Zacks Small-Cap Research

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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Antares Pharma, Inc. (ATRS - NASDAQ)

Multiple "Shots" on Goal; Initiating with $3.30 Target.

Based on our DCF model and a 15% discount rate, ATRS is valued at approximately $3.30 per share. Our model applies a range of probabilities for ANDA and sANDA approval and eventual commercialization.

Current Price (11/11/2016)	$1.87
Valuation	**$3.30**

INITIATION

Antares Pharma is a specialty pharmaceutical company that develops and commercializes self-administered parenteral pharmaceutical products and technologies. The company has developed strategic alliances with several leading pharmaceutical companies to use their drug delivery systems to enhance their partners' drug compounds and delivery methods.

ATRS develops and manufactures novel, pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. Currently, Antares has five marketed products and six products in development.

At the current price, we view Antares shares as undervalued, with substantial upside given the growth expected in current products and near-term launch of several others. We initiate with a target price of $3.30 per share and believe that expansion of their relationship with Teva and AMAG can provide additional upside to our valuation.

SUMMARY DATA

52-Week High	**1.91**
52-Week Low	**0.67**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**833,444**
Shares Outstanding (mil)	**155.1**
Market Capitalization ($mil)	**290.0**
Short Interest Ratio (days)	**3.23**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**28.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**23.4**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$8.3 A	$14.4 A	$11.1 A	$11.8 A	$45.7 A
2016	$12.3 A	$12.2 A	$13.5 A	$12.8 E	$50.9 E
2017					$52.1 E
2018					$97.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.05 A	-$0.01 A	-$0.04 A	-$0.04 A	-$0.14 A
2016	-$0.05 A	-$0.04 A	-$0.04 A	-$0.04 E	-$0.16 E
2017					-$0.09 E
2018					$0.08 E

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INITIATING COVERAGE

We are initiating coverage of Antares Pharma, Inc. (NASDAQ: ATRS) with a $3.30 price target based on our estimates for a rollout of six new products over the next three years and growth of current portfolio assets. Antares has developed a suite of drug injection devices that it provides to pharmaceutical partners in the delivery of generic and branded drug products. The company has internally developed products that are currently marketed and a pipeline of additional injectors for which an NDA, ANDA or sANDA is in development or has been submitted to the FDA. We see a strong growth trajectory from new and existing injectors as well as collaborations with additional partners that may nearly double the level of current revenues by 2018.

The company's wholly-owned product, Otrexup, was launched in February 2014 and is currently growing at a double digit rate. Other products with current sales include Vibex sumatriptan for treatment of migraines with partner Teva, and several royalty and licensing deals. The pipeline is full with internally developed Vibex QS T for low testosterone and generic launches of epinephrine, exenatide and teriparatide injection with partner Teva and improved delivery for Makena with AMAG. Antares primary role in the collaborations is to provide the injection delivery devices for use with partner drug product.

The company's proprietary suite of injectors have several advantages relative to needle and syringe and other injectors. The Vibex line provides for a rapid injection with reliable dosing for subcutaneous or intramuscular administration. No sharps disposal is needed due to the retractable needle and the injector is patient-friendly as fine gauge needles are used and the needle remains hidden until it injects. The design of the auto-injector is adaptable to conventional pre-filled syringes and can be easily used in emergency situations, providing a versatile product for use with new medicines from both current and new partners.

As of September 30 2016, Antares held approximately $31.8 million in cash on its balance sheet and expects to burn near $6 million per quarter in development and operational costs. The company currently holds sufficient cash to operate the company until year-end 2017. We believe that growth from current marketed products and launches of new products will result in substantially lower cash burn in 2017.

Based on the current products that already have sales and the new pipeline products in development, we anticipate modest growth until 2018, when several generics are expected to launch driving a more than doubling of revenues. We also anticipate that Antares will begin to generate positive annual earnings in 2018 and grow both topline and earnings at double digit rates for the years following. Continued sales improvement for Otrexup, launch of QS T and the generic injectable EpiPen, exenatide, teriparatide, as well as the Makena injectable over the next two years are all impetus for sales and earnings growth. These products are in various stages of development and are entering markets of approximately $6 billion in sales, of which we expect ATRS will gain a material market share along with its partners.

Given the large potential market for current and pipeline products, we have a favorable view on the shares of Antares Pharma and initiate with a target price of $3.30.

INVESTMENT THESIS

Antares Pharma has developed a suite of pen and autoinjectors for use with internally and partner-developed pharmaceutical products. This include both generic and 505(b)(2) medicines. Currently, Antares has three injectors that are currently marketed and six products in development. Two of the company-marketed products have recently been launched and are in the early stages of growth. Products in development should provide substantial growth over the next five years, driving material topline growth and substantial margin improvement.

The company's line of auto injectors provide ease of use and many other characteristics which improve drug delivery, patient compliance, efficacy and rapidity of drug action. With an emphasis on narrow bore needles and needle-free injectors, Antares' products are in most cases painless and eliminate a psychological hurdle for many young patients and those averse to needles.

Key reasons to own ATRS shares:

- **Growth and improving margin profile for Otrexup**
- **Approval and first sales of fully-owned QuickShot TRT over next year**
- **Launch of generic EpiPen with partner Teva in 2018**
- **Launch of generic injectable Byetta (exenatide) and Forteo (teriparatide)**
- **Launch of injectable Makena for pre-term birth**

In the following sections we provide additional detail regarding Antares' products and pipeline and further elaborate on the etiology of the diseases addressed by the company's portfolio of products. The report also discusses Antares' strategy and manufacturing process for its suite of auto injectors.

COMPANY BACKGROUND

Summary of Products

Otrexup

Otrexup is the company's proprietary methotrexate injection which is intended for adults with severe, active rheumatoid arthritis (RA), and children with active polyarticular juvenile idiopathic arthritis (pJIA), after treatment with other medicines including non-steroidal anti-inflammatory (NSAIDS) have been used and did not work well. The injection is also used to control the symptoms of psoriasis after the failure of other treatments.



Sumatriptan

In conjunction with Teva Pharmaceutical (NYSE: TEVA), Antares launched generic Imitrex in June 2016. Sumatriptan injection is intended for treatment of migraine headaches and was first approved as an oral therapy. Improved bioavailability, absorption and more rapid onset of action supported the development of an injectable format.



Zoma Jet

ZOMA-Jet is a needle-free injector for use with human growth hormone (somatropin). Somatropin is not taken orally as the digestive system reduces bioavailability to ineffective levels. Antares provides the injector for partner Ferring, who is responsible for marketing the drug in the EU and Asia Pacific and by JCR in Japan. The device can administer injectable drug by employing a spring to push the active ingredient in solution or suspension through a microfine 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. Zoma-Jet is particularly effective for individuals who are averse to needles, such as children, patients starting an injection treatment program and those who are allergic to metal. The device is reusable, and can be used for 3,000 injections, or approximately two years.



Vibex

Vibex is Antares' flagship product and is currently used for OTREXUP administration and a version of which will be used for Teva's EpiPen when marketed. The device has a fixed injection volume of between 0.2 and 1.0 ml and is used in both subcutaneous and intra-muscular injections. The primary container is a 1.0 ml long prefilled syringe.



Vibex Push Button

The Vibex Push Button builds on the Vibex platform and adds a push button to the standard injector. This is a fixed dose product that is used for Teva's sumatriptan. As with Vibex, this is a 0.2 to 1.0 ml volume injector used for subcutaneous and intramuscular administration.



Vibex Variable Dose

The variable dose model allows the patient to select the dose by using a rotating dial on the end of the injector. The prefilled syringe has a capacity of 0.2 to 1.0 ml and in used for subcutaneous and intramuscular administration.



QuickShot™

The QuickShot auto-injector provides a fixed dosage of viscous and aqueous formulation medicines. QuickShot is used for testosterone therapy (QS T) and the as yet unannounced new product in development (QS M) for a central nervous system (CNS) indication.



BigShot

The Big Shot auto-injector is similar to the QuickShot product, but provides a larger capacity of 1.0 to 2.25 ml.



Multi-Dose Pen

The multi-dose pen is a pen-injector that administers a fixed dose of drug. The injection volume ranges from 0.02 to 3.0 ml and it is only intended for subcutaneous use. The primary container consists of a 1.5 ml or 3.0 ml cartridge, or dual chamber cartridge. The multi-dose pen will be used with future launches of teriparatide and exenatide.



Needle Free

The needle free device provides a novel administration technique which uses a high pressure stream of medicine to penetrate the skin. This method provides a more dispersed distribution of medication and also eliminates the needle which benefits needle-averse patients. Needle free injectors are used with partner JCR and Ferring for distribution of human growth hormone in a variety of markets worldwide.



