Zacks Small-Cap Research

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Antares Pharma, Inc. (ATRS - NASDAQ)

CRL to Delay Xyosted Launch; Target Price to $3.00

Based on our DCF model and a 15% discount rate, ATRS is valued at approximately $3.00 per share. Our model applies a range of probabilities for development projects seeking ANDA and sANDA approval and eventual commercialization.

Current Price (10/20/2017)	$2.18
Valuation	**$3.00**

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. Currently, Antares has seven injectors that are either marketed or in development.

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	**1.41**
One-Year Return (%)	**37.0**
Beta	**0.27**
Average Daily Volume (sh)	**1,981,215**
Shares Outstanding (mil)	**156.4**
Market Capitalization ($mil)	**341.0**
Short Interest Ratio (days)	**6.8**
Institutional Ownership (%)	**37.0**
Insider Ownership (%)	**9.39**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**26.0**
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	**72.2**
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)
2016	$12.3 A	$12.2 A	$13.5 A	$14.2 A	$52.2 A
2017	$12.0 A	$13.4 A	$14.3 E	$14.4 A	$54.1 E
2018					$74.1 E
2019					$119.4 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.05 A	-$0.04 A	-$0.04 A	-$0.03 A	-$0.16 A
2017	-$0.03 A	-$0.02 A	-$0.04 E	-$0.05 E	-$0.14 E
2018					-$0.07 E
2019					$0.13 E

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What's New

Xyosted Receives CRL

The FDA delivered a complete response letter (CRL) to Antares (NASDAQ: ATRS) on Friday, October 20. In the three paragraph update provided by the company, Antares highlighted concerns by the FDA that Xyosted could cause a "meaningful increase in blood pressure" and that it may be associated with depression and suicidality. According to the release there was no mention of Chemistry, Manufacturing and Controls (CMC) concerns, which suggests the remedies required can be accomplished in-house.

CRL have become increasingly common with many in the industry blaming the increased workload and strict time constraints on the agency which forces them to employ unorthodox methods to gain additional review time. The CRL provides one way to do this. Additionally, there is an increased focus on CMC issues and good manufacturing processes at third-party testing, manufacturing and supply, which has also contributed to a material proportion of CRLs, although this does not appear to be a factor in this case. The issuance of the CRL will cause a delay for Antares' launch of Xyosted and may also require additional studies, such as bridging studies, a new design or a reassessment of the underlying data. At this point, additional requirements are unclear as the path forward will be determined following an anticipated meeting with the FDA.

In 2008, the FDA changed its philosophy regarding responses to NDAs. Prior to this change, the agency issued three classes of letters falling in approved, approvable and not approved categories. The CRL is seen as "a more consistent and neutral"[1] mechanism to communicate why the FDA has decided not to approve the application in its present form.[2] Since this change some analysis has been performed to examine the likelihood of a CRL being issued and ultimate approval following this letter.

A study conducted by Datamonitor examined 348 NDAs and BLAs and found that 42% of submissions receive a CRL and that 55% of this group receiving a CRL were eventually approved. The study also reviewed the delay incurred as a result of the CRL and identified a median 13 month delay for Class 2 resubmissions and a 4.4 month delay for a Class 1 resubmissions.[3] While the data set was limited, it does provide some idea of the likelihood of eventual approval and how long it might take.

In another study performed by the Biotechnology Industry Organization (BIO) which looked at 748 NDAs, about half of NDA and BLA filings for new molecular entities (NMEs) with the FDA result in the issuance of a CRL. During the period of analysis 337 CRLs were issued, of which 147 were approved after the first resubmission. This indicates a 44% approval rate for the first resubmission after a CRL.[4] While Xyosted does not contain an NME, we apply the assumption that similar probabilities will apply to compounds pursuing the 505(b)(2) pathway.

Based on these studies and our own experience with complete response letters, we estimate a 50/50 chance of eventual approval and a year delay in commercialization.

As a reminder, Antares submitted a 505(b)(2) NDA with the FDA in December 2016 for Quick Shot Testosterone (Xyosted). This followed two Phase III studies (QST-13-003 and QST-15-005) which provided positive data on safety and efficacy on the underlying drug testosterone enanthate which has been used in numerous branded products for over 60 years. The broad and long duration of use of this product suggests that its safety should be substantially understood at this point providing a degree of confidence that it will be approved when the FDA has its questions answered.

