Zacks Small-Cap Research

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Antares Pharma, Inc. (ATRS - NASDAQ)

Xyosted Secures FDA Approval

Based on our DCF model and a 15% discount rate, ATRS is valued at approximately $5.00 per share. Our model applies a range of probabilities for development projects seeking ANDA and sANDA approval and eventual commercialization.

Current Price (10/1/2018)	$3.26
Valuation	**$5.00**

OUTLOOK

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 using Antares' 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 branded and generic pharmaceutical products. Antares has eight injectors that are either marketed or in development internally or with partners including AMAG, Teva and Pfizer.

At the current price, we view Antares shares as undervalued, with appreciation potential given the growth expected in current products and near-term launch of several others. We believe that continued achievement of their milestones and expansion of their relationship with Teva and AMAG can provide additional upside to our valuation.

SUMMARY DATA

52-Week High	**4.09**
52-Week Low	**1.58**
One-Year Return (%)	**-5.0**
Beta	**-0.71**
Average Daily Volume (sh)	**1,219,938**
Shares Outstanding (mil)	**157.4**
Market Capitalization ($mil)	**513.2**
Short Interest Ratio (days)	**4.48**
Institutional Ownership (%)	**39.2**
Insider Ownership (%)	**7.7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**19.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**14.8**
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)
2017	$12.0 A	$13.4 A	$15.1 A	$14.0 A	$54.5 A
2018	$12.7 A	$14.2 A	$17.4 E	$18.9 E	$63.2 E
2019					$146.9 E
2020					$241.4 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.03 A	-$0.02 A	-$0.03 A	-$0.02 A	-$0.11 A
2018	-$0.04 A	-$0.03 A	-$0.01 E	-$0.01 E	-$0.07 E
2019					$0.22 E
2020					$0.60 E

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What's New

FDA Approval of Xyosted

Antares Pharma, Inc. (NASDAQ: ATRS) announced that the FDA had approved Xyosted following the FDA's announced PDUFA date of September 29th. The approval was for the first subcutaneous testosterone enanthate product for once-weekly, at-home self-administration with the disposable QuickShot auto injector. Three dosage strengths will be available before year-end of 50 mg, 75 mg and 100 mg.

Prior to approval, investors were concerned that the FDA was hesitant to approve new testosterone therapies, due to blood pressure elevation in competing products and cardiovascular risk. However, there was limited evidence in studies subsequent to this concern substantiating a safety risk.

Similar to other testosterone treatments, Xyosted received a black box warning for blood pressure and cardiovascular risk calling for periodic monitoring for hypertension six weeks after initiating therapy. In contrast to topical testosterone products, Xyosted is able to avoid transference risks. Antares' product is also easier to use compared to other injectables as it does not require a doctor's visit and can be injected either once or multiple times per week to maintain consistent drug levels.

Next steps for Xyosted are for Antares to hire its sales force. The company has submitted conditional job offers to sales representatives with extensive physician contacts in the primary care, urology and endocrinology specialties. They plan to have 60 reps on board and first sales to commence before year end 2018. 10,000 physicians in primary care and urology specialties have been identified as potential high volume prescribers and will be the target providers for the sales force. In the back office, a comprehensive patient support program is being developed which will provide co-pay assistance to commercially insured patients, and benefits investigation and prior authorization support for physicians. Using a discounted pricing approach to gain market share, pricing will be targeted at a $450 to $500 per month WACC, which is a discount to the leader in the space. Our estimates call for 1.4% penetration in the market next year growing to 5.0% in 2020 given the superior characteristics of the injectable product.

Based on the FDA approval of Xyosted, we adjust our model to reflect 100% probability of ultimate commercialization for the drug/device up from 50% previously. Xyosted, given its full ownership in-house has the most potential in the Antares portfolio. The high level of certainty for commercialization increases our target price from $3.75 to $5.00.

Xyosted Background

The FDA delivered a complete response letter (CRL) to Antares on October 20, 2017 for Xyosted. The FDA highlighted concerns that the injection could cause high blood pressure and be associated with depression and suicidality, adverse reactions listed on the label for other testosterone therapies. According to the release there was no mention of Chemistry, Manufacturing and Controls (CMC) issues.

During the Type A meeting in February 2018 the company met with the FDA to discuss a resubmission plan in response to the CRL related to Xyosted. Notes were provided to the company in late March, after which the company prepared and submitted the necessary documents and information. The FDA considered the resubmission to be a complete, Class 2 response and circulated a September 29, 2018 PDUFA date.

On October 1, 2018, Antares announced FDA approval of Xyosted.

Summary

Despite a CRL last year, Antares was able to persevere and obtain FDA approval. The company put in place a plan to identify high potential prescribers for Xyosted and has teed up a sales force to execute on this prioity. We adjust our estimates to reflect full commercialization of Xyotsed, which increases our revenue and earnings estimates for 2019 and beyond. The impact of this changes raises our target price to $5.00. This follows our previous target price increase two months ago related to the generic epinephrine pen approval which will be commercialized by Teva.

