payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer.

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®, XYOSTED™ or any of our other products or product candidates for which we may receive regulatory approval may not be available or adequate in either the U.S. or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

The sale of XYOSTED™ and OTREXUP® requires significant resources, and if we do not achieve the sales expected, we may lose the substantial investment we have made in these products.

We have and expect to continue to devote substantial resources to establish and maintain a sales and marketing capability for XYOSTED™ and OTREXUP®. If we are unsuccessful in our commercialization efforts and do not achieve the sales levels 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 may not receive the final payment under our asset purchase agreement with Ferring, and we may be obligated to refund a portion of the purchase price to Ferring if the transaction is not completed as anticipated.

On October 10, 2017, we entered into an asset purchase agreement with Ferring to sell the worldwide rights, including certain assets, related to the needle-free auto injector device product line (previously defined as the "Ferring Transaction"). Pursuant to the asset purchase agreement, the purchase price for the purchased assets is to be paid to us by Ferring in four installments aggregating to $15.25 million (less a $750,000 credit for use of the purchased assets by us through the completion date). Only the final installment of $5.25 million (less one third of the credit noted above) has not been paid to us. A condition precedent to Ferring's obligation to make the final payment under the asset purchase agreement is the transfer to Ferring of the CE Mark, a certification indicating that a product has met EU consumer safety, health or environmental requirements. The transfer of the CE Mark has not been completed, in part due to regulatory delays caused by the withdrawal of the United Kingdom from the EU. The asset purchase agreement provides that, if the Ferring Transaction is not completed on or prior to October 10, 2019, then either we or Ferring may terminate the asset purchase agreement upon written notice to the other party. The asset purchase agreement also provides that, if the applicable EU regulatory authority issues a notice of withdrawal of the CE Mark as of October 10, 2017 (other than as a result of actions by Ferring not contemplated by the asset purchase agreement), then Ferring may terminate the asset purchase agreement upon written notice to us. Although we anticipate that the Ferring Transaction will be completed within the timeframe described above, it is possible that the conditions precedent to Ferring's obligation to make the final payment may not be satisfied, or that the applicable EU regulatory authority will issue a notice of withdrawal of the CE Mark as of October 10, 2017, and that the Ferring Transaction may not be completed. If the asset purchase agreement is terminated due to the failure of the conditions precedent to Ferring's obligation to make the final payment to be satisfied on or prior to October 10, 2019, we will be required to return $7.5 million in payments made by Ferring ($9.5 million if the termination is due to the withdrawal of the CE Mark by the applicable EU regulatory authority or the failure of the Ferring Transaction to be completed because of our uncured material breach of any covenant or agreement in the asset purchase agreement) and Ferring will be required to return to us all purchased assets we transferred to Ferring. Termination of the transaction would result in the reversal of the gain on sale of assets previously recognized in the consolidated financial statements and negatively impact the Company's results from operations in the period in which the termination may occur.

We rely on third parties to perform many necessary services for XYOSTED™ and 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, sample administration 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 also rely on third parties to administer our drug price reporting and rebate payments, and contracting obligations under federal programs; however, we are responsible

for compliance with the program requirements. 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 regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If our employees or any third-party service providers fail to comply with applicable laws and regulations, we and/or they may face regulatory or False Claims Act enforcement action. Moreover, 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.

Our employees, independent contractors, consultants, commercial partners, manufacturers, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or contract research organizations ("CROs") could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act ("FCA") case against us based on the actions or inactions of these third parties even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

We rely on third parties to manufacture our and our partners' products. If we do not develop and maintain relationships with manufacturers and/or assemblers of our and our partners' drug/device products or product candidates, or if such third parties are unable to manufacture or supply product, or assemble and package the final products, we may be unable to successfully manufacture, assemble, package and sell our and our partners' products, which could have a material adverse effect on our business.

We do not possess the facilities to manufacture commercial quantities of our or our partners' drug/device combination products or components, including OTREXUP®, XYOSTED™, VIBEX® Sumatriptan Injection USP, epinephrine auto-injector devices, Makena® auto injectors or any other of our or our partners' products or product candidates. We also do not possess the facilities to manufacture clinical supplies of any product candidates or components. We must contract with third parties and/or our partners to produce products, components, and product candidates and to assemble and package products and components according to specifications and government regulations. The future development and delivery of our and our partners' products and product candidates depends on the capability, timely, profitable and competitive performance of these third parties and/or our partners. There is also no assurance that such third parties and/or our partners will be willing to manufacture, assemble or sell the drug/device products or components. A limited number of manufacturers exist that are capable of manufacturing our and our partners' products, components, and product candidates. We and our partners may fail to contract with the necessary third parties or we and our partners may contract with third parties on terms that may not be favorable to us.

