ANTARES PHARMA, INC.
Form 10-K
March 12, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (D) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2014

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For transition period from _____ to _____

Commission file number 1-32302

ANTARES PHARMA, INC.

(Exact name of registrant as specified in its charter)

A Delaware corporation **I.R.S. Employer Identification No. 41-1350192**
100 Princeton South, Suite 300, Ewing, NJ 08628

Registrant s telephone number, including area code: (609) 359-3020

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

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

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

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

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

Table of Contents

ANTARES PHARMA, INC.

FORM 10-K

TABLE OF CONTENTS

PART I

PART II

PART III

PART IV

Table of Contents

PART I

Item 1. BUSINESS

Forward-Looking Statements

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

- our expectations regarding commercialization of OTREXUP (methotrexate) injection for subcutaneous use;
- our expectations regarding product developments with Teva Pharmaceutical Industries, Ltd. (Teva);
- our expectations regarding product development and potential United States Food and Drug Administration (FDA) approval of Vibex® QuickShot (Vibex® QS T) (testosterone injection);
- our expectations regarding product development and potential FDA approval of Vibex® Sumatriptan (sumatriptan injection);
- our expectations regarding product development and potential FDA approval of Vibex® epinephrine pen (epinephrine auto injector);
- our expectations regarding trends in pharmaceutical drug delivery characteristics;
- our anticipated continued reliance on contract manufacturers to manufacture our products;
- our sales and marketing plans;

product development and commercialization plans regarding our other products and product candidates;

our future cash flow and our ability to support our operations;

our ability to raise additional funds, if needed; and

other statements regarding matters that are not historical facts or statements of current condition.

These forward-looking statements are based on assumptions that we have made in light of our industry experience as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this annual report, you should understand that these statements are not guarantees of performance results. They involve risks, uncertainties and assumptions. Although we believe that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect our actual financial results or results of operations and could cause actual results to differ materially from those in the forward-looking statements. You should keep in mind that forward-looking statements made by us in this annual report speak only as of the date of this annual report. Actual results could differ materially from those currently anticipated as a result of a number of risk factors, including, but not limited to, the risks and uncertainties discussed under the caption Risk Factors. New risks and uncertainties come up from time to time, and it is impossible for us to predict these events or how they may affect us. We do not undertake to update or revise the forward-looking statements in this annual report after the date of this annual report, except as required by law. In light of these risks and uncertainties, you should keep in mind that any forward-looking statement in this annual report or elsewhere might not occur.

Overview

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

Table of Contents

We develop and manufacture for ourselves and with partners, novel, pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. We have developed variations of the needle-free injector by adding a small shielded needle to a pre-filled, single-use disposable injector, called the Vibex® pressure assisted auto injection system. This system is an alternative to the needle-free system for use with injectable drugs in unit dose containers and is suitable for branded and generic injectables. We also developed a disposable multi-dose pen injector for use with standard cartridges. We have entered into multiple licenses for these devices mainly in the United States (U.S.), Europe and Canada with Teva Pharmaceutical Industries, Ltd. (Teva).

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

We are currently conducting clinical studies of Vibex® QS T, for testosterone replacement therapy. On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company s ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males. We also have initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system (CNS) indication.

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

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

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

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

Table of Contents

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

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

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

History

On January 31, 2001, we (Antares, formerly known as Medi-Ject Corporation, or Medi-Ject) completed a business combination to acquire the operating subsidiaries of Permatec Holding AG (Permatec), headquartered in Basel, Switzerland. Medi-Ject was, at that time, focused on delivering drugs across the skin using needle-free and pressure-assisted, needle-based technology, and Permatec specialized in delivering drugs across the skin using gel technologies. With both companies focused on drug delivery, but on different sectors, it was believed that a business combination would be attractive to both pharmaceutical partners and to our stockholders. Upon completion of the transaction, our name was changed from Medi-Ject Corporation to Antares Pharma, Inc.