Disease Areas:

Hypogonadism

Hypogonadsim, also known as andropause, is manifested in lower production of sex hormone, or testosterone, in males which results in reduced sex drive, sexual dysfunction, depression, weight gain and fatigue among other symptoms. There are two types of hypogonadism: primary and secondary. The primary type is due to a problem with the testicles and the defect is inherent within the gonad. The secondary type is related to a problem in the hypothalamus or pituitary gland. These areas in the brain produce hormones that signal the production of testosterone in the body.

Testosterone is important for the development and maturation of the male reproductive system, muscle growth and bone density. Testosterone in the body enters cells and activates a network of proteins that result in metabolic conversions. If there is a problem with the testicles, hypothalamus or pituitary gland, and testosterone production is reduced, then testosterone replacement therapy (TRT) may be an appropriate treatment.

Testosterone Market

Testosterone therapy has been used for more than 70 years and research in the 1990s found that there was an inverse relationship between age and testosterone production.

Intramuscular injections of testosterone enanthate were the most common therapy 25 years ago, but this changed in the early 2000s as gels and patches were used, each with their own costs and benefits. In more recent years, formulations were improved and numerous new products entered the market in gel form, injections and patches. There are also several oral formulations currently in development from Repros Therapeutics (NASDAQ: RPRX), Clarus Therapeutics (Private) and Lipocine (NASDAQ: LPCN).

Injectable testosterone replacement therapy (TRT) has been growing as a proportion of the total in recent years given the benefits of the injection over other methods of administration. According to Symphony Health Solutions, the injectable TRT market grew by almost 12% to $237 million in a two-year period ending in 2015. Most injections now are performed in a physician's office with a vial, 19 gauge needle and syringe given deep in the muscle tissue of the buttocks every two to four weeks.

According to researchers at Boston University, hypogonadism affects four to five million men in the United States.[1] An article in Forbes magazine cited[2] a population of 13 million men who experience low testosterone and the Urology Care Foundation[3] found that hypogonadism affects about 40% of men over 45. In response, TRT is given to men to bring testosterone levels back into their normal range and improve strength and bone density as well as reduce fat mass.

Due to direct to consumer marketing, the testosterone market grew to peak sales of $2.3 billion in 2013 with over 10 distinct products on the market. However, in 2014 the EMA and FDA raised concerns about the relationship between testosterone and polycythemia,[4] which places the patient at increased risk of thrombus or clot formation leading to strokes, heart attacks, pulmonary embolism, and possibly death. These concerns led to a reduction in marketing and calls for additional studies to be performed on TRT, tempering sales.

However, a later study published in 2014 and funded by the NIH did not find any link between testosterone use and heart attack. The study included more than 25,000 Medicare beneficiaries using testosterone for up to eight years. For comparison, it included a control group that included men of the same age, race, Medicaid eligibility and health status that did not use testosterone. This was a cross-sectional study, and further controlled trials may be necessary before there is a high degree of confidence in the relationship between testosterone use and cardiovascular risk.

In response to the growth in injectable TRT, and to address several of the shortcomings of the in-office, intramuscular procedure, Antares is pursuing a once-weekly autoinjection which employs a fine needle and subcutaneous administration. Antares QS T has advantages compared to the current injection process allowing for

[1] Prevalence, Diagnosis and Treatment of Hypogonadism in Primary Care Practice. Culley C. Carson III, M.D., Boston University School of Medicine.
[2] Growing An Empire On Low Testosterone. Karsten Strauss, Forbes Staff. May 3, 2013
[3] http://www.urologyhealth.org/urologic-conditions/low-testosterone-(hypogonadism)
[4] Polycythemia is defined as an abnormally increased concentration of hemoglobin in the blood, through either reduction of plasma volume or increase in red cell numbers.

self-injection and less pain. The ability to inject at home also allows for potentially more frequent dosing at lower levels in order to maintain steady testosterone levels throughout the week.

According to IMS health data,[5] gels comprise the majority of category sales, with Abbvie's AndroGel making up over half of the total. Despite this leading position, gels have several drawbacks, including accidental exposure to women or children family members and inconvenient and messy application. The gel application is also time consuming, as the individual must wait for the gel to dry before getting dressed. Injectable solutions have been increasing in importance; however, this in many cases requires a visit to the doctor's office for a painful, intramuscular injection. Antares' solution uses a small gauge, almost painless needle for its auto-injection technology, which allows the patient to quickly perform the procedure by himself without potential risk of transference to family members.

Antares' Phase 3 Study

Antares completed a Phase 3 study (QST-13-003) which was completed in February 2015 and provided positive top line data and achievement of the primary endpoint. The study had a population of 150 subjects of which 137 completed the study. The FDA guidelines call for 75% of the population to have a C_{avg} between 300 and 1100 ng/dL, and Antares' study showed a 98.5% success rate for completers. The FDA guidance also seeks greater than 85% of the population have a C_{max} of less than 1500 ng/dL and the study achieved a 100% rate below this threshold for completers.

Exhibit I – Summary of QST-13-003 Study Results vs. Protocol Outcomes

Population/Analysis	C_{avg} Lower limit of the 95% 2-sided C. I.	C_{avg} % in Range 300 – 1100 ng/dL n (%)	C_{max} <1500 ng/dL n (%)	C_{max} >1800 ng/dL n (%)
Primary analysis* N=150	87.3%	139 (92.7%)	137 (91.3%)**	0%
Completers N=137	94.8%	135 (98.5%)	137 (100%)	0%
Protocol-Required Outcomes	≥65%	75%	≥85%	≤5%

* All patients with 1 or more doses, C_{avg} 0-168 hours post week 12 injection or last measured concentration carried forward
**Patients without a C_{max} determination at week 12 are assigned above 1500 ng/dL

The FDA requested that Antares conduct and additional study following the Phase 3 trial, subsequently named QST-15-005 to take a further look at safety and tolerability. This study consists of a screening phase, a treatment titration phase, and a treatment phase for evaluation of safety and tolerability assessments.

On September 22, 2016, Antares announced the completion of the QST-15-005 clinical program noting four patients with serious adverse events in the 133 patient panel. Only one of the serious adverse events, deep vein thrombosis, was associated with the testosterone therapy and is consistent with known adverse events. No hives, pulmonary oil micro-embolism or anaphylaxis was noted. Pain was minimal with only one report of mild pain out of 965 injections. ATRS currently anticipates filing its 505(b)(2) NDA before the end of the year 2016.

Migraine and Cluster Headache

A migraine is an intense headache that can last from a couple hours to several days. Pain is exacerbated by physical activity and individuals may also suffer from nausea, vomiting and sensitivity to light, sound or smell. Research suggests that migraines come from both genetic and environmental factors and it is thought that changing hormone levels may influence their onset. Abnormal brain activity and alteration in nerve signals, chemicals and blood flow to the brain are other supposed causes. Sometimes triggers for the conditions can come from foods,

[5] As of December 2015

sensory stimuli, hormonal fluctuations or stress. In many cases, migraines and cluster headaches can be debilitating and intensely painful, prompting the sufferer to aggressively seek relief.

According to the American Migraine Foundation, approximately 36 million or 12% of the population suffer from migraines with the majority of sufferers being women. In about one third of cases, a migraine is preceded by an aura, which are visual and sensory distortions prior to the onset of the pain. Nausea is a common feature among migraine sufferers and can be intensified by physical activity or sensory stimulation.

Treatment

Treatment with medications for migraines includes analgesic and triptan classes of drugs. Analgesics are oral non-specific pain medications that don't require prescriptions, while triptans are migraine specific, require a prescription and can be administered either orally, nasally or injected. Seven different triptans are available, including almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan.

Triptan Method of Action

Triptans have an agonist effect on serotonin 5-HT or 5-hydroxytryptamine (5-HT). 5-HT is a chemical found in the brain and other parts of the body and works by attaching to specific sites (receptors) on various cells of the body. Once bound to these receptors it creates a set of reactions within the cells including causing blood vessels to narrow (constrict). It is thought that this constriction may counteract some of the activity during a migraine and may stabilize the change in activity of some brain chemicals.

Triptans should be administered during a migraine attack, as there is evidence that taking a triptan too early in a migraine attack may be less effective. Therefore, it should be taken as migraine is developing. In situations where timing of drug administration and onset of action are critical, injections are preferred, as they are almost immediately bioavailable as compared to an oral drug, which must first pass through the GI system. Of the triptans, sumatriptan is the most seasoned, receiving approval in 1991 and used widely.