Our and our partners' contract manufacturers must comply with all applicable manufacturing requirements, including cGMPs for drug products and QSRs for medical devices. Before approving any marketing application, FDA will inspect the product manufacturing facilities. We and/or our partners must obtain FDA approval for a product's or product candidate's manufacturing process and facilities to receive product marketing approval, which we and/or our partners may never obtain or may not be able to maintain. Moreover, following product approval, FDA regularly also inspects drug and device manufacturers to ensure continued compliance with FDA's requirements and requires reporting certain manufacturing issues. If we or our partners are not able to obtain or maintain this approval and

regulatory compliance, 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 manufacturer may face regulatory consequences, including enforcement actions and/or product recalls. Additionally, use of third-party 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. Failure by a contract manufacturer to supply product, could have a material adverse effect on our ability to generate revenue and profit.

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 or device 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 or device master file. If the contract manufacturer fails to maintain a drug or device 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 in the event

a contract manufacturer is no longer available to us. We may also be required to gather data and conduct studies and analyses to support the use of a new manufacturer or manufacturing process.

We rely on multiple commercial supply arrangements with third-party manufacturers for, including, without limitation:

- the production and supply of the methotrexate, sumatriptan and testosterone drug substance in pre-filled syringes;
- the manufacture of prefillable syringes;
- the manufacture of device components;
- the manufacture and partial assembly of VIBEX® and Quickshot 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 and management of manufacturing staff;
- the possible breach of the manufacturing agreement or purchase orders 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 or purchase orders 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. To the extent that a contract manufacturer cannot deliver adequate quantities of clinical supplies that meet the applicable quality standards, our or our partners' product development efforts may be delayed. To the extent that a contract manufacturer cannot deliver adequate quantities of commercial products that meet the applicable quality standards, our or our partners' commercialization efforts would be inhibited and as a result our revenue and profit may be adversely impacted. 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. Departures from the applicable quality standards can also necessitate product recalls. 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. We may also be required to replace manufacturers, which would be time consuming and expensive, and we may not be able to reach favorable agreements with or FDA approval for alternative manufacturers. 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 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 depend on Teva to manufacture the drug and finished packaged product and to distribute and commercialize the epinephrine auto-injector in the U.S.

We have entered into a license, development and supply agreement with Teva, pursuant to which we developed and are the exclusive supplier of the device for an epinephrine auto injector product marketed by Teva in the U.S. Teva's generic epinephrine injection was approved by the FDA in August 2018 and launched in limited quantities in late fourth quarter of 2018.

There is no guarantee that our partnership with Teva will be successful. Teva controls the manufacture and supply of the drug, epinephrine, and the final assembly of the devices and packaging of the finished product, and has complete control over the launch

and continuous commercialization and sale of the epinephrine auto injector product. If, at any time, Teva ceases to manufacture and supply the epinephrine drug or fails to produce sufficient supplies of the drug, Teva will be unable to produce a finished product and we may be unable to sell our auto injectors for this product to Teva resulting in less revenue for us.

In addition, if Teva is unable to complete the final assembly and packaging of the finished epinephrine auto injector product, we may receive less revenue than desired or expected. If Teva is unable to produce sufficient supplies of the drug or finished epinephrine auto injector product in accordance with the applicable manufacturing requirements or otherwise fails to comply with applicable regulatory requirements, Teva may be subject to regulatory enforcement action, which could impact its ability to produce, market, commercialize, sell, and distribute the finished drug product, and in turn, our revenue. We rely on Teva to commercialize and distribute the product, including determining the price and payer coverage. If Teva is unsuccessful in commercializing the product, the resulting revenue may be lower than expected. Additionally, Teva controls the business strategy, manufacturing and distribution decisions concerning the epinephrine auto injector product. Such decisions by Teva may be beyond our control and may impact the success of the epinephrine auto injector product. As a result, we may receive less revenue than desired or expected. Further, Teva is subject to potential competition regarding other generic versions of the epinephrine auto injector product, and such additional competition could result in receiving less revenue than expected.

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 are responsible for 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 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. Moreover, because we hold the FDA approved application for this product, we are responsible for FDA regulatory compliance. Should Teva fail to comply with the applicable regulatory requirements, they or we may be subject to regulatory enforcement action. Any enforcement action could impact the ability to produce, market, commercialize, sell, and distribute the finished drug product, and in turn, our revenue. 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.

We depend on AMAG to manufacture and supply the drug and distribute and commercialize a variation of our VIBEX® QuickShot® subcutaneous auto injector for use with AMAG's progestin hormone drug Makena® worldwide.

We have entered into a license, development and supply agreement with AMAG to distribute a variation of our VIBEX® QuickShot® subcutaneous auto injector for use with AMAG's progestin hormone drug Makena®, the

Makena® Auto Injector. AMAG launched the Makena® Subcutaneous Auto Injector in March 2018.