Table of Contents

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

Market Overview

Our focus is specifically on the market for delivery of self-administered injectable drugs, comprised of non-biologic, small molecule drugs and biological products or biosimilars. We believe that many injectable products currently offered in vials could be replaced with user-friendly auto injectors promoting better compliance and improvement in dose accuracy. Several manufacturers of injectable products have introduced convenient alternatives to vials, such as prefilled syringes and injector systems, and an increasing proportion of people who self-administer drugs are transitioning to prefilled syringes and other injector systems when offered. We believe that our injection technologies and products offer further improvements in convenience and comfort for patients self-administering injectable products as well as provide the appropriate technique to the patient to accurately self-inject. Additionally, the delivery of pharmaceutical therapies through injection systems often improves the systemic bioavailability of those treatments by overcoming absorption barriers common with oral and, in some cases, transdermal delivery. Improved bioavailability is considered beneficial when considering the role of route of administration on pharmaceutical efficacy. Our business model of developing our own pharmaceutical products in targeted therapeutic categories using our pressure-assisted auto injectors and pen injectors has the potential for further market penetration in the future. Also, partnering with pharmaceutical manufacturers of injectable products that are outside of our therapeutic focus offers us additional potential to profit from our proprietary injector systems.

SELF-ADMINISTRATION OF INJECTABLE DRUGS

Injectable drugs are used in managing chronic medical conditions presenting a need for repeated injections over time and are also used in management of acute conditions where the rapid onset of an injected drug is desirable.

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

Condition	*Products*
Diabetes	Humalog (Lilly), Humulin (Lilly), Novolog (Novo Nordisk), Apidra (Sanofi Aventis), Lantus (Sanofi Aventis), Levemir (Novo Nordisk), Byetta (Lilly)
Growth deficiency	Genotropin (Pfizer), Tev-Tropin (Teva), Humatrope (Lilly), Nutropin AQ (Roche), Noridtropin (Novo Nordisk), Saizen/Serostem (EMD Serono), Omnitrope (Sandoz)
Rheumatoid Arthritis	Enbrel (Amgen), Humira (Abbvie), Simponi (Centocor Ortho Biotech), Cimzia (UCB)
Multiple Sclerosis	Avonex (Biogen Idec), Betaseron (Bayer), Copaxone (Teva), Rebif (EMD Serono)
Chronic Hepatitis C	Intron-A (Merck), Pegasys (Roche), Peg-Intron (Merck)

Anemia/Neutropenia	Aranesp (Amgen), Neulasta (Amgen)
Migraine	Imitrex (GSK, Par, Sandoz), Sumavel (Zogenix), Alsuma (Pfizer) Sumatriptan Autoinjector (Sun Pharma)
Allergic Emergency	Epipen (Pfizer), Twinject (Amedra), Auvi-Q (Sanofi)

Table of Contents

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

Non-biologic injectable drugs

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

THERAPEUTIC PRODUCTS AND PRODUCT MARKET OPPORTUNITIES FOR OUR INJECTOR SYSTEMS

OTREXUP (methotrexate) injection

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

OTREXUP is indicated for use in adults with severe, active RA or children with pJIA, and adults with severe recalcitrant psoriasis. RA is a chronic autoimmune disease, resulting in pain, stiffness, swelling, joint damage, and loss of function of the joints. According to a 2008 study sponsored by the Arthritis Foundation, RA affects approximately 1.5 million Americans, which is almost 0.5% of the U.S. population. The disease onset generally occurs between the ages of 40 to 70 years and is about three times as prevalent among women as among men. According to Symphony Health Solutions, a healthcare data and analytics company, U.S. sales of biologic agents products approved to treat rheumatoid arthritis were approximately $17.3 billion in 2014. Some of these agents are also approved for other indications including plaque psoriasis, Crohn s disease, ulcerative colitis, juvenile idiopathic, ankylosing spondylitis, and psoriatic arthritis, making it difficult to determine the proportion of sales attributable to use in rheumatoid arthritis.