Rheumatoid Arthritis (RA)

RA is an autoimmune disease that affects joints which is believed to be caused by a variety of genetic and environmental factors. It is the most common type of autoimmune arthritis that affects the wrist and small joints of the hands, including the knuckles and middle joints of the fingers. It is triggered by the body's immune system which attacks the joints causing inflammation and thickening of the joint capsule. Approximately 1.3 million individuals in the United States have RA with women comprising 75% of the total. The disease frequently affects individuals from their fifth to seventh decade of life, becoming more common with increasing age. Both genetic and environmental factors contribute to rheumatoid arthritis, with smoking being the most common environmental factor.

Symptoms

RA is a chronic disease that can cause pain, stiffness, swelling and limited motion, which may last for several hours after waking up in the morning. Other signs of RA include:

- Loss of energy
- Low fever
- Loss of appetite
- Dry eyes and mouth from a related health problem
- Nodules which grow under the skin near joints such as the elbow and hand

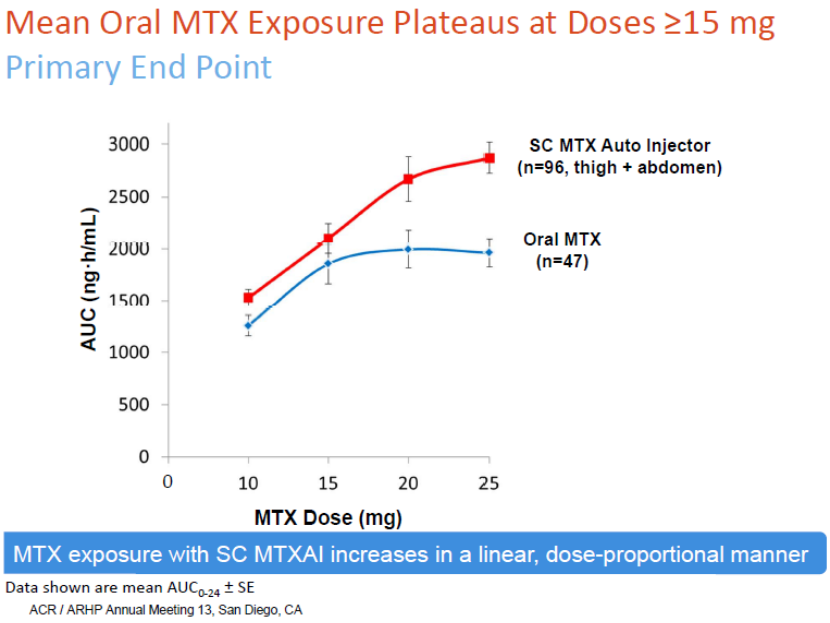
Treatment

A class of medications known as disease-modifying antirheumatic drugs (DMARDs) are used as first line therapy for RA and have been used to slow its progression. This class includes both biologics and small molecule medicines which are able to stall or slow the progression of the disease. The most widely used DMARDs include methotrexate, leflunomide, hydroxychloroquine and sulfasalazine. These are frequently used in combination with other drugs such as nonsteroidal anti-inflammatory drugs (NSAIDs).

The primary therapy used in the initial control of RA is oral methotrexate. Methotrexate, as a folic acid antagonist, blocks the synthesis of purines and pyrimidines by inhibiting several key enzymes. This action reduces cell

proliferation, and has immunosuppressive effects in RA. Some patients do not exhibit an adequate response with oral methotrexate and seek a parenteral solution. Intramuscular (IM) or subcutaneous (SC) administration of methotrexate avoids several side effects, such as gastrointestinal discomfort, nausea, vomiting and stomach pain. Subcutaneous administration also results in improved bioavailability. At lower dose levels, from 10 to 15 mg administered once a week, methotrexate is about 70% bioavailable, however at doses above 15 mg, oral methotrexate plateaus in the plasma at just below 2,000 ng*h/ml as illustrated in the following exhibit.

Exhibit II – SC vs. Oral Methotrexate Concentration



For RA patients who are having problems of efficacy at higher doses of oral methotrexate, a switch to SC may provide continued disease control and delay the need for biologic therapy due to the greater linear response between dose and plasma concentration for the injected therapy. A number of studies were conducted that demonstrated auto injected methotrexate is safe and well tolerated.

A benefit from maintaining methotrexate use longer for RA is overall reduction in treatment costs. A study conducted in the UK found that using SC methotrexate (MTX) after the failure of oral MTX would save more than £9 million (more than $15 million in US currency) annually in new patients. In the United States, currently it is estimated that fewer than 5% of methotrexate patients are using parenteral drug administration, suggesting material upside in penetration if the economic argument can be made to payors, patients and physicians.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Juvenile Idiopathic Arthritis is the most common type of arthritis in children with six subtypes, including polyarticular juvenile idiopathic arthritis (pJIA). The polyarticular version causes inflammation in five or more joints, usually in the joints of the hands, but it may also present itself in larger joints as well including the jaw. Based on data provided by the Arthritis Foundation, nearly 300,000 children have arthritis, and one in 1,000[6] children have JIA, suggesting that approximately 72,000 individuals between birth and age 18 are afflicted. 25% of those afflicted with JIA suffer from the polyarticular form.

First line treatment for pJIA is use of non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injections. Methotrexate is a second line treatment which helps suppress joint inflammation in the majority of pJIA

Psoriasis

Psoriasis is an autoimmune disease that is characterized by red, itchy and scaly skin. It generally affects the outside of the elbows, knees or scalp, but can appear anywhere. Sufferers report that psoriasis is itchy, burns and stings. Psoriasis is associated with other serious health conditions, such as diabetes, heart disease and depression

[6] William C. Shiel Jr., MD, FACP, FACR, Ed. "Juvenile Rheumatoid Arthritis"

and is thought to have a genetic cause triggered by environmental factors. Psoriasis is most common in Caucasians, affecting 3.6% of the population and 1.9% of African-Americans.[7]

The disease is characterized by excessive and rapid growth of the epidermal layer of the skin which presents itself as psoriasis lesions. Excessive production of skin cells, especially after healing from a wound, are the product of the disorder and skin cells regenerate every 3 to 5 days, rather than the more common 28 to 30 days. Immune cells are thought to move from the dermis to epidermis and secrete inflammatory cytokines which in turn causes the predominant cell type in the epidermis (kerotinocyte) to proliferate.

Treatment options for psoriasis includes steroid creams, vitamin D3 cream, ultraviolet light and immune suppressing drugs such as methotrexate. In a person with psoriasis, methotrexate binds to and inhibits an enzyme involved in the rapid growth of skin cells and slows their proliferation.

Anaphylaxis

Anaphylaxis is an allergic reaction to a number of specific allergens or allergic triggers. There are many symptoms that result including itchy rash, throat or tongue swelling, shortness of breath, vomiting, lightheadedness among others that start within minutes to hours after the exposure to the allergen. Some common triggers include peanuts, other kinds of nuts, wheat, fish, shellfish, milk, eggs or insect stings.

If an individual is allergic to a substance or antigen, the immune system overreacts by releasing chemicals that cause symptoms, also called inflammatory mediators. Immunoglobulin E binds to the antigen, which in combination activates FcεRI[8] receptors on mast cells and basophils. This, in turn stimulates the release of histamine which initiates contraction of airways and vasodilation. Increased fluid leakage from blood vessels and heart muscle depression may also occur.

Treatment

If an individual is exposed to an allergen, and begins to show a negative response, timely treatment is necessary. Epinephrine, which is equivalent to adrenaline, is the only first line treatment for anaphylaxis and is injected intramuscularly for rapid absorption. The label recommends that the drug be injected into the outer thigh, with a second injection advocated if there is an insufficient response.

Method of Action

Epinephrine is equivalent to the naturally created hormone adrenaline. It is normally produced by both the adrenal glands and certain neurons, with a fundamental role in the fight-or-flight response. The hormone increases blood flow to muscles, output of the heart, pupil dilation, and blood sugar by stimulating alpha and beta receptors.

Market

Currently, Mylan (NYSE: MYL) holds the majority of the IM injectable epinephrine market, with near $1 billion in annual sales and over 90% share. There are some competitors to EpiPen, but they have had trouble gaining a foothold. The primary competitor, Sanofi's Auvi-Q, was withdrawn in October 2015 due to dosage problems, but may return in 2017.[9] A second device, the Adrenaclick, only holds a very small portion of market share according to data from IMS Health due to supply problems. Since Adrenaclick isn't considered to be therapeutically equivalent to the EpiPen, it can't be substituted by a pharmacist when filling a prescription.