There is no guarantee that our partnership with AMAG will be successful. AMAG controls the manufacture and supply of the drug, hydroxyprogesterone caproate, and has complete control over the launch and continuous commercialization and marketing of Makena® Auto Injector worldwide. If, at any time, AMAG ceases to manufacture and supply us with hydroxyprogesterone caproate or fails to produce sufficient supplies of the drug, we will be unable to produce a finished product or sell our auto injectors for this product to AMAG. In addition, if AMAG is unable to produce sufficient supplies of the drug in accordance with cGMPs or otherwise fails to comply with the applicable regulatory requirements, we also will be unable to produce a finished product and/or we and/or AMAG may be subject to regulatory enforcement action, which would impact the ability to produce, market, commercialize, sell, and distribute the finished drug product, and in turn, our revenue. We rely on AMAG to commercialize and distribute the product worldwide and if AMAG is unsuccessful in commercializing the product, the resulting revenue may be lower than expected. Additionally, we may disagree with AMAG on certain business strategies or its manufacturing and distribution decisions. Such decisions by AMAG may be beyond our control and may impact the success of the Makena® Auto Injector and we may receive less revenue than desired or expected.

We are also relying on AMAG to convert patients from using the current intramuscular formulation of Makena® to the subcutaneous formulation of Makena®. However, such decisions will be made by AMAG and may be beyond our control, which could impact the sales of the product and we may receive less revenue than desired or expected. Further, we and AMAG are subject to competition for generic versions of the intramuscular formulation of the drug, which is less costly for patients. This competition could result in more patients utilizing the intramuscular formulation rather than the subcutaneous auto injector, thus resulting in us receiving potentially less revenue than expected.

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 raw materials, components, 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 XYOSTED™, OTREXUP®, Sumatriptan Injection USP, generic epinephrine injection devices, the Makena® subcutaneous auto injector and other partnered products:

- The suppliers of the active pharmaceutical ingredient ("API") for methotrexate and testosterone;
- Pharmascience for supply of commercial quantities of methotrexate pre-filled syringes;
- Fresenius for the supply of commercial quantities of testosterone pre-filled syringes;
- Nypro for the supply of commercial quantities of the VIBEX® auto injectors for OTREXUP® and certain epinephrine injection devices;
- ComDel for the supply of commercial quantities of the VIBEX® auto injectors for Sumatriptan Injection USP;
- Teva for the supply of commercial quantities of the pre-filled syringes for Sumatriptan Injection USP;
- Phillips for the supply of commercial quantities of the VIBEX® QuickShot® device for XYOSTED™ and the Makena® subcutaneous auto injector product;
- Minnesota Rubber and Plastics ("MRP") for the manufacture and assembly of needle-free devices and certain related disposable component parts for Ferring;
- Sharp for assembly and packaging of XYOSTED™, OTREXUP®, Sumatriptan Injection USP and Makena® subcutaneous auto injector; and
- Cardinal for services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management for XYOSTED™ and OTREXUP®.

If any of these or other third parties are unable to supply its respective component for any reason, including due to violations of the FDA's QSR or cGMP requirements, our or our partners' ability to manufacture the finished product will be adversely affected and our ability to meet the distribution requirements for any product sales of such products and the resulting revenue therefrom will be negatively affected. We and our partners could also face enforcement actions or may need to engage in recalls due to issues with component suppliers. 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 our 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 or of 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 do not develop and maintain relationships with manufacturers of our device products, then we may be unable to successfully manufacture and sell our products.

Manufacturing of our needle-free device involves the assembly of products from machined stainless steel and composite components in limited quantities. Manufacturing of our VIBEX® auto injector devices for OTREXUP®, Sumatriptan Injection USP

and Epinephrine Auto Injectors, and the manufacturing of our Vibex® QuickShot® auto injector for Makena® and XYOSTED™, involves high volume production of numerous complex parts as well as assembly of those parts. The manufacture of our device products must also comply with applicable regulatory requirements. To the extent that manufacturers do not comply with the applicable regulatory requirements, we, they, or our partners may be subject to regulatory enforcement action or may need to undertake recalls.

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, validation and qualification, 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, Phillips and ComDel to manufacture our auto injector devices. Any failure by our contract manufacturers 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 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 needle-free devices and certain related disposable component parts on our behalf that we sell to our partners Ferring and JCR. There can be no assurance that MRP will be able to continue to meet regulatory requirements or our own quality control standards. Therefore, there can be no assurance that we will be able to continue to successfully produce, manufacture and sell the needle-free products to our partners Ferring and JCR.

Our pharmaceutical partners retain the right to audit the quality systems of our manufacturing partner, and there can be no assurance that our manufacturers 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 products to third parties. Such products may 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.

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. Moreover, to the extent that manufacturers do not comply with the applicable regulatory requirements, we, they, or our partners may be subject to regulatory enforcement action.

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, or otherwise promoted or marketed approved products in a manner that is inconsistent with FDA's requirements.

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 or other foreign regulatory agencies. 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. As the sponsor of FDA approved products, we and our partners will not only be responsible for the actions of the companies but also can be held liable for the actions of employees and contractors, requiring that all employees and contractors engaging in regulated functions, such as product promotion, be adequately trained and monitored, which requires time and monetary expenditures.

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, consent decrees, corporate integrity agreements, 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.

Moreover, in addition to the regulatory restrictions on off-label promotion, there are other FDA restrictions on and requirements concerning product promotion and advertising, such as requirements that such communications be truthful and non-misleading and adequately supported. FDA also has requirements concerning the distribution of drug samples. In the event that 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 other regulators may take the position that we are not in compliance with promotional, advertising, and marketing requirements, and, if such non-compliance is proven, we may be subject to significant liability, including administrative, civil and criminal penalties and fines, in addition to regulatory enforcement actions.