Methotrexate is the most commonly prescribed disease modifying anti-rheumatic drug (DMARD), used in an estimated 70% of rheumatoid arthritis patients. A November 2012 analysis utilizing United Healthcare data and conducted by Optum found that methotrexate is usually started at 7.5 mg, 10 mg or 15 mg given orally, once-a-week, and titrated up for greater therapeutic effect, or until the patient incurs side effects. The maximum oral dose given is generally 20 mg to 25 mg per week (8 to 10, 2.5 mg tablets given in one dose). Studies have reported as many as 30% to 60% of patients experience gastrointestinal side effects with oral methotrexate, preventing further dose escalation or requiring discontinuation in some patients. Also, the extent of oral absorption of methotrexate varies considerably between patients. In a study performed by Schiff et al published in *The Annals of Rheumatic Diseases* in 2014,

researchers showed that the bioavailability of methotrexate delivered via subcutaneous injection was dose proportional and continued to increase compared with oral drug, which plateaued at 15 mg. According to studies by Dr. Wegrzyn published in *The Annals of Rheumatic Diseases* in 2004, Dr. Mainman published in *Clinical Rheumatology* in 2010, Dr. Bakker published in *The Annals of Rheumatic Diseases* in 2010, and Dr. Braun published in *Arthritis and Rheumatism* in 2008, RA patients switching from oral to parenteral methotrexate may improve clinical response or lower the incidence of gastrointestinal side effects.

Table of Contents

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

Psoriasis is believed to be an autoimmune disease, characterized by thick patches of inflamed, scaly skin, created by abnormal, rapid, and excessive proliferation of skin cells. The National Psoriasis Foundation, a non-profit health agency dedicated to curing psoriatic disease, stated in 2015 that psoriasis is the most prevalent autoimmune disease in the U.S. According to current studies, as many as 7.5 million Americans, or approximately 2.2% of the population suffer from psoriasis, with a higher incidence in Caucasians. And, according to information published by the World Psoriasis Day consortium in 2015, 125 million people worldwide, or 2% to 3% of the total population have psoriasis.

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

We believe that OTREXUP offers physicians and patients an important alternative to oral methotrexate tablets and vials of the injectable form of the drug administered with a needle and syringe. According to a studies by Dr. Wegrzyn published in *The Annals of Rheumatic Diseases* in 2004, Dr. Mainman published in *Clinical Rheumatology* in 2010, Dr. Bakker published in *The Annals of Rheumatic Diseases* in 2010, and Dr. Braun published in *Arthritis and Rheumatism* in 2008, many patients who start on oral methotrexate may have an inadequate clinical response due in part to a lack of efficacy or poor tolerability.Although published studies have demonstrated switching to a parenteral route of administration can improve absorption, a 2012 report by Source Healthcare Analytics found that fewer than 5% of patients on methotrexate are being prescribed the injectable form.

Instead, patients who fail to achieve adequate response on oral methotrexate are often prescribed a biologic response modifier (biologic). Biologic therapies have been demonstrated to improve the patient s therapeutic response when added to methotrexate. However, according to Source Healthcare Analytics data published in 2013, the average retail price for biologics was in excess of $32,000 annually, excluding administrative and other fees that could be incurred. A number of peer-reviewed articles by key thought leaders in the rheumatology community have called on clinicians to optimize methotrexate therapy for rheumatoid arthritis and ensure that the drug is given adequate time to achieve the desired results before biologic therapies are initiated. Biologics have shown to have their own limitations including increasing the risk of serious infections and certain malignancies and are not appropriate for all patients.

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

OTREXUP may offer physicians and patients a convenient, practical and cost-effective option for administering parenteral methotrexate as an alternative to proceeding directly from oral methotrexate to biologics. Additionally, OTREXUP is a self-contained injection device designed to minimize accidental contact with methotrexate, a hazardous drug agent.

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

Table of Contents

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

Vibex® QS T (testosterone)

Vibex® QuickShot® Testosterone (QS T) is our proprietary combination product that consists of testosterone and our next generation Vibex® QuickShot® (QS) auto injector in development for the treatment of testosterone deficiency or testosterone replacement therapy. The Vibex® QS auto injector is designed specifically to provide a fast injection of highly viscous fluids such as testosterone in oil.

The U.S. testosterone replacement therapy (TRT) market in 2014 was approximately $2.8 billion according to a Symphony Health Solutions report, and declined approximately 9% compared to 2013. There is significant competition within the TRT market among many pharmaceutical companies including Abbvie, Inc. (formerly Abbott), Eli Lilly and Company (Lilly), Endo Pharmaceuticals, Inc (Endo), Pfizer, Inc. (Pfizer), Actavis PLC (Actavis), Sandoz, Inc. (Sandoz), Mylan, Inc. (Mylan), Bedford Laboratories (Bedford), and Teva.