In mid-August this year, as parents and students were gathering supplies for back to school,[10] several media reports emerged, highlighting the high cost of EpiPens. Due to an approximate one-year shelf life, many families purchase a set of pens for children at the beginning of the school year. Purchasers and media alike were surprised by the 30% year over year price increase to over $600. As a result of the material shift to high deductible health care plans in recent years, more families were absorbing the full retail cost of the pens, giving ammunition to politicians and media alike to target the issue. As the consumer and media uproar crescendoed regarding the high price of Mylan's EpiPen, Mylan elected to launch an authorized generic. The focus on the lack of a generic

[7] www.psoriasis.org
[8] Fc epsilon RI is the high-affinity receptor for the Fc region of immunoglobulin E (IgE), an antibody isotype involved in the allergy disorder and parasites immunity.
[9] http://www.nytimes.com/2016/10/27/business/an-epipen-rival-is-about-to-return-to-the-shelves.html?_r=0
[10] Epinephrine injector sales are seasonal with peak sales occurring at the end of the summer and beginning of the fall.

competitor may also increase the scrutiny of the FDA and its process for approving generics potentially helping with a focused and timely review of Teva's application.

Vibex Epinephrine Injector

Teva and Antares have been working for many years to obtain approval for a generic epinephrine injector. The duo initially applied to market a generic EpiPen in 2009, and the patent holders subsequently filed suit. In 2012, the patent holders, including Mylan came to an agreement with Teva and Antares that allowed for first sales in 2015, pending FDA approval. However, in January 2015, Mylan filed a citizen's petition regarding Teva's generic. While the citizen's petition was ultimately rejected, the effort delayed the FDA's review of the ANDA by six months. In March 2016, the FDA issued a complete response letter (CRL) to Teva and Antares, highlighting several major deficiencies. Currently, Teva and Antares are in discussions with the FDA addressing the issues raised in the CRL. We anticipate that the resubmission for the EpiPen generic ANDA will be occur early next year, followed by a second half 2017 approval and ultimate sales in 2018.

Osteoporosis

Osteoporosis is a disease where bone loses its density as the body reabsorbs old bone and creates new bone. The name is from the Greek πορώδη οστά for porous bones. As we age, and without sufficient mineral levels in the body, the insides of bone become increasingly porous due to the loss of calcium phosphate. As a result of this process, the bones are brittle and prone to fracture or breakage. One of the causes of decreased bone mass is a reduction of hormones (estrogen in women and testosterone in men) circulating in the body as a result of aging or other factors. Other non-modifiable risk factors include being female, Caucasian or Asian. Having a family history of osteoporosis and a slender build are other factors which contribute. Modifiable risk factors include excessive alcohol consumption, smoking, insufficient calcium and vitamin D, and a variety of medications including steroids among others.

Treatment

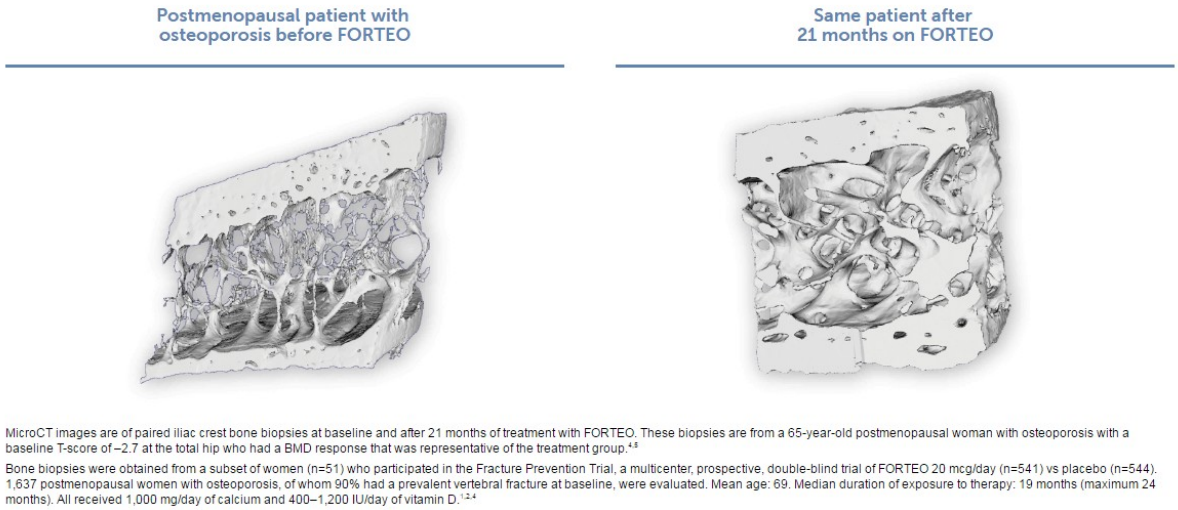
If a patient is diagnosed with osteoporosis, the most widely prescribed medications are bisphosphonates. Some of the commonly prescribed examples in this class include alendronate, risedronate, ibandronate and zoledronic acid. Bisphosphonates inhibit the reabsorption of bone by encouraging osteoclasts to undergo apoptosis, or cell death, thereby slowing bone loss. Hormone therapy is another common approach to treating the disease; however, there are many side effects, some of them serious. If bisphosphonate or hormone therapy has intolerable side effects or is ineffective, then other options such as denosumab or teriparatide may be used.

Teriparatide (brand name Forteo) is similar to parathyroid hormone[11] and stimulates bone growth by increasing serum calcium and increasing bone reabsorption. Fluctuating levels of teriparatide will stimulate osteoblasts[12] more than osteoclasts,[13] thus incentivizing new bone formation. The drug is injected on a daily basis under the skin and comes in a pre-metered dose pen with 28 days of medication. Teriparatide cannot be used indefinitely, and after approximately two years of therapy, the patient must be switched to another drug to maintain effectiveness[14] as the therapy initially contributes to maintaining bone density, but its impact diminishes over time.[15]

Teriparatide was first approved in November 2002 and indicated for the treatment of osteoporosis in postmenopausal women and to increase bone mass in men with primary or hypogonadal osteoporosis.

[11] Parathyroid hormone is a mediator between levels of calcium between the blood and the bones. Disrupting the hormone can prevent the body from taking calcium from the bones.
[12] Osteoblasts are cells that synthesize bone.
[13] Osteoclasts are a type of bone cell that breaks down bone tissue.
[14] http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21318s004lbl.pdf
[15] https://www.ncbi.nlm.nih.gov/pubmed/19401368?dopt=abstract

Exhibit III – Teriparatide (Forteo) Impact on Bone[16]



MicroCT images are of paired iliac crest bone biopsies at baseline and after 21 months of treatment with FORTEO. These biopsies are from a 65-year-old postmenopausal woman with osteoporosis with a baseline T-score of –2.7 at the total hip who had a BMD response that was representative of the treatment group.[4,5]

Bone biopsies were obtained from a subset of women (n=51) who participated in the Fracture Prevention Trial, a multicenter, prospective, double-blind trial of FORTEO 20 mcg/day (n=541) vs placebo (n=544). 1,637 postmenopausal women with osteoporosis, of whom 90% had a prevalent vertebral fracture at baseline, were evaluated. Mean age: 69. Median duration of exposure to therapy: 19 months (maximum 24 months). All received 1,000 mg/day of calcium and 400–1,200 IU/day of vitamin D.[1,2,4]

Earlier this year Teva filed a Paragraph IV certification for Teriparatide, which is marketed by Eli Lilly (NYSE: LLY). On March 16, 2016, Lilly filed a lawsuit in response to the Paragraph IV filing, beginning the 30 month stay. Revenues for Forteo, according to Lilly's 2015 annual filing, were $736 million outside the U.S. and $612 million in the United States, which on a global basis increased 2% over the prior year.

Diabetes Mellitus Type 2

Type 2 diabetes (DM2) is a long-term metabolic disorder characterized by high blood sugar, insulin resistance, and relative lack of insulin. In the beginning stages of the disease, the pancreas manufactures extra insulin to compensate for low insulin levels. However, as the disease progresses, the pancreas cannot produce sufficient insulin to maintain normal blood glucose levels. DM2 is a chronic disease that exhibits symptoms including polyuria, polydipsia, polyphagia and weight loss. This disease causes polyuria through osmotic diuresis, due to the high blood sugar leaking into the urine, carrying excess water along with it.

Treatment for mild DM2 can be as simple as exercise and diet changes. However, in more severe forms of the disease, behavioral changes are augmented with oral medications or insulin. Oral metformin is the first line treatment, and if it fails, other classes are considered, including glucagon-like peptide-1 (GLP-1) analogs. Globally, there are five approved GLP-1 receptor agonists, including exenatide,[17] which was approved in 2005.