[1] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084143.htm
[2] https://www.healthcarelawinsights.com/wp-content/uploads/sites/278/2015/01/CRL_Whitepaper.pdf
[3] http://www.raps.org/focus-online/news/news-article-view/article/2761/
[4] http://www.raps.org/focus-online/news/news-article-view/article/1138/bio-analysis-resubmissions-after-third-round-of-fda-review-not-worth-the-effort.aspx

The normal process a company follows after the issuance of the CRL is to review the response, consult with the FDA and follow up with additional work required. Below we highlight the major steps required.

1) Receipt of CRL
2) Review contents of CRL with experts to identify ways to address the concerns
3) Request post-action meeting with FDA within 30 days
4) Hold Type A meeting with FDA and determine path forward
5) Conduct additional data collection and analysis required
6) Resubmit data to FDA
    a. Class 1 resubmission (2 months)
    b. Class 2 resubmission (6 months)
7) FDA response

Using both our experience with other CRLs issued and a review of studies of CRL analysis discussed above, we estimate the process outlined above will add approximately one year to our previous launch date. First revenues were anticipated to occur in 2018 and are now shifted one year later to 2019. We continue to assume the same ramp in sales as previously forecasted from about 10,000 patients in year 1 to almost 60,000 patients ten years later. Our model reduces the probability of ultimate commercialization from 65% to 50%. As new information becomes available regarding the complexity of required studies, whether a Class 1 or Class 2 resubmission is appropriate, and the time required to address any deficiencies we will adjust our estimates accordingly.

Based on our adjustments, the target price for Antares moves from $3.75 per share to $3.00 per share with the change due entirely to the anticipated delay of Xyosted and our adjusted probability of success. CRLs have become increasingly common, and research shows that they occur for about 40% of NDA and BLA submissions. Whether this is attributable to an overworked FDA that needs to buy extra time or changing needs from the agency throughout the process, it is an occurrence which is an increasingly common part of the drug development process.

Given the long history of efficacy and safety data for testosterone enanthate, we believe it is a well understood drug that combined with the strong data generated from Antares' clinical trials will ultimately support approval. Our adjusted assumptions generate a new price target of $3.00 per share.

PROJECTED FINANCIALS

Antares Pharma, Inc. - Income Statement

Antares Pharma, Inc.	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E	2018 E	2019 E
Total Revenues	**$52,222**	**$12,007**	**$13,416**	**$14,258**	**$14,380**	**$54,061**	**$74,119**	**$119,356**
Cost of Product Sales	$23,909	$5,448	$3,633	$5,977	$6,016	$21,074	$33,425	$47,148
Cost of Development Revenue	$4,908	$771	$1,983	$1,161	$1,210	$5,126	$2,640	$1,760
Gross Profit	$23,405	$5,788	$7,800	$7,120	$7,154	$27,862	$38,054	$70,448
Product Gross Margin	*44.8%*	*48.2%*	*58.1%*	*49.9%*	*49.8%*	*51.5%*	*51.3%*	*60.5%*
R&D	$21,127	$3,086	$3,160	$2,500	$2,500	$11,246	$10,000	$10,000
SG&A	$26,395	$7,467	$7,360	$11,000	$12,000	$37,827	$38,962	$40,131
Other expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($24,116)	($4,766)	($2,720)	($6,380)	($7,346)	($21,211)	($10,908)	$20,317
Operating Margin	*-46.2%*	*-39.7%*	*-20.3%*	*-44.7%*	*-51.1%*	*-39.2%*	*-14.7%*	*17.0%*
Total Other Income	($122)	$30	($120)	$0	$0	($90)	$0	$0
Pre-Tax Income	($24,239)	($4,736)	($2,840)	($6,380)	($7,346)	($21,301)	($10,908)	$20,317
Taxes & Other	$100	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($24,339)	($4,736)	($2,840)	($6,380)	($7,346)	($21,301)	($10,908)	$20,317
Reported EPS	**($0.16)**	**($0.03)**	**($0.02)**	**($0.04)**	**($0.05)**	**($0.14)**	**($0.07)**	**$0.13**
Shares Outstanding	154,992.1	155,215.0	155,926.1	156,877.3	157,834.3	156,463.2	159,123.1	161,828.2