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. We are substantially dependent on these partners to perform their obligations under our agreements with them, in accordance with all applicable regulatory requirements. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of, fail to perform their contractual obligations in accordance with all regulatory requirements, or are unable to receive marketing approval for our and our partners' products as planned, our revenues and profits may not reach expectations or may decline. While we have agreements with our partners, we do not have any direct control over their activities. For instance, 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 or our partners to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability.

For example, 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 and epinephrine received FDA approval, there is no assurance that development of the other two products will continue or that they will ultimately receive FDA approval in a timely manner or at all, or if FDA approved, they will be a significant revenue source for us.

We currently depend on a limited number of customers for the majority of our revenue, and the loss of any one of these customers could substantially reduce our revenue and impact our liquidity.

For the year ended December 31, 2018, we derived approximately 31% of our revenue from Teva and 29% from AMAG. In addition, we derived a significant portion of our product sales revenue from wholesale distributors, including McKesson and AmerisourceBergen, which accounted for approximately 12% and 11%, respectively, of total revenues in 2018. In the future, we expect to continue to generate a significant portion of our revenue from these customers as a result of our recent launch of XYOSTED™, and the launches of AMAG's Makena® subcutaneous auto injector and Teva's generic Epinephrine Injection USP.

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 we do not broaden our customer base, we will continue to depend on these 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 are 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 XYOSTED™, OTREXUP® or our partnered device products, such as Sumatriptan Injection USP, Makena® subcutaneous auto injector and generic epinephrine injection, 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 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 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 medical doctors do not prescribe our products or our partners' products, or the medical profession, including clinics or other institutional providers, or patients do not accept our products or our partners' products, or group purchasing organizations or other similar buying groups do not offer our products to their members, or pharmacy benefit managers, health plans, health maintenance organizations, or other 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, the medical community, the medical profession, including clinics and other institutional providers, patients, group purchasing organizations and other similar buying groups, pharmacy benefit managers, health plans, health maintenance organizations, and other managed care organizations. 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;
- the approved indications and claims for products, and any restrictions on the use of such products, including warnings, contraindications, restrictions, and REMS;
- the ability to maintain an acceptable product safety and efficacy profile;
- 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;
- medical practice and standard of care;
- 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 XYOSTED™, 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, clinics and other providers may not purchase, 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' sales force;
- the adequacy and effectiveness of our or our third parties' 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 payers 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 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. Moreover, our partners and licensees will be subject to many of the same regulatory risks as we are. To the extent that they are not able to comply with the applicable regulatory requirements, or are not able to obtain or maintain regulatory product approvals, we and they may be subject to regulatory enforcement action, their performance of their obligations under their contracts with us may be inhibited, and we may not be able to realize the benefit of the relationship.

We are relying on partners such as Teva, AMAG and Pfizer for future milestone, sales and royalty revenue. Our partners may fail to obtain FDA approval of a product with our technologies or may be unsuccessful in commercializing a product. Significant delays in anticipated launches of these products in development may occur. 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 at any stage to demonstrate the safety and effectiveness of a product or may not be completed on schedule or at all. 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 for a number of reasons. For example, 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, a greater number of patients may be required than initially anticipated, or patients may drop out after enrolling or be lost to follow-up 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 and QSRs. 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, the 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. For example, the FDA may issue a CRL in response to one of our or our partners' marketing applications. If a CRL is issued for any of our or our partners' product candidates, we or our partner will be delayed in marketing that product candidate, we or our partner may need to conduct additional clinical trials and collect additional data and information, including manufacturing information, make revisions to manufacturing processes, and the FDA could convene an advisory committee to obtain expert advice on issues that resulted in the CRL being issued. Clinical trials may also be suspended, placed on hold, or terminated by us, institutional review boards, the 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 for any number of reasons. For example, the FDA or foreign regulatory authorities may disagree with our or our partners' conduct of the studies or study design, may find manufacturers or manufacturing procedures to be inadequate, may find that product candidates are not safe and effective or that they present unacceptable adverse events or risks, or may find that studies were not conducted in accordance with the applicable regulatory requirements. Moreover, if granted, such approvals may be subject 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 foreign regulatory agencies 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.

An increase in the number of competitors targeting generic and 505(b)(2) ANDA opportunities and seeking U.S. market exclusivity 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. There is substantial competition in the pharmaceutical industry. We and our partners will face competition from generic drug products, drug products that are similar to our or our partners' products, drug products containing the same active ingredient as our or our partners' products, and drug products for the same indication as our or our partners' products.

Our or our partners' products may be eligible for periods of regulatory exclusivity. For those products being developed using the 505(b)(2) NDA pathway, we or our partners may be eligible for three years of marketing exclusivity, provided that we or they conduct clinical trials, other than bioavailability or bioequivalence trials, that are essential to approval of the application. This, however, is a limited exclusivity, in that it will not block full competitor NDAs and only protects the change presented by the 505(b)(2) application. Competitors may also not refer to our or our partners' drug products as reference listed drugs, in which case, they would not be blocked by the three-year period of exclusivity.