Exenatide is a hormone that has similar properties as the body's own GLP-1, which regulates glucose metabolism and insulin secretion. Exenatide enhances glucose-dependent insulin secretion in the pancreatic β-cell which is a critical regulator of metabolism. The drug also suppresses inappropriately elevated glucagon secretion, and slows the emptying of the stomach. Other diabetes medicines, such as injectable insulin, are effective at lowering blood sugar, but can exceed their target and cause blood sugar to become too low, resulting in hypoglycemia. Exenatide binds and activates the human GLP-1 receptor in vitro. This leads to an increase in both glucose-dependent synthesis of insulin, and in vivo secretion of insulin from pancreatic β-cells, by mechanisms involving cyclic AMP and/or other intracellular signaling pathways. Exenatide promotes insulin release from pancreatic β-cells in the presence of elevated glucose concentrations.

Byetta (exenatide injection) improves glycemic control by reducing fasting and postprandial glucose concentrations in patients with type 2 diabetes. The drug is manufactured by Amylin Pharmaceuticals, a subsidiary of Bristol Myers (NYSE: BMY) and marketed by AstraZeneca (NYSE: AZN). Exenatide injection has two formulations: Byetta and Bydureon. Byetta is a twice daily regimen and is expected to lose its intellectual property protections in 2017, at which time Teva expects to launch a generic competitor. AstraZenica is currently shifting its Byetta patients to Bydureon, which is a once-weekly injection of exenatide, modified for slow release. Pricing for Bydureon is higher than Byetta, which has resulted in a portion of the market remaining with the less expensive therapy. In 2015, total

[16] http://www.forteo.com/information-for-hcps.aspx#
[17] Exenatide is marketed at Byetta (a twice per day subcutaneous injection) and Bydureon (a once weekly injection). The drug is manufactured and marketed by Amylin Pharmaceuticals a subsidiary of AstraZeneca (NYSE: AZN).

sales[18] of Byetta were $316 million and Bydureon $580 million. We anticipate that generic exenatide injection will compete only against Byetta.

Pre-Term Birth

Normal gestation for a human child is 40 weeks. At 37 weeks and earlier, the birth is considered pre-term[19] and affects about one in ten infants born in the United States. According to CDC statistics, pre-term birth is the leading cause of death for infants in the United States, with the highest rate of loss in those born very pre-term, before 32 weeks in the womb. Early birth also can cause additional problems such as breathing difficulties, feeding complications, jaundice and neurological disabilities.

Some of the key risk factors for pre-term birth including a previous pre-term birth, pregnancy with multiples, in vitro fertilization, poor nutrition, stress or other factors, some of which may be unknown. In cases where a mother has had a singleton pre-term birth, she may be at risk for a second pre-term birth and may benefit from treatment with hydroxyprogesterone caproate injection.

Treatment

Aside from good health practices, there are a few treatments that may address pre-term birth. It is difficult to provide treatment for this condition because it is difficult to predict. In some cases, where a woman has already had an early birth, there are some therapies that can be applied. For some, a surgical procedure known as cervical cerclage can help women who develop preterm labor because of a short cervix. Cervical cerclage stitches the cervix closed during the second trimester and the stitches are removed during week 36 of the pregnancy. Bed rest is also recommended as in some cases exertion or pressure on the cervix may cause it to open before full-term is reached. Hormone treatment is also used and progesterone has been shown to reduce chances of a pre-term birth. Currently, the only FDA-approved hormone treatment for pre-term birth is Makena.

Makena

Makena (hydroxyprogesterone caproate injection) is a steroidal progestin and derivative of 17α-hydroxy-progesterone (17α-OHP) and is intended for intramuscular use. It was initially approved by the FDA in February 2011 to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered at less than 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity. The drug was approved under an orphan indication providing seven years of exclusivity, expiring in February 2018.

AMAG Pharmaceuticals (NASDAQ: AMAG) acquired Makena in 2014 in a transaction with privately held Lumara Health. Now, with less than two years of exclusivity remaining, AMAG is seeking a new formulation of Makena using an autoinjector in an effort to extend exclusivity protection further. The current formulation of Makena is a deep intramuscular injection with the most common side effects being pain and other discomfort around the injection site. Due to the viscous nature of the compound being injected, a large gauge needle was required to perform the several-minute procedure using a needle and syringe. In an effort to reduce pain, AMAG intends to switch to a subcutaneous auto-injector using a much smaller needle. The auto-injector is able to rapidly pass the medicine through the higher gauge needle due to a very strong spring that uses intense pressure to inject the compound. AMAG expects that the reduction in pain will allow for continued orphan protection and another seven years of exclusivity when the current protection expires in early 2018.

AMAG's current plans are for a 2Q:17 submission of an sNDA to the FDA followed by a ten-month review. If approved according to the anticipated timeline, the new product may be available for the market prior to the February 2018 loss of exclusivity.

[18] https://www.astrazeneca.com/content/dam/az/our-company/investor-relations/presentations-and-webcast/2016/Fourth%20quarter%20and%20Full-Year%20results%202015%20press%20release.pdf
[19] http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm

Zomajet

Antares has a relationship with Ferring Pharmaceuticals, a private New Jersey-based pharmaceutical company with a global reach throughout Europe, China and India. Antares manufactures the Zoma-jet needle free injector for Zomacton (somatropin) injection, indicated for children with growth failure due to inadequate normal growth hormone. Currently Zomajet is marketed in Japan by JCR Pharmaceuticals (TYO: 4552) and in the EU by Ferring. The drug's current status in the US regulatory process has not been recently detailed by Ferring.

Elestrin

Elestrin (estradiol gel) is a gel product manufactured by Meda Pharmaceuticals, which was recently acquired by Mylan in August of this year. The product is indicated for treatment of moderate to severe vasomotor symptoms (hot flashes) due to menopause and is delivered in a metered pump dose. Antares receives royalty revenues from sales of Elestrin which began after the company entered into a license agreement in December 2009.

Gelnique

Gelnique (oxybutynin gel) is bladder relaxant used to control interactive bladder with symptoms of urge urinary incontinence, urgency and frequency. Gelnique is manufactured and marketed by Allergan (NYSE: AGN). Antares receives royalty revenues from Allergan for sales of Gelnique.

Chemistry, Manufacturing and Controls

In the approval process, the FDA places substantial weight on chemistry, manufacturing and controls (CMC) and a large proportion of complete response letters that are issued are related to deficiencies found in this area. Where Antares is supplying the injector for a partner who submits a new drug application, the partner performs both and administrative and on-site review to ensure that there are no obvious issues (such as an FDA warning letter) that might prevent approval. In cases where Antares is leading the new drug application (Otrexup and QS T for example), Antares performs its own administrative and on-site pre-inspection for manufacturing, testing, and supply partners prior to submission. This effort is taken to reduce the likelihood that any CMC issues might hinder approval. In the exhibit below, we highlight the key third parties that supply inputs for Antares. These suppliers manufacture the components and injectors for Antares and also assemble the devices under their direction.

Exhibit IV – Antares' Third Party Partners

Third Party Partner	Action	Product
Minnesota Rubber and Plastics	Manufacture & Assemble	Needle Free Devices & Related Components
Phillips Medisize Corporation	Manufacture & Assemble	Vibex QS T, Pen, Exenatide Pen
ComDel Innovation, Inc	Manufacture	Vibex Sumatriptan
Nypro Inc.	Manufacture	Vibex Injectors
Pharmascience Inc.	Supply MTX in US and Canada	Otrexup
Sharp Corporation	Assemble & Package	Otrexup

RISKS

All investments contain an element of risk which reflects the uncertainty of the business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are betting on a new technology that has not yet even been fully defined have a much higher level of perceived risk.

The biotechnology space includes companies at both ends of the spectrum, from mega-cap pharmaceutical powerhouses that have multiple products currently generating revenues, to small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products yet.

For smaller early-stage companies, investing in drug development is an extended process. The timeframe for conducting pre-clinical research to eventually marketing a novel drug can take from 12 to 15 years or even longer given market conditions. And with, on average, only one in one thousand compounds eventually making it to the market, the risks are substantial. Generic drug launches are also risky endeavors as company's holding patents and exclusivity have many tools at their disposal to delay the launch of generic competitors. Some of these methods include a stay of proceedings when a potential generic competitor submits a Paragraph IV filing, filing a citizen's petition, development of new chemical entities, or new forms of delivery.

Even if a company has a strong, experienced team that is developing a device or therapy with a high likelihood of success and a large addressable market, securing funding may be a high hurdle to overcome. Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to access; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain a company and it is not readily available, the company in need may be forced to suspend operations, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route for progressing or force a company to accept onerous terms.