According to the Urology Care Foundation in June 2014, low serum testosterone, also known as hypogonadism or andropause, affects roughly 39% of men over the age of 45. The prevalence of low testosterone increases with age. Researchers have found that the incidence of low testosterone increases from approximately 20% of men over 60, to 30% of men over 70 and 50% of men over 80 years of age. In May 2014, Forbes.com estimated 13 million men in the U.S. suffer from lower than average testosterone. Symptoms and health risks associated with low testosterone include reduced libido, compromised sexual function, loss of bone density, reduced muscle mass, lethargy, mood disorders, impaired cognition, and cardiovascular disease. Several factors, including low awareness, embarrassment and stigma associated with low testosterone are believed to contribute to the relatively low diagnosis and treatment levels.

Testosterone replacement therapy is given to restore patients testosterone levels to within the normal range, The potential benefits of therapy include restored libido and erectile function, increased energy levels, and improved mood. TRT can also improve body composition by decreasing fat mass, increase lean body mass, potentially increase muscle strength, and stabilize or increase bone mineral density, as well as reduce bone fractures.

Topical formulations, such as Androgel, Testim, Fortesta, Axiron, dermal patches and buccal delivery are the most frequently prescribed versions of TRT. An NDA for an oral formulation of TRT indicated in hypogonadism secondary to obesity was submitted to the FDA by Repros Therapeutics, Inc. in February 2015.

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

Currently, injectable testosterone is available and represents a significant percentage of all TRT prescriptions. These injections, prescribed as a combination of a vial, needle, and syringe, are usually given deep into the muscle tissue of the buttocks with large bore needles (typically 19 gauge needles). Injection testosterone is an esterified formulation in

oil that is absorbed slowly from the muscle tissue, producing a sustained increase in serum testosterone over time, requiring repeated injections typically administered in the physician s office every two to four weeks. The higher doses given to facilitate less frequent injections are sometimes associated with supra-physiologic levels. Such high levels may lead to polycythemia, a proliferation of red blood cells, which places the patient at increased risk of thrombus or clot formation leading to strokes, heart attacks, pulmonary embolism, and possibly death. Excessive variability between peak testosterone levels occurring shortly after the injection to the lowest levels immediately preceding a dose are also associated with mood swings.

Table of Contents

For these reasons, we are developing Vibex® QS T, a once-weekly subcutaneous injectable testosterone product that could be conveniently self-administered at potentially lower dosages given more frequently than is generally practical with repeated visits to the physician s office. The Vibex® QS T utilizes a small gauge needle for patient comfort. On February 25, 2014, we released positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company s ongoing, multi-center, phase III clinical study (QST-13-003) evaluating the efficacy and safety of QS T administered once-weekly in testosterone deficient adult males. Participants in the study will remain on QS T and will be followed for an additional 40 weeks, and the collection of safety data is ongoing.

Tjet® / Zomajet® (hGH)

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

According to Symphony Health Solutions, hGH sales in the U.S. were $1.6 billion in 2014. There is significant competition within the hGH market between major pharmaceutical companies such as F. Hoffmann-La Roche AG, Pfizer, Novo Nordisk, Inc, Sandoz, Teva and EMD Serono, Inc. among others. We believe that product attributes, including patient comfort and ease-of-use, play a key role, along with price and promotion, in determining performance in the market.

The Zomajet®/Tjet® device can administer injectables by using a spring to push the active ingredient in solution or suspension through a micro-fine opening in the needle-free syringe. The opening is approximately half the diameter of a standard 30-gauge needle. A fine liquid stream then penetrates the skin, and the dose is dispersed into the layer of fatty, subcutaneous tissue. The drug is subsequently distributed throughout the body, successfully producing the desired effect.

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

Patient Candidates for Needle-Free Injection

Young adults and children

Patients looking for an alternative to needles

Patients unable to comply with a prescribed needle program

Patients transitioning from oral medication

New patients beginning an injection treatment program

Patients with metal allergies

The Zomajet®/Tjet® device is primarily used in the U.S., Europe, Asia, Japan and elsewhere to provide a needle-free means of administering human growth hormone to patients with growth retardation. We typically sell our injection devices to partners in these markets who manufacture and/or market human growth hormone directly. The partners then market our device with their growth hormone. We receive benefits from these agreements in the form of product sales and royalties on sales of their products.