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 or our partners are able to receive exclusivity for our products, our or their sales, profits, and profitability can be positively impacted. However, we or they may not be granted the periods of regulatory exclusivity, or granted exclusivities and other protections may not adequately protect the products from competition. For example, exclusivity does not prevent physicians from prescribing a similar product even if it is not approved for the same indication. Were this to occur, we or they may be subject to ANDA and/or 505(b)(2) competition sooner than we anticipate. We or our partners may also be subject to increased generic competition sooner than anticipated as FDA has taken steps to facilitate the approval of generic products in an effort to increase competition in the prescription drug market.

Further, regardless of any granted exclusivities, we or our partners may face competition from products that are not otherwise blocked by our or our partners' patents or exclusivities. Moreover, for 505(b)(2) products, we or our partners may face competition from other products intended for the same use and/or that otherwise contain the same active ingredients, which may be less expensive than our or our partners' products. Any increase or changes in the competitive landscape for our or our partners' products may impact product sales and the amount that can be charged for a given product.

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, to the extent that another company receives a period of regulatory exclusivity, the FDA would not make our application effective during that company's exclusivity period. This would delay our and our partners' marketing of products and may prevent us or them 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 generally triggered by commercial marketing of the generic product or an authorized generic drug product. 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 any granted 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 payers 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. Moreover, to the extent that competitors are able to receive FDA approval for and launch their competing products before us or our partners, they may develop a larger market share.

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.

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. There is no guarantee, however, that we will be able to obtain patents that may be included in the Orange Book. Moreover, the rules for submitting patents to the Orange Book are detailed and complex. To the extent that we do not include a patent in the Orange Book, we would not be able to avail ourselves of the protections provided in the Hatch Waxman Act, including the possibility of a 30-month stay. To the extent that we include a patent in the Orange Book that should not be included, we could also face legal action.

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. We may also determine that it is not in our business interest to file a patent infringement law suit in response to a paragraph IV certification.

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 will not be subject to litigation, 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 payers, 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. Product liability claims can also result in regulatory consequences, including, but not limited to investigations and regulatory enforcement actions, as well as recalls, revocation of approvals, or labeling, marketing or promotional restrictions or changes. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business. Such claims can also impact our ability to initiate or complete clinical trials.

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. Recalls are costly and take time and effort to administer. A recall could also result in product liability claims by individuals and third party payers. In addition, product liability claims or other safety issues 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.

We depend on information technology and computer systems to operate our business, and any failures or interruptions in our internal computer systems, including a data breach or cybersecurity incident, could have a negative impact on our business.

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. Cybersecurity attacks are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information, corruption of data. 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 health 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

Our and our partners' product candidates are subject to the inherent risk of product development, in that they may not receive regulatory marketing approval on a timely basis or at all. If we or our partners fail to obtain, or have delays in obtaining, regulatory approvals for any product candidates, our business, financial condition and results of operations may be materially adversely affected.

We and our partners are not permitted to market any product candidates in the U.S. unless and until we or they obtain regulatory approval from the FDA. To market the product in the U.S., we or our partners must submit to the FDA and obtain FDA approval of a marketing application. We and our partners have historically used FDA's 505(b)(2) NDA and ANDA pathways. 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.

To conduct our and our partners' clinical and preclinical studies, we and they rely on third parties, including Contract Research Organizations and clinical trial sites to carry out the studies in accordance with the written protocol, instructions, our and our partners' agreements with them, and the applicable regulatory requirements. There is no guarantee that we or our partners will be able to negotiate agreements with these third parties on acceptable terms, on a timely basis, or at all. To the extent that these third parties do not carry out their responsibilities, as is required, or to the extent that we, our partners, or such third parties terminate the applicable agreements, we or our partners may need to replace them, which may take significant time, effort, and expense. Additionally, we or our partners may be subject to regulatory enforcement action for such third parties', our, or our partners' actions and FDA or foreign regulatory authorities may find that the study data generated cannot form the basis for approval of a marketing application, requiring that we or our partners conduct additional preclinical and clinical studies. Moreover, investigators and CROs may be subject to conflicts of interest that compromise or appear to compromise the resulting data. Such third-parties may also have relationships with other entities that they may prioritize over the conduct of our or our partners studies.

Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we or our partners could encounter problems that cause us or they 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, CROs, and clinical trial sites to follow the applicable regulatory requirements, including GCPs. We or our partners may also not have sufficient funding to conduct or complete a clinical trial or pay the substantial FDA application user fees. 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 or, in the case of a generic drug product, bioequivalent to the reference listed drug;
- may not find that we have adequately bridged to the reference listed drug, in the case of a 505(b)(2) application;
    - may not find the data, including foreign data, from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
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may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we or our partners do;

- may not approve the manufacturing processes or facilities associated with our product candidates;
- may not agree with the pathway that we or our partners have chosen for our product candidates, requiring us to pursue more difficult approval pathways, including submitting full NDAs, or may not agree with our or our partners' intended indications;
- may find that our or our partners 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 or gather additional information or data;

- may change approval policies (including with respect to our product candidates' class of drugs), adopt new regulations;
- may not meet their review goal dates; 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 or our partners may have the exclusive right to commercialize our product candidates allow competitors to bring products to market before we do.