FDA or other governmental regulatory approvals are a material uncertainty to which all drugs must submit before they are legally marketed. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Isolating companies that have a long history of research success in drug development, with opinion leaders and experts in the field are key elements that can help mitigate this risk. Companies that have had previous success with the FDA or other regulatory agencies also are more attractive than those who may be new to the process. Some accelerated pathways to approval have been put forth such as the Orphan Drug Act, however, changes in sentiment or perceived safety for pharmaceuticals drugs could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place.

Currently, Antares Pharma has six products that are in development and are awaiting regulatory approval. Approval rates for ANDAs are historically very low on their first pass in front of the FDA. A Wall Street Journal article noted that generics launched in 2015 spent four years on average with the agency, and noted that only 2% of ANDAs were approved on their initial submission.[20] Ultimately, the majority are approved; however, the additional delay adds expense and reduces the period over which the product can be sold.

In recent years, contract research organizations (CROs) have taken on a larger role in the development of drug candidates as the complexity and cost of trials has increased. Finding appropriate populations to participate in clinical trials has become increasingly difficult due to the shift to personalized medicine and orphan indications that address a small population. This shift has increased the dependence on these specialized CROs for project management and clinical monitoring services which add additional risks and dependence on third parties.

Antares relies on third party manufacturers for sourcing injector parts, the injectable medicines, as well as the assembly and manufacturing of products. Risks of poor manufacturing processes, quality control issues and product delays may postpone ultimate production of the device and combination product. Additionally, the company relies on partners to submit drug and device applications to regulatory agencies, guide the product thorough the regulatory process and ultimately market it to consumers. The partner may lack the desire or skill to successfully

[20] Wall Street Journal Article "How Obama's FDA Keeps Generic Drugs off the Market," August 19, 2016

move the product thorough the regulatory process and may have other competing products under its control that receive greater company resources.

Drug price inflation has gained increased attention over the last several years and has contributed materially to the increase in health care costs over the last decades. As new therapies have been approved, drug prices have set new records and increased at a substantial rate. For example, in 1996, new cancer drugs cost roughly $54,000 for each additional year of life they provided. However, by 2013, this amount increased to over $200,000. The inflation rate for established drugs has also been very high. In a Forbes article, Novartis' leukemia drug Gleevec was highlighted. This drug cost $24,000 in 2001 when it was first approved; and 14 years later, in 2015, had risen to a cost of $90,000. This represents a 10% compound annual growth rate over that period. Other price moves such as the 5,000% price hike for Turing Pharmaceutical's Daraprim and Valent Pharmaceuticals 500% and 200% price increase for Isuprel and Nitropress last year combined with similar moves by other companies may create a situation where further increases are unsustainable. We also cite the broad response to Mylan's EpiPen price increases which have pressured the company to offer lower priced alternatives.

We highlight three risks that come from these pricing increases. First, health care may become unaffordable for a broad segment of the population, reducing the market size to a level below what we could otherwise reasonably forecast. Second, sharp price increases will attract the attention of elected officials and regulators who may create legislation and implement regulations that limit drug profitability. Third, the government may impose additional non-price related regulation and disclosure that can increase costs for the industry. We note that Antares does not have pricing discretion over many of its products and pricing for generic products are largely determined by the levels set of already existing branded products.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these eventualities and our target price reflects an assumption of these risks faced by all biotechnology companies.

COMPARABLES

There is a broad spread of competitors with Antares working in closely related spaces, the most important of which we include below.

Exhibit V – Antares Pharma Peers[21]

Ticker	Company	Price	MktCap (MM)	EV	Therapeutic Area
AMPH	Amphastar Pharmaceuticals Inc	$20.93	$964	$940	Injectable & topical products
BDSI	BioDelivery Sciences International, Inc.	$2.00	$113	$77	Buccal patch: pain and opioid dependence
BDX	Becton Dickinson	$170.36	$35	$10,246	Med devices. Rasuvo injector.
BJCT	Bioject Medical Technologies, Inc.	$0.00	$0	$0	Injectable technology. Sold to Inovio.
CSRT	Consort Medical (Bespak)	£1,085	£533	£632	Drug delivery including injection devices
LPCN	Lipocine Inc	$3.55	$66	$33	Competitor in TRT and pre-term birth
TLGT	Teligent Inc	$7.57	$447	$476	Sells injectible products
WST	West Pharmaceuticals	$77.55	$5,680	$5,709	Drug delivery components & packaging
YPSN	Ypsomed Holding, AG	CHF 178.10	CHF 2,150	CHF 2,174	Pen injector manufacturer in diabetes
Private	Owen Mumford				Injector manufacturer in UK
Private	Haselmeier				Swiss injector manufacturer

Amphastar (NASDAQ: AMPH) holds a portfolio of approximately 20 injectable and topical products competing in the specialty generic and branded over the counter market.

BioDelivery Sciences (NASDAQ: BDSY) produces a buccal film that seeks novel drug delivery in the pain and opioid dependence markets. The company is also working with partners to expand into other therapeutic areas.

Becton Dickinson (NYSE: BDX) is a large cap competitor that manufactures medical devices, instrument systems and chemical reagents. BDX's products include hypodermic needles and syringes; insulin syringes and pen needles. BDX manufactures a competing methotrexate injector called Rasuvo.

Bioject Medical (OTCMKTS: BJCT) develops needle free injectors. Bioject's physical and intellectual assets were acquired by Inovio (NASDAQ: INO) in March 2016 and they intend to use the technology for immunization injections.

Consort Medical (OTCMKTS: CSRT) develops drug delivery devices in the parenteral, nasal and ophthalmic routes of administration. Consort has a portfolio of auto-injectors that it manufactures for a wide variety of applications.

Lipocine (NASDAQ: LPCN) is developing oral solutions for the testosterone and pre-term birth markets, alternatives to Antares' QS T product and AMAG's Makena.

Teligent (NASDAQ: TLGT) markets and sells generic injectable pharmaceutical products.

West Pharmaceuticals (NYSE: WST) manufactures components that go into drug delivery systems. The company also makes packaging for injectable drugs.

Ypsomed (SWX: YPSN) is a Swiss pen injector manufacturer and emphasizes the diabetes, growth disorder and infertility markets.

Owen Mumford (Private) is a UK based manufacturer of injectors, lancets and other medical products and is focused on the diabetes, blood testing and customized devices for global partners.

Haselmeier (Private) builds a variety of injectors with manual, auto, variable and other types of operation. The company builds injectors on behalf of large pharmaceutical companies such as Merck, Sanofi-Aventis and Biocon.

[21] Price and market capitalization data is as of November 11, 2016

MANAGEMENT PROFILES

Robert F. Apple, President and Chief Executive Officer

Mr. Apple was promoted to President and CEO in January 2016 and was appointed to the Board of Directors in March 2016. Mr. Apple has over 21 years of senior leadership experience in the pharmaceutical industry focusing on operations, strategy, sales and finance. Mr. Apple joined Antares in February 2006 as Senior Vice President, CFO and Corporate Secretary and in 2009 was promoted to the position of Executive Vice President, CFO and President of the Parenteral Products Division. In September 2014, Mr. Apple was promoted to the position of Executive Vice President, Chief Operating Officer of Antares. Prior to joining the company, Mr. Apple served as Chief Operating and Financial Officer at InKine Pharmaceutical Company, Inc. from 2003 to 2005, and CFO from 1997 to 2002. From 1995 to 1997, Mr. Apple was employed by Genaera Corporation, Inc., a biotechnology company, where he held the position of Corporate Controller. From May 1994 until July 1995, Mr. Apple was employed by Liberty Technologies, Inc. as Corporate Controller. Prior to May 1994, Mr. Apple held various positions of increasing responsibility at Arthur Andersen & Company LLP. He holds a B.A. degree in accounting from Temple University and is a CPA.

Peter J. Graham ESQ., Senior Vice President, General Counsel, Human Resources, Chief Compliance Officer and Corporate Secretary

Mr. Graham joined the Company in July 2015 as SVP, General Counsel, Chief Compliance Officer, Human Resources and Corporate Secretary and has almost 20 years of legal and executive management experience in publicly and privately held pharmaceutical and medical device companies. From 2010 until 2015, Mr. Graham served as Executive Vice President, General Counsel, Chief Compliance Officer and Global Human Resources for Delcath Systems, Inc., a late stage clinical development company focused on cancers of the liver. From 2008 until 2010, Mr. Graham was Vice President, General Counsel and a member of the Executive Committee of ACIST Medical Systems, Inc., a subsidiary of Bracco, SpA., a global company specializing in cardiovascular and diagnostic imaging solutions. Prior to ACIST, Mr. Graham spent 11 years at E-Z-EM, Inc., a global medical device and pharmaceutical company specializing in CT and MR imaging solutions serving as Senior Vice President, Chief Legal Officer, Global Human Resources and Secretary. From 1997 until 2004, Mr. Graham also served as General Counsel and Corporate Secretary for AngioDynamics, Inc.(then a wholly owned subsidiary of E-Z-EM), a leading provider of interventional medical devices. Mr. Graham earned his J.D. at Yeshiva University's Benjamin N. Cardozo School of Law in 1995, and his B.A. in Political Science at the University of Wisconsin-Madison.