The Zomajet®/Tjet® device has been sold for use in more than 30 countries to deliver hGH. The product is reusable, with each device designed to last for approximately 3,000 injections (or approximately two years) while the needle-free syringe is disposable after approximately one week when used by a patient for injecting from multi-dose vials. Our pharmaceutical partner, JCR, markets hGH in Japan as the Twin-Jector® EZ II Needle-free Injector. Our pharmaceutical partner, Ferring, has an established branded product in the hGH market using our needle-free injector, marketed as the Zomajet® 2 Vision for their 4 mg formulation and Zomajet® Vision X for their 10 mg formulation. Since Teva launched the Tjet® needle-free device in late 2009, gross sales of hGH Tev-Tropin® increased year over year until Teva initiated a recall of the drug product, Tev-Tropin® (not the device which we supply), in April 2014 having halted sales of the drug earlier in 2014. We do not know when sales of Tev-Tropin®

Table of Contents

will resume. In December 2014, Ferring acquired the U.S. rights to Tev-Tropin® from Teva and assumed Teva s obligations under the Supply Agreement. We sell the Tjet® and Zomajet® devices along with disposables to our partners as well as receive a royalty on net sales of the hGH product.

Vibex® with Epinephrine

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

The EpiPen® is the global market leader in the epinephrine auto injector market. In the U.S., according to Symphony Health Solutions, sales of epinephrine injection products were approximately $1.8 billion in 2014 with the EpiPen® accounting for 87% of the total. Mylan, Inc. reported that EpiPen® has a 90% world market share in the U.S. and worldwide. Epinephrine is utilized for the treatment of severe allergic reactions (anaphylaxis) to insect venom, foods, drugs and other allergens as well as anaphylaxis to unknown substances or exercise-induced anaphylaxis.

Vibex® with Sumatriptan

We have a license agreement with Teva for our Vibex® system that we have designed for a product containing sumatriptan. We are in the process of preparing for commercialization, including engaging a third party to prepare commercial tooling and molds, and await FDA approval of the product as a generic substitute of GlaxoSmithKline plc (GSK) branded product, Imitrex® STATdose Pen®. According to Catamaran, Inc., a pharmacy management company, the total U.S. anti-migraine market is expected to be valued at $3.2 billion in 2015. In the U.S., according to Symphony Health Solutions, sales of migraine products were about $2.7 billion in 2014. Oral drugs accounted for $2.2 billion of the total. Injectable and nasal products combined accounted for about $465 million of the total value.

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

According to a survey commissioned by the National Headache Foundation, migraine affects nearly 37 million Americans. Migraine headaches are often characterized by a headache of moderate or severe intensity, nausea (the most common characteristic), one-sided and/or pulsating quality, aggravated by routine physical activity, duration of hours to 2-3 days; and an attack frequency anywhere between once a year and once a week. Healthcare professionals frequently prescribe triptans to stop migraine attacks, such as GSK s Imitrex (sumatriptan) and Amerge (naratriptan); Pfizer s Relpax (eletriptan), Merck & Co., Inc. s (Merck) Maxalt (rizatriptan), Impax Laboratories Zomig (zolmitriptan), Janssen Pharmaceuticals Axert (almotriptan), and Endo Pharmaceuticals Frova (frovatriptan) to relieve acute symptoms of a migraine attack (Medco claims database study).

The majority of patients who use triptans take oral tablets. While oral triptans have benefited many migraine sufferers, they are most consistently effective when taken at a relatively early stage in the migraine attack. None is as effective and as rapid-acting as injectable sumatriptan in treating a migraine headache that has reached the moderate to severe level of intensity.

About 9% of triptan prescriptions are currently for injectable triptans. Sumatriptan is the only injectable triptan approved for use in the U.S. Sumatriptan is currently available in an oral formation, a nasal spray (Imitrex, GSK and generic), a needless injector (Sumavel, Astellas/Zogenix), and a transdermal patch (Zecuity, Teva).