Undesirable side effects caused by any product candidate that we or our partners 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 or our partners 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.

By example, with regard to XYOSTED™, we submitted a 505(b)(2) NDA to the FDA in December 2016, the NDA submission was accepted and assigned a PDUFA target date for completion of its review by October 20, 2017, and on October 20, 2017, we received a CRL from the FDA. We provided a resubmission to the FDA in response to the CRL on March 29, 2018 and, on September 28, 2018, XYOSTED™ was approved by the FDA. However, even if product candidates are approved, they may be subject to certain limits or other costly and burdensome requirements. For instance, the product candidates 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.

Failure to obtain, or delays in obtaining, regulatory approvals may:

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

Moreover, the reference listed drugs for our or our partners' product candidates will impact our or our partners' ultimate product approvals. By example, the labels for our or our partners' product candidates, in the case of ANDA products will, and in the case of 505(b)(2) NDA products may include the same warnings, precautions, limitations, and other safety information as the reference listed drugs. Any future actions or inquiries by the FDA with respect to the reference listed drug may require that we or our partners make changes to our labeling, change or abandon development programs that rely on such reference listed drugs, 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.

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. We, alone or with our partners, have and may in the future pursue marketing approval for products from regulatory authorities in the U.S. and other countries for products developed internally and pursuant to our license agreements. In the future we, or our partners, may need to seek approval for or submit FDA notifications regarding changes, including changes to manufacturing, manufacturers, and product labeling, to existing products or for newly developed products. We or

our partners may need to support these applications or notifications with certain data or information that would need to be collected or developed. Moreover, FDA may ultimately not approve any such changes. 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.

Moreover, the regulatory path for approval of 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.

We and our partners' product candidates may also be subject to additional regulatory review. By example the product candidates will be reviewed by different offices within FDA to ensure that the drug labeling adequately discloses all relevant information and risks. Additionally, the instructions for use for the product candidates will be 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.

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

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

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 a NDA or ANDA. Based on evolving regulatory policies, we or our partners may not be able to use the 505(b)(2) or ANDA pathways in the future, requiring that we or they pursue the costlier and time consuming 505(b)(1) full NDA pathway. We or our partners may also face delays or impediments to the approval of any product candidates if a competitor files a citizen petition with FDA.

Moreover, any FDA intervening approvals of drug products that are the same or similar to our or our partners' product candidates could impact our potential market position and prospects, as well as impact the approval of our or our partners' product candidates. By example, should FDA approve a product that is pharmaceutically equivalent to one of our or our partners' 505(b)(2) NDA product candidates before we or they submit a marketing application, we or they would be required to change the marketing application to an ANDA application. Similarly, should FDA approve a product that is more similar to any of our or our partners' ANDA product candidates than the current reference listed drug, we or our partners may be required to change the reference listed drug for the ANDA. Either of these scenarios could require additional development work, and clinical or preclinical studies. FDA intervening approvals could also delay the timeframe within which we or our partners may submit product applications to FDA or within which FDA may make approvals of such applications effective, due to periods of patent protections and regulatory exclusivities

for the newly approved product. Because 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, we would not know whether there are any intervening products or applications until such product or application is approved.

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 or our partners 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 leads them to question 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.

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.

Because our and our partners' products and product candidates are considered to be drug/device combination products, the approval and the post-approval requirements that we and they are required to comply with will be more complex.

Our and our partners' products and product candidates are considered to be drug/device combination products by FDA, consisting of a drug product and a drug delivery device. If marketed individually, each component would 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 our and our partners' 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. These products and product candidates will be and have been subject to the FDA drug approval process, and will not require a separate FDA clearance or approval for the device component. Even though these products and product candidates are subject to the drug approval process, we, our partners, and any of our respective contractors will be required to comply with FDA regulatory requirements related to both drugs and devices. For instance, drug/device combination products must comply with both the drug cGMPs and device QSRs. Depending on whether the drug and device components are at the same facility, however, FDA's regulations provides a streamlined method to comply with both sets of requirements. Additionally, drug/device combination products will be subject to additional FDA and constituent part reporting requirements. The development of drug/device combination products will also be more complex because the sponsor of the product application will need to demonstrate the safety and efficacy of both the drug and device components of the product. These requirements will require additional effort and monetary expenditure to ensure that our and our partners' products and product candidates.