Fred M. Powell, Senior Vice President, Chief Financial Officer

Effective October 31, 2016, Mr. Powell was appointed SVP and CFO. Most recently, he served as Vice President and CFO for Celator Pharmaceuticals, which was a public biopharmaceutical firm engaged in the development of a portfolio of cancer therapies. At Celator, he was responsible for the accounting, corporate finance and financial planning functions and played an integral role in the sale of Celator to Jazz Pharmaceuticals. Prior to joining Celator, Mr. Powell was the CFO of OraPharma, Inc. where he helped develop and grow the specialty healthcare company with annual sales of approximately $100 million until its acquisition by Valeant Pharmaceuticals in June, 2012. Mr. Powell was also CFO of BMP Sunstone Corporation, a public U.S. specialty pharmaceutical company with annual sales in excess of $150 million, which was eventually sold to Sanofi-Aventis for $520 million. He also held senior finance and administration positions at Eximias Pharmaceutical Corporation, Innaphase Corporation and ERT. Mr. Powell began his career with KPMG Peat Marwick and is a graduate of Penn State University.

Peter Sadowski, Ph.D., Senior Vice President, Technology Portfolio and Intellectual Property

Dr. Sadowski joined Medi-Ject Corporation, a predecessor company to Antares Pharma, in March 1994 as Vice President, Product Development. In 2001 Dr. Sadowski became Vice President of the Company's Devices Group where he led the conceptualization and development of the VIBEX mini-needle injection technology platform. In 2009 he was promoted to Senior Vice President and General Manager, Parenteral Products Group. Prior to joining the Company, Dr. Sadowski led product development teams at Molecular Genetics, Inc., GalaGen, Inc., and American Biosystems, Inc. Dr. Sadowski holds a Ph.D. in microbiology from the University of Minnesota.

John J. Howarth, Vice President of Corporate Affairs

Mr. Howarth joined Antares in February 2012 as Vice President of Corporate Affairs. Prior to joining the Company, Mr. Howarth was employed at King Pharmaceuticals as Vice President of Investor Relations, joining King through its acquisition of Alpharma. Prior to King Pharmaceuticals, Mr. Howarth held senior leadership positions spanning 25 years in investor and media relations at KOS Pharmaceuticals and Elan Corporation, and positions of increasing responsibility in finance and corporate development at Warner Lambert Company. Mr. Howarth received his B.S. degree in Accounting from Boston College and his M.B.A. in Finance from Seton Hall University.

3Q:16 Financial Results

On September 9, 2016, Antares Pharma reported third quarter results achieving revenues of $13.5 million and a ($0.04) loss per share. Total revenues rose by 22% due to an 83% increase in auto and pen injector device sales driven by sumatriptan injection sales to Teva and device sales to AMAG for the Makena program. Otrexup sales increased 9% to $3.9 million for the period. Development revenue fell 19% to $2.1 million, with the decline attributable to the shift of work on the epinephrine injector from development to sale of prelaunch devices to Teva. Licensing and royalty revenues both fell year over year, but only make up a small proportion of total revenues.

Operating income for the third quarter of 2016 was a loss of ($6.1) million or ($0.04) per share, compared to a loss of ($5.7) million and ($0.04) per share in the same period in 2015. Cost of product sales increased at a faster rate than product sales, resulting in a lower margin year over year. Research and development expenses rose on a year over year basis by 16% to $6.0 million due to higher personnel costs, FDA fees and QST development. S&GA expenses fell by 15% due to a reduction in litigation fees and lower share based compensation costs compared to 3Q:16.

For the first nine months of 2016, cash from operations was an $11.7 million draw, helped by a $3.3 million build in accounts payable which partially offset the net loss of $19.8 million. This compares to cash from operations of negative $29.5 million for the first nine months of 2015. Capital expenditures of $4.4 bring total free cash flow to negative $16.1 million, or $5.4 million per quarter.

Cash as of September 30, 2016 was $31.8 million, a $4.8 million sequential decline. Antares last raised capital in a stock issuance 2Q:15 which provided $43.2 million in net proceeds. The company carries no debt on its balance sheet but does have long-term lease liabilities of $29 million that extend to March 2022.

VALUATION AND RECOMMENDATION

We take a conservative view on timing, pricing and peak revenue potential for Antares' pipeline of products. The company currently has five products currently generating revenues and a very attractive portfolio of six additional devices that are currently in development. Two exciting development stage opportunities include the quick shot testosterone injector that will be fully owned by the company, and the generic epinephrine injectable device, which has received substantial attention in recent months regarding the pricing of Mylan's branded EpiPen.

In this section, we will discuss the variables that are inputs for our valuation approach for Antares' portfolio of products. The probability-adjusted value for each of these assets does not include any tax effect or allocated general & administrative costs, as these are incurred on a corporatewide basis. We employ a 15% discount rate for our NPV model and adjust each product by a probability determined by our estimate of eventual sales.

Exhibit VI – Summary of Product Valuations

Product	Base Value	Probability	Adj. Value
QS T	$5.18	50%	$2.59
Sumatriptan	$1.14	100%	$1.14
Otrexup	$0.92	100%	$0.92
Injectable epinephrine	$0.72	80%	$0.58
Teriparatide	$1.30	30%	$0.39
Exenatide	$0.37	85%	$0.31
Makena injectable	$0.86	35%	$0.30
Total	**$10.49**		**$6.23**
Value of remaining businesses and expenses			($1.43)
ATRS pre-tax value			$4.80
Impact of taxes on valuation			($1.50)
Target Price			**$3.30**

One of the most exciting products for Antares is Quick Shot Testosterone (QS T). This is due to the improved dynamics of a near painless auto-injection compared to the gels, patches and in-office intramuscular injection now predominantly used in this $2 billion market. Antares will develop the QS T product internally and submit a new drug application (NDA) to the FDA in order to gain approval. The company will also develop a sales force of approximately 75 to market the product to specialists. Our model anticipates that Antares will be able to launch this product in 2018, initially achieving a 1% penetration into the ~500,000 scrip per month market. This is expected to grow to 6% penetration by year four and pricing is expected to start at just above $300 per month per scrip. Gross margins are expected to be in the mid-70% range and after adjusting for sales related expenses, margins are forecast to eventually rise to the 60% range. Due to the early stage of this program where safety data has been completed, and NDA submission is expected before year end, we apply a 50% probability of approval to the QS T program.

Sumatriptan was recently launched by Teva and Antares has already received product revenues for injectors. We anticipate royalty revenues to emerge in 4Q:16. Including Teva, the near $200 million market for the drug is currently comprised of four players: Dr. Reddy (NYSE: RDY), Sun Pharma (NSE: SUNPHARMA) and Sandoz (Private). While Teva is the new entrant, we believe that the company's distribution network and relationships can eventually capture a quarter of total sales. Antares' agreement with Teva provides for a 50/50 profit split which we believe will yield almost $3 million in revenues for 2017 and almost $15 million in 2018. Our forecasts anticipate a slightly better than 60% gross margin on sumatriptan related sales (product and royalty) to Antares. As the product is already launched, we attach a 100% probability of the product being marketed.

After FDA approval in October 2013, Otrexup was launched by Antares in January 2014. Originally Antares had partnered with LEO Pharma (Private) to sell injectable methotrexate into the psoriasis market, however, the partnership was dissolved in June 2015 due to LEO's failure to achieve performance obligations. Antares owns all the economics of Otrexup and we anticipate that the company can eventually achieve about a 0.32% of market share of the 1.3 million addressable population with RA. This includes a small contribution from pJIA. We do not include any revenues associated with psoriasis at this time. Antares currently has a sales force of 36 individuals which market Otrexup to rheumatologists. We forecast margins on the Otrexup line to currently be in the high teens, however, as sales continue to grow off of the fixed cost base, we anticipate segment margins to reach near 30%. Otrexup is currently being sold, therefore we apply a 100% probability of sales.