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

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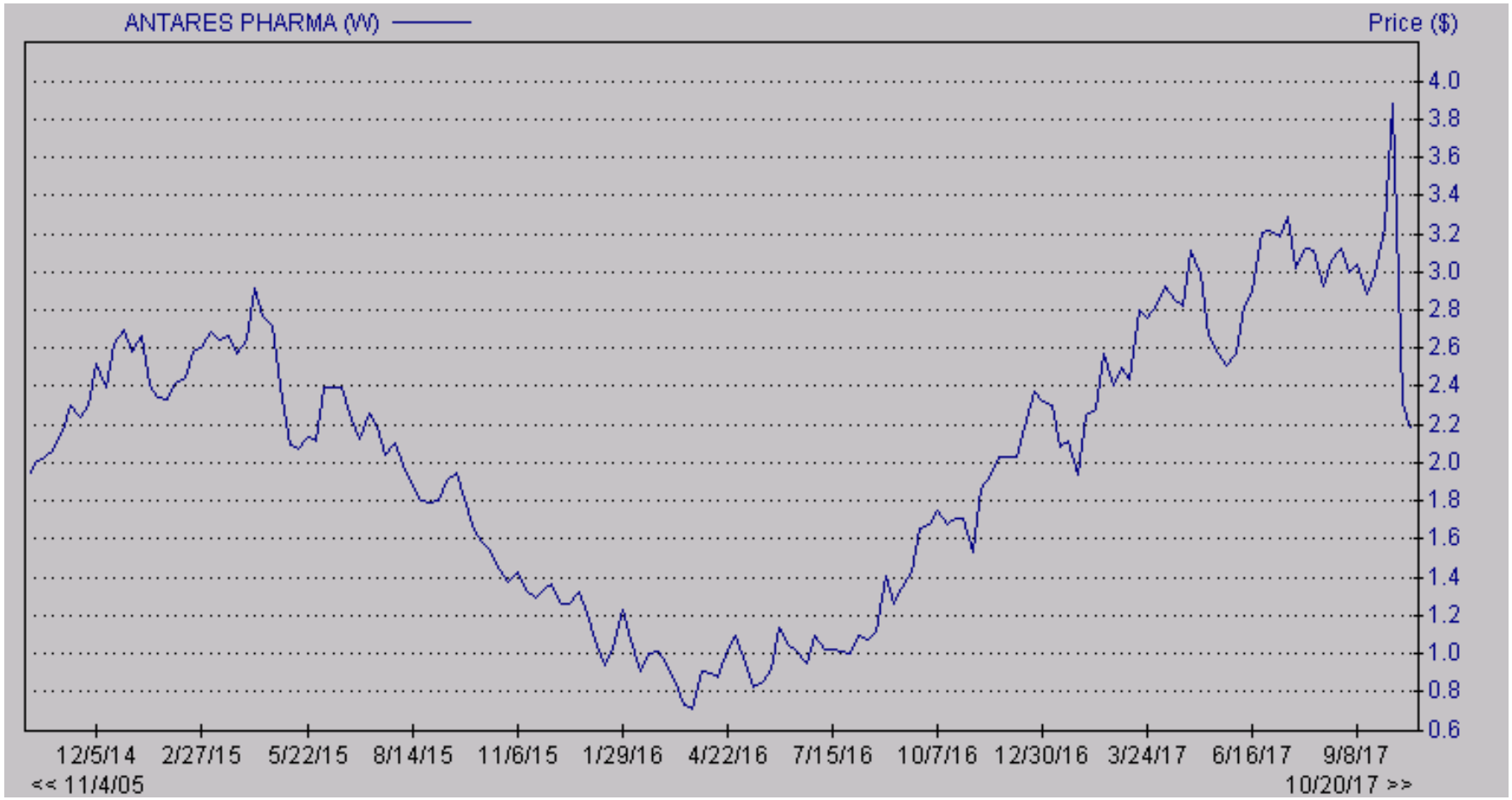
HISTORICAL STOCK PRICE



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