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

Our and our partners' products and product candidates are subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies, including requirements related to research, development, pre-clinical and clinical testing before and after product approval, manufacture, safety, effectiveness, record keeping, reporting, labeling, packaging, storage, distribution, safety, deviation, and other reporting, approval, facility registration and product listing, the payment of user fees, advertising, marketing, promotion, sale, distribution, sampling, import and export of pharmaceutical and medical device products. Because our and our partners' products and product candidates are drug/device combination products, we and they will have to comply with more regulatory requirements that would otherwise be required for products that are not combination 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. Moreover, were we or our partners to seek regulatory approval for additional indications or uses of any products that we or they may have already received marketing approval for, we or they would be subject to the risks of product development, including the failure to obtain regulatory approval.

The applicable governmental 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.

The FDA will continue to monitor the product after approval for continued safety, efficacy, and compliance. We, our partners, and contractors will also be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. 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 warning letters, untitled letters, cyber letters, 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, removal of the product from the market, labeling or promotional material modifications, product recalls, market withdrawals, field corrections, clinical holds and suspensions of clinical studies, fines, penalties, disgorgement, corporate integrity agreements, consent decrees, seizure, injunctions, prohibition on importing and exporting, dear healthcare provider letters, adverse publicity, FDA debarment, debarment from government contracts or refusal of orders under existing contracts, and exclusion from federal healthcare programs, among other consequences. Any of these events could have other material and adverse effects on our operations and business.

We and our contractors, distributors, prescribers, and dispensers are required to comply with regulatory requirements related to controlled substances for XYOSTED™, which will require the expenditure of additional time and will incur additional expenses to maintain compliance.

XYOSTED™ is a drug/device combination product in which the drug product is testosterone. Testosterone is a Schedule III controlled substance. Accordingly, we, and our contractors, distributors, prescribers, and dispensers must comply with Federal controlled substances laws and regulations, enforced by the U.S. Drug Enforcement Administration ("DEA"), as well as state controlled substances laws and regulations enforced by state authorities. These requirements include, but are not limited to, registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, and other requirements. These requirements are enforced by DEA through periodic inspections.

To continue to engage in controlled substance activities, we, and our contractors, distributors, prescribers, and dispensers must maintain controlled substance registrations. To the extent that we and our contractors, distributors, prescribers, and dispensers cannot obtain or maintain the necessary controlled substance registrations, we and these other third parties would not be able to continue engaging in controlled substance operations. This would prevent the continuing commercialization of XYOSTED™ or would require that we find alternative contractors, which would take additional time and expenses, also delaying or interrupting the commercialization of XYOSTED™. Moreover, even if we, and our contractors, distributors, prescribers, and dispensers are able to obtain and maintain the necessary controlled substance registrations, compliance with the applicable controlled substance requirements will require significant efforts and expenditures, which could also inhibit the successful commercialization of XYOSTED™. If we, and our contractors, distributors, prescribers, and dispensers do not comply with the applicable controlled substance requirements, we or they may be subject to administrative, civil or criminal enforcement, including civil penalties, refusals to renew necessary registrations, revocation of registrations, criminal proceedings, or consent decrees.

54

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payers 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 and similar laws in some state and foreign markets. 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 in the U.S. 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 participating in the 340B drug discount program, 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 payer (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 U.S. 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 payers, including commercial insurers; state transparency laws requiring manufacturers to report pricing information; 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. 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, are 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 is 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, 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"), expanded healthcare coverage within the U.S., primarily through the establishment of state exchanges 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, particularly where Medicaid patients are enrolled in managed care plans, manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Moreover, legislative changes to the Healthcare Reform Act remain possible. Recently, the law's individual health insurance mandate was repealed and manufacturers' responsibility for the cost of prescriptions in the Medicare Part D donut hole has increased. 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. For example, California recently enacted a law providing transparency into drug price increases which imposes new reporting requirements on manufacturers, and CMS reduced the Medicare Part B reimbursement rate for drugs purchased by hospitals under the 340B program. CMS has also proposed reducing prices of products paid by Medicare Part B by basing their reimbursement rate on the average price among other industrialized countries, and eliminating the AKS safe harbor for rebates typically provided to Pharmacy Benefit Managers ("PBMs") and health plans that are included in their formulary cost effectiveness determinations. These proposals, if adopted, could have a significant impact on our business.

To help patients afford our products XYOSTED™ and 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 (including any discounts or rebates we offer) 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 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. We and our partners may only make claims that are within the FDA approved label for the approved product. FDA may not include all information in the approved label that is necessary for successful marketing. If we or a pharmaceutical company partner fails to use acceptable marketing claims we may be subject to enforcement actions.

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

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, clinical trial results, 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 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 biotechnology 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 or derivative litigation.

We are at risk of securities class action and similar litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. For example, on October 23, 2017, Randy Smith filed a complaint in the District of New Jersey on behalf of a putative class of persons who purchased or otherwise acquired Antares securities against Antares, Robert F. Apple and Fred M. Powell. In addition, in January 2018, three stockholders filed separate derivative actions, one in the District of New Jersey and two in the Superior Court of New Jersey Chancery Division, Mercer County, purportedly on our behalf, against certain directors and officers, as well as the company as a nominal defendant. Even if we are successful and ultimately prevail, litigation could be costly to defend and divert management’s attention and resources, which could further materially harm our financial condition and results of operations.