PROJECTED FINANCIALS

Antares Pharma, Inc. - Income Statement

Antares Pharma, Inc.	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$54,515**	**$12,703**	**$14,162**	**$17,425**	**$18,891**	**$63,182**	**$146,943**	**$241,397**
Cost of Product Sales	$22,317	$6,536	$6,677	$7,313	$7,943	$25,804	$63,394	$94,091
Cost of Development Revenue	$5,149	$650	$283	$750	$750	$2,994	$2,240	$2,240
Gross Profit	$27,050	$5,517	$7,202	$9,362	$10,198	$34,384	$81,309	$145,066
Product Gross Margin	*49.6%*	*43.4%*	*50.9%*	*53.7%*	*54.0%*	*54.4%*	*56.9%*	*61.0%*
R&D	$13,147	$3,320	$3,650	$4,000	$4,000	$14,970	$15,000	$14,000
SG&A	$30,353	$7,816	$7,463	$7,660	$7,700	$30,639	$31,558	$32,505
Other expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($16,451)	($5,619)	($3,911)	($2,298)	($1,502)	($11,225)	$34,751	$98,561
Operating Margin	*-30.2%*	*-44.2%*	*-27.6%*	*-13.2%*	*-7.9%*	*-17.8%*	*23.6%*	*40.8%*
Total Other Income	($292)	($574)	($609)	$0	$0	$0	$0	$0
Pre-Tax Income	($16,743)	($6,193)	($4,520)	($2,298)	($1,502)	($11,225)	$34,751	$98,561
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($16,743)	($6,193)	($4,520)	($2,298)	($1,502)	($11,225)	$34,751	$98,561
Reported EPS	**($0.11)**	**($0.04)**	**($0.03)**	**($0.01)**	**($0.01)**	**($0.07)**	**$0.22**	**$0.60**
Shares Outstanding	156,054.1	156,724.0	157,024.0	157,981.8	158,945.5	158,707.0	161,405.0	164,148.9

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

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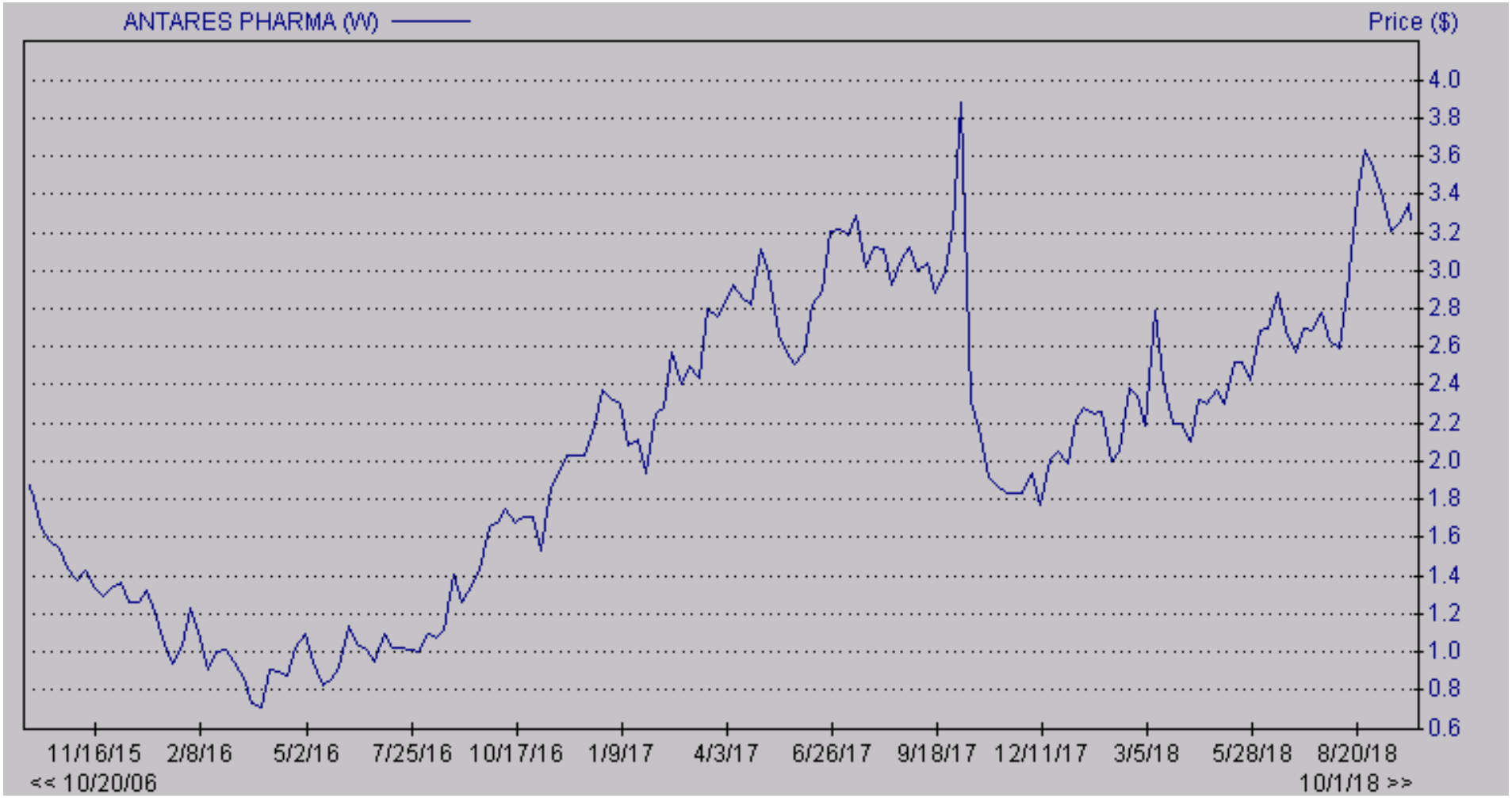
HISTORICAL STOCK PRICE

Antares Pharma, Inc. – Share Price Chart



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