Injectable epinephrine has been a dramatic area of focus in recent months as annual price increases of Mylan's EpiPen coincide with the back to school spike in pen purchases. Partner Teva submitted an ANDA for a generic version of EpiPen in 2009, however, action by Mylan to delay approval and an eventual issuance of a complete response letter earlier this year has delayed the launch of a generic competitor. Currently, Teva and Antares are in discussions with the FDA in order to address the deficiencies noted and resubmit the application. We forecast an early 2018 launch of a generic epinephrine injection assuming a mid-year 2017 approval by the FDA.

Antares' deal with Teva is comprised of a reimbursement of cost plus margin on injectors plus a high single digit margin on sales. Our analysis of the two components of value for ATRS suggests an approximate total value to Antares of 10% of Teva revenues. Our forecast anticipates an initial 15% penetration into the market in 2018, growing to 33% by 2020. Pricing for the 2-pack is expected to be approximately $240 based on a standard generic discount to average wholesale branded price. We see an annual 3% increase in both price and cost and an overall gross margin of 50%.

The teriparatide deal is injector cost plus margin and a royalty from the high single digits to the mid-teens. Overall, we estimate this to be 12% of revenues and cover the generic sale of injectable teriparatide on a global basis. The global market for this drug is $1.3 billion based on 2015 Forteo sales. Assuming a market share initially of 6% in 2019 growing to 32% by 2024 and applying a 20% discount to branded Forteo pricing, we generate revenues from $70 million in initial years growing to $500 million over time of which 12% is paid in a royalty and product cost reimbursement to Antares. Overall margin for this product is in the mid-80% range. We apply a slightly lower probability of approval of 30% given the anticipated launch in 2019 and the higher degree of complexity of the molecule.

The exenatide arrangement with Teva is cost plus margin on injectors and a royalty ranging from the high single digits to the mid-teens. Overall, we estimate this to be about 12% of injectable exenatide revenues. After initial market share gains of 10% when the product launches in 2018, we anticipate that Teva and Antares can gain market share of 25% by 2021. Growth after 2021 is pegged at 3%. Generic pricing is anticipated to be approximately 80% of branded pricing and unit costs for injectors is forecast to be $10. These assumptions yield a margin in the low 80% range. We apply an 85% probability of approval to eventual sales of exenatide.

Makena is currently marketed by AMAG to prevent pre-term birth for second pregnancies. The product is currently protected from competition due to orphan exclusivity which is set to expire in 2018. Current administration of hydroxyprogesterone caproate uses a large bore needle in the doctor's office which is frequently very painful for the patient and is thought to discourage adherence to the full length of therapy. Antares is developing a thinner, almost painless needle for subcutaneous injection in conjunction with AMAG for a new formulation of the drug. AMAG hopes to obtain orphan status and an additional seven years of exclusivity for this new method of administration based on lower levels of pain and greater patient compliance. The structure of the agreement between Antares and AMAG is cost reimbursement plus high single to low double digit royalties plus milestones. We estimate an overall 12% of Makena revenues to reflect the royalty plus milestones and a $10 per injector cost. Generally the course of therapy is between 16 and 20 weeks with one shot per week. However, patients have historically only received an average of 13 shots. We carry this average forward to determine revenues and costs. Initially, margins for the Makena relationship are forecast to be in the high 80% range, however, both revenues and margins are expected to decline following the expiration of exclusivity in 2025, assuming this is approved and granted orphan status by the FDA. We attach a of 35% probability of success to Makena given the relatively narrow argument for the reduction in pain.

Antares royalties and licensing revenues for the Zoma-Jet, Elestrin and Gelnique products are forecast to stay flat with recent performance. These are small products with limited growth potential and are considered to be relatively immaterial to our overall valuation and thesis.

Our model forecasts operating expenses to move from $48 million in 2016 to $40 million in 2019. The decrease will come from lower research and development costs offset by a rise in selling, general and administrative expenses. Research and development expenses will fall in coming years as Antares shifts its efforts towards launching and building products currently in development. Sales, general and administrative costs will accelerate over the next years as the sales teams are built up for Otrexup and QS T. Cash burn over the next four quarters is expected to range around $5.5 million per quarter, but should improve as royalty revenues from sumatriptan are received and even more so in 2018 when several new products are anticipated to contribute to earnings. Taxes will be a combination of federal and state income taxes and are estimated at 38.3% of pre-tax income following the use of available net operating losses.

Based on the assumptions above, our DCF model generates a target price of $3.30 per share.

CONCLUSION

Antares has a proprietary portfolio of injectors which exhibit a number of features superior to both oral, topical and needle and syringe drug administration. Oral administration can in many cases be variable in terms of bioavailability for drugs with an extensive first-pass metabolism and also lead to gastrointestinal issues for some medicines. Additionally, when rapidity of action is needed, injections are far superior to the oral route as they allow for local blood supply to take up the drug quickly, which is important for compounds such as sumatriptan which is used in migraine relief. And competing topical solutions can be messy, are slow to administer and are potentially transferrable to others such as the gels used for TRT.

As compared to a needle and syringe, Antares injectors also feature rapid injection with hidden, narrow-gauge needles. Even in cases where very viscous solutions are required to be injected, the high-tension spring action of the injectors allows a fine and nearly painless needle to be used.

Given these benefits, several established branded and generic drug manufacturers have partnered with Antares to provide the injector part of their drug system. Large multinational generic manufacturers such as Teva to smaller branded companies such as AMAG recognize the benefits of both parenteral administration and Antares' products. Currently, Antares has three injectors currently on the market and six others in development and on file with the FDA. We believe that drivers such as QS T and generic injectable epinephrine will join growth from Otrexup and sumatriptan to provide a substantial jump in revenues and profitability in 2018.

The company already has a full pipeline of products, but has the potential for continuing to add new injectable medicines to its development program. Currently, Antares has its as yet unidentified compound for quick shot QS M in CNS and neurology in development and we anticipate that other partners and internal opportunities will arise where the benefits of auto-injection are apparent.

Key reasons to own:

- **Growth and improving margin profile for Otrexup**
- **Approval and first sales of fully-owned QuickShot TRT expected in next year**
- **Launch of generic EpiPen with partner Teva in 2018**
- **Launch of generic injectable Byetta (exenatide) and Forteo (teriparatide)**
- **Launch of injectable Makena for pre-term birth**

In summary, we see an attractive portfolio of injectors and development pipeline. Given the late stage of several NDAs, we anticipate a large jump in revenues in 2018 as several new products generate new sales. Fixed cost leverage for currently marketed drugs offeres another aveune for earnings growth as Otrexup and sumatriptan reach critical mass and begin to exhibit attractive margins. Based on our view for each of the injector products, we initiate ATRS with a target price of $3.30.

PROJECTED FINANCIALS

Antares Pharma, Inc. - Income Statement

Antares Pharma, Inc.	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
Total Revenues	**$45,658**	**$12,319**	**$12,228**	**$13,479**	**$12,835**	**$50,861**	**$52,118**	**$96,971**
Cost of Product Sales	$12,925	$6,248	$5,217	$7,206	$5,500	$24,170	$24,000	$41,751
Cost of Development Revenue	$6,533	$528	$2,102	$827	$800	$4,257	$3,900	$3,900
Gross Profit	$26,200	$5,543	$4,910	$5,445	$6,535	$22,434	$24,218	$51,320
Product Gross Margin	*57.4%*	*45.0%*	*40.2%*	*40.4%*	*50.9%*	*44.1%*	*46.5%*	*52.9%*
R&D	$19,732	$5,648	$3,948	$5,958	$4,800	$20,354	$10,000	$10,000
SG&A	$26,931	$7,603	$7,015	$5,623	$7,250	$27,491	$28,315	$29,165
Other expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($20,462)	($7,708)	($6,052)	($6,136)	($5,515)	($25,411)	($14,097)	$12,155
Operating Margin	*-44.8%*	*-62.6%*	*-49.5%*	*-45.5%*	*-43.0%*	*-50.0%*	*-27.0%*	*12.5%*
Total Other Income	($22)	$52	($9)	$15	$0	$58	$0	$0
Pre-Tax Income	($20,484)	($7,656)	($6,061)	($6,121)	($5,515)	($25,353)	($14,097)	$12,155
Taxes & Other	$175	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*-1%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($20,659)	($7,656)	($6,061)	($6,121)	($5,515)	($25,353)	($14,097)	$12,155
Reported EPS	**($0.14)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.04)**	**($0.16)**	**($0.09)**	**$0.08**
YOY Growth	-						-	-
Shares Outstanding	146,594.1	154,858.1	154,936.1	155,060.8	155,243.0	155,024.5	157,624.9	160,304.6

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE



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