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

As of March 1, 2019, we had options outstanding that are exercisable, at exercise prices ranging from $0.53 to $4.54 per share, for an aggregate of approximately 10.6 million 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, 2019, our officers and directors beneficially owned an aggregate of approximately 9.1 million shares (or approximately 5.4% 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.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

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.

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. This lease will terminate in October 2019.

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

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

Item 3. LEGAL PROCEEDINGS
On October 23, 2017, Randy Smith filed a complaint in the District of New Jersey, captioned Randy Smith, Individually and on Behalf of All Others Similarly Situated v. Antares Pharma, Inc., Robert F. Apple and Fred M. Powell ("Smith"), Case No. 3:17-cv-08945-MAS-DEA, on behalf of a putative class of persons who purchased or otherwise acquired Antares securities between December 21, 2016 and October 12, 2017, inclusive, asserting claims for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 against Antares, Robert F. Apple and Fred M. Powell. The Smith complaint contends that defendants made false and/or misleading statements and/or failed to disclose that: (i) Antares had provided insufficient data to the FDA in connection with the NDA for XYOSTED™; and (ii) accordingly, Antares had overstated the approval prospects for XYOSTED™. On July 27, 2018, the court entered an order appointing Serghei Lungu as lead plaintiff, Pomerantz LLP as lead counsel, and Lite DePalma Greenberg, LLC as liaison counsel for plaintiff. On August 3, 2018, the parties submitted a stipulation and proposed order, setting forth an agreed-upon schedule for responding to the complaint, which the court granted. Pursuant to that order, plaintiff filed a Consolidated Amended Class Action Complaint on October 9, 2018. On November 26, 2018, defendants filed a motion to dismiss. Plaintiff filed an opposition to the motion on January 10, 2019 and defendants filed a reply in support of their motion on February 25, 2019. The Company believes that the claims in the Smith action lack merit and intends to defend them vigorously.

On January 12, 2018, a stockholder of our Company filed a derivative civil action, captioned Chiru Mackert, derivatively on behalf of Antares Pharma, Inc., v. Robert F. Apple, et al. ("Mackert"), in the Superior Court of New Jersey Chancery Division, Mercer County (Case No. C-000011-18). On January 17, 2018, another stockholder filed a derivative action in the same court, captioned Vikram Rao, Derivatively on Behalf of Antares Pharma, Inc. v. Robert

F. Apple, et al. (“Rao”) (Case No. C-000004-18). Both complaints name Robert F. Apple, Fred M. Powell, Thomas J. Garrity, Jacques Gonella, Anton Gueth, Leonard S. Jacob, Marvin Samson and Robert P. Roche, Jr. as defendants, and the Company as nominal defendant, and they assert claims for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets arising from the same facts underlying the Smith securities class action. The plaintiffs seek damages, corporate governance and internal procedure reforms and improvements, restitution, reasonable attorneys’ fees, experts’ fees, costs, and expenses. The parties have filed a stipulation consolidating the two actions and staying the proceedings pending the court’s decision on defendants’ anticipated motion to dismiss the Smith action.

On January 17, 2018, a stockholder of our Company filed a derivative civil action, captioned Robert Clark, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al. ("Clark") (Case No. 3:18-cv-00703-MAS-DEA), against Robert F. Apple, Thomas J. Garrity, Jacques Gonella, Leonard S. Jacob, Marvin Samson, Anton G. Gueth and Robert P. Roche, Jr. as defendants, and Company as a nominal defendant. The action was filed in the U.S. District Court for the District of New Jersey and asserts claims for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and a violation of Section 14(a) of the Securities Exchange Act of 1934. This complaint relates to the same facts underlying the Smith securities class action and the other derivative actions. The plaintiff in Clark seeks damages, corporate governance and internal procedure reforms and improvements, reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses. The parties have filed a stipulation staying the action pending the court's decision on defendants' anticipated motion to dismiss the Smith action.

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".

Common Shareholders

As of March 1, 2019, we had 71 shareholders of record of our common stock and approximately 19,249 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 and the NASDAQ Biotechnology Stock Index. The graph covers the period beginning December 31, 2013, through December 31, 2018. The graph assumes $100 was invested in each of our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Stock Index on December 31, 2013 (based upon the closing price of each). Total Return assumes reinvestment of dividends.

	December 31,					
	2013	2014	2015	2016	2017	2018
Antares Pharma, Inc.	$100.00	$57.49	$27.07	$52.13	$44.52	$60.85
NASDAQ Composite Index	100.00	113.40	119.89	128.89	165.29	158.87
NASDAQ Biotechnology Index	100.00	134.10	149.42	117.02	141.66	128.45

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

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, 2018, 2017, 2016, 2015, and 2014 and should be read in conjunction with those statements (amounts expressed in thousands, except per share amounts).

	At December 31,				
	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash and cash equivalents	$27,892	$26,562	$27,715	$32,899	$34,029
Total assets	88,277	74,338	66,325	84,562	68,773
Long-term debt	25,126	24,858	—	—	—
Accumulated deficit					