Several manufacturers offer versions of injectable sumatriptan with a delivery device, including GSK (Imitrex StatDose), Pfizer (Alsuma) Zogenix, Inc. (Sumavel DosePro), and Sun Pharma (generic sumatriptan autoinjector) and recently Dr. Reddy s Laboratories (generic sumatriptan autoinjector). Two companies, Par Pharmaceutical Companies, Inc. and Sandoz, market authorized generic versions of GSK s Imitrex STATdose. At least three companies, including Bedford Labs, Teva, and Fresenius Kabi have FDA approval to market injection sumatriptan in prefilled syringes, although we are not aware of any that presently market this product configuration. Additionally, several generics manufacturers offer injectable sumatriptan in vials.

Table of Contents

Disposable Pen Injector with Exenatide

Our multi use, disposable pen injector complements our portfolio of single-use pressure assisted auto injector devices. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. Our disposable pen injector is designed for chronic conditions such as diabetes, which require daily injection of a product. Depending on dose, our pens can hold up to thirty days of drug dosing. We are planning to scale up tooling and molds for commercial scale production. Although differing from the other pressure assisted injection strategies common to the above portfolio of injection therapy, this device includes a dosing mechanism design that is drawn from our variable dose needle-free technology. We have signed a license agreement with Teva for our pen injector device for two products: Pen 1 which is undisclosed and under development in Europe and Pen 2 , an exenatide pen which has an ANDA under active review at the FDA.

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

Other Injectable Drugs

Other injectable drugs that are presently self-administered and may be suitable for injection with our systems include therapies for the treatment of gout, epileptic seizure, Alzheimer s Disease, blood clots, multiple sclerosis, inflammatory diseases, impotence, infertility, AIDS and hepatitis.

We believe that many injectable drugs currently under development will be administered by self-injection once they reach the market. Our belief is supported by the continuing development of important chronic care products that can only be given by injection, the ongoing effort to reduce hospital and institutional costs by early patient release, and the gathering momentum of new classes of drugs that require injection.

A partial list of such drugs (and their manufacturer) introduced in recent years that require self-injection include Cimzia® (UCB), Simponi® (Centocor Ortho Biotech), Enbrel® (Amgen, Pfizer) and Humira® (Abbvie) for treatment of rheumatoid arthritis, Epogen® and Aranesp® (Amgen) for treatment of anemia, Forteo (Lilly) for treatment of osteoporosis, Intron® A (Merck) and Roferon® (Roche) for hepatitis C, Lantus® (Sanofi Aventis) and Byetta® (Bristol Myers) for diabetes, Rebif® (EMD Serono) for multiple sclerosis, Copaxone® (Teva) for multiple sclerosis and Gonal-F® (EMD Serono) for fertility treatment.

THERAPEUTIC PRODUCTS AND PRODUCT MARKET OPPORTUNITIES FOR TRANSDERMAL GEL PRODUCTS

Our transdermal gels consist of a hydro-alcoholic base including a combination of permeation enhancers. The gels are designed to be absorbed quickly through the skin after application, which is typically to the arms, shoulders, or abdomen, and release the active ingredient into the blood stream predictably over approximately a 24 hour period of time.

Oxybutynin Gel 3%

Our topical oxybutynin gel 3% product for the treatment of OAB was approved by the FDA in December 2011. According to Symphony Health Solutions, the U.S. OAB market value was about $3.2 billion in 2014. In July 2011, we licensed our oxybutynin gel 3% product to Actavis for commercialization in the U.S.. The product was approved

Table of Contents

by the FDA in December 2011 and in April 2012 we announced, with Actavis, the launch of Gelnique 3% in the U.S. Actavis is currently marketing Gelnique 3% along with Gelnique 10% with a large sales force focused on urologists. Gelnique has not experienced the patient acceptance originally anticipated and is a small product in this field. We receive royalties on net sales of both Gelnique 3% and Gelnique 10%.

Elestrin®

Elestrin® is a transdermal estradiol gel for the treatment of moderate-to-severe vasomotor symptoms associated with menopause. According to Symphony Health Solutions, the U.S. hormone replacement market, including estrogens, progestogens, and estrogen-progestogen and estrogen-androgen combinations, was $3.2 billion in 2014. According to industry estimates, approximately six million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone therapy. Elestrin®, which is currently being marketed by Meda as an estrogen replacement gel for the treatment of hot flashes, has been steadily growing month over month but is still a relatively small product in this market. We receive a single digit royalty from Meda on the net end sales of Elestrin®.

Nestragel (Contraception)

According to IMS Health, a healthcare information, services and technology company, the U.S. contraceptives market in 2014 was $5.8 billion. Oral contraceptives account for the majority of the market with the remainder consisting of hormonal implants and patches, injections and intra-uterine systems. Transdermal contraceptive systems potentially provide women an attractive alternative to the pill by offering convenience and discretion. The Company has a development agreement with the Population Council, an international, nonprofit research organization, to develop a novel hormonal contraceptive comprising a combination of the progestin Nestorone® and a form of estrogen, called 17b-estradiol (E2), which is chemically identical to the naturally occurring estrogen. This combination was chosen because of its potential for offering a superior tolerability and safety profile compared to other commonly used hormonal contraceptives. Nestorone is a novel synthetic progestin that has been shown to be effective at stopping ovulation at a low dose. It is not active when taken orally and is therefore especially appropriate for topical application.

We have a joint development agreement with the Population Council to develop a contraceptive formulation product containing Nestorone® using the Population Council s patented compound and other proprietary information covering the compound, and our transdermal delivery gel. We are responsible for research and development activities as they relate to the gel and the Population Council will be responsible for clinical trial design development and management. Together, we are looking for a commercial development partner to complete the development of this product.

Technology and Product Platforms

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

Disposable (Vibex®) Injectors

A significant challenge beyond discovery of new molecules is how to effectively deliver them by means other than conventional needle and syringe. The majority of these molecules have not, to date, been amenable to oral administration due to a combination of several factors, including breakdown in the gastrointestinal tract,

fundamentally poor absorption, or high first pass liver metabolism.

Pressure assisted auto injection is a form of parenteral drug delivery that continues to gain acceptance among the medical and patient community. Encompassing a wide variety of sizes and designs, this technology operates by using pressure to force the drug, in solution or suspension, through the skin and deposits the drug into the subcutaneous tissue. We have designed disposable, pressure assisted auto injector devices to address acute and chronic medical needs, such as rheumatoid arthritis and psoriasis, allergic reactions, migraine headaches, acute pain and other undisclosed therapies. Our proprietary Vibex® disposable auto injector systems combine a spring-based power source with a shielded needle, which delivers up to 0.5 ml of the needed drug solution subcutaneously or intramuscularly.

Table of Contents

In order to minimize the anxiety and perceived pain associated with injection-based technologies, the Vibex® system features a triggering collar that shields the needle from view. The patented retracting collar springs back and locks in place as a protective needle guard after the injection, making the device safe for general disposal. In clinical studies, this device has outperformed other delivery methods in terms of completeness of injection and user preference, while limiting pain and bleeding. A summary of the key competitive advantages of the Vibex® system is provided below:

Competitive Advantages of Vibex® Disposable Injectors

Rapid injection

Eliminates sharps disposal

Ease of use in emergencies

Reduces psychological barriers since the patient never sees the needle

Reliable subcutaneous or intramuscular injection

Designed around conventional pre-filled syringes

The primary goal of the Vibex® disposable pressure assisted auto injector is to provide a fast, safe, and time-efficient method of self-injection. This device is designed around conventional single dose pre-filled syringes, which is a primary drug container, offering ease of transition for potential pharmaceutical partners. We have signed two license agreements with Teva for our Vibex® system. One of these agreements is for a product containing epinephrine and the other is for sumatriptan. We also developed the Medi-Jet auto injector, based on the Vibex® system, for delivery of methotrexate (OTREXUP) for treatment of RA, pJIA and psoriasis.

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

Disposable Pen Injector System

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Needle-Free Injectors

Needle-free injection combines proven delivery technology for molecules that require parenteral administration with a device that eliminates the part of the injection that patients dislike the needle. Improving patient comfort through needle-free injection may increase compliance and mitigate the problem of daily injections. Needle-free delivery eliminates the risk of needlestick injuries as well, which occur frequently in institutions in the U.S., and can result in disease transmission to healthcare workers. One of the primary factors influencing development in the

Table of Contents

category of needle-free injection is the inherent problematic dependence on needles. It is also recognized that greater willingness to accept injection therapy could have a beneficial impact on disease outcomes. However, needle-free devices may be commercially limited due to the high cost of the product and the need for consumable disposables.

Research and Development