Zacks Small-Cap Research

November 8, 2017
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)

CRL Overhang but Market Share Gains Drive Earnings Beat

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 (11/7/2017)	$1.79
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	**1.50**
One-Year Return (%)	**9.8**
Beta	**0.24**
Average Daily Volume (sh)	**2,208,167**
Shares Outstanding (mil)	**156.7**
Market Capitalization ($mil)	**280.5**
Short Interest Ratio (days)	**6.8**
Institutional Ownership (%)	**36.9**
Insider Ownership (%)	**9.4**
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	**12.8**
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)
2016	$12.3 A	$12.2 A	$13.5 A	$14.2 A	$52.2 A
2017	$12.0 A	$13.4 A	$15.1 A	$14.4 E	$54.9 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	-$0.03 A	-$0.03 E	-$0.12 E
2018					-$0.05 E
2019					$0.14 E

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

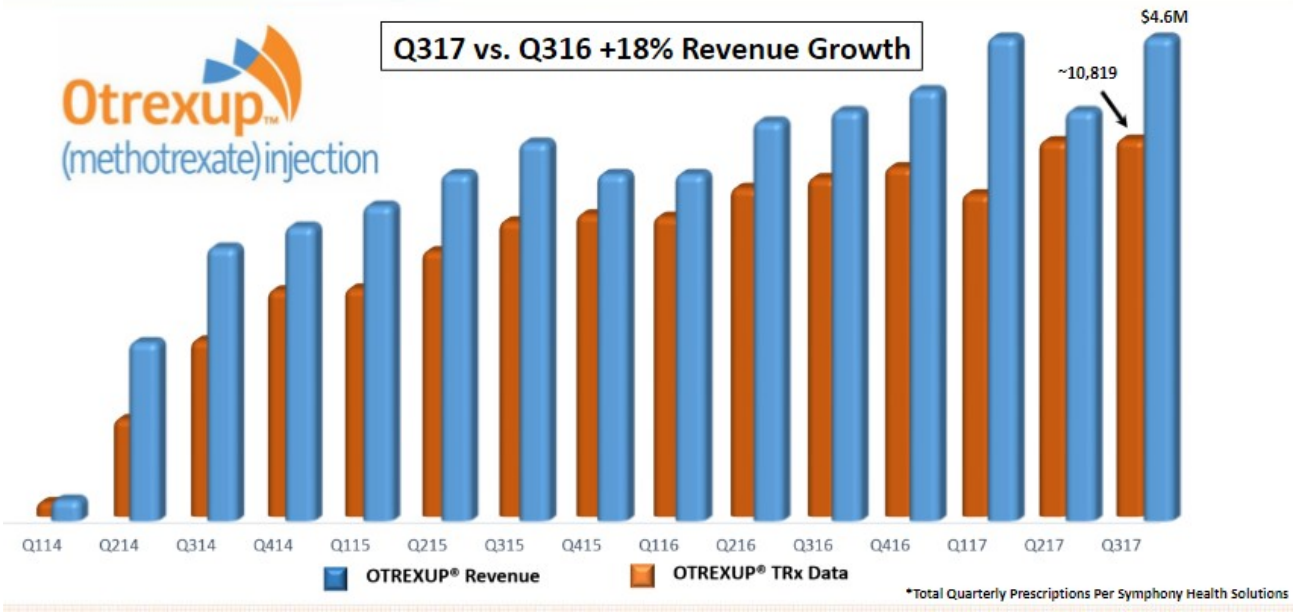
What's New

Third Quarter Operational and Financial Results

Antares Pharma, Inc. (NASDAQ: ATRS) announced third quarter results on November 7, 2017, achieving 12% revenue growth and a loss of ($0.03) per share. Third quarter revenues of $15.1 million compare to our $14.3 million estimate, which had not anticipated the strong trends in Otrexup and auto/pen injector sales. Net loss of ($0.03) per share was ahead of our ($0.04) estimate. Gross margin was up 300 basis points to 43.4% compared to 40.4% in 3Q:16 due to stronger Otrexup sales.

Antares' market share continued to increase in its key revenue generating products. Otrexup experienced an 18% increase in sales over last year's third quarter on a price increase and higher volumes.

Exhibit I – Otrexup Revenue and Prescriptions[1]



Sumatriptan revenues increased 88% to $6.4 million as Antares benefitted from greater unit sales and the profit sharing agreement concurrent with Teva's one percentage point increase in market share to 27%. The most recent weekly data ending October 27 indicated a market share of 31%, suggesting continued share gains and the benefit of Teva's relationships with Walgreens and CVS.

Exhibit II – Sumatriptan Auto Injector Market Share[2]



[1] Graphic sourced from Antares' 3Q:17 slide presentation. Note TRx volumes are retail sales only.
[2] Data provided by Symphony Health Solutions and included in Antares' 3Q:17 slide presentation.

Needle-free Injector device sales declined 37% to $758,000 while Auto/Pen Injectors were up 34%. Total product sales, which is the combination of Otrexup, Needle Free Injector devices and Auto/Pen Injectors, rose 21% to $13.3 million. Development revenue fell by 29% to $1.5 million due to lower revenue from Teva's exenatide program and from AMAG's Makena program as we move closer to expected launch dates. 3Q:17 Licensing revenue was not material in the quarter and Royalties fell 24% to $220,000.

Gross profit for the first quarter was $6.5 million which represents a margin of 43% as contributions from Otrexup helped drive the 300 basis point year over year increase. R&D declined by 45% compared to 3Q:16 as efforts to develop QST tapered off. SG&A was up 46% on a year over year basis to $8.2 million as expenses related to prelaunch sales, such as hiring of district managers and marketing for XYOSTED were recognized.

As of September 30, 2017, Antares held $37 million in cash on its balance sheet. We anticipate a $6 to $7 million per quarter cash burn rate in development and operational costs suggesting sufficient funds to support operations until 2019. We have reduced our SG&A expenses for the fourth quarter and for 2018 as the delay in Xyosted sales will push forward the hiring and associated expenses of the salesforce.

New Products

- QST receives CRL issued October 20, 2017
- Partner Teva
  - Exenatide
    - Settlement with AstraZeneca for exenatide in US
    - FDA review date of October 15, 2017 passed
    - ANDA under active FDA review
    - ATRS executing on purchase order for commercial devices
    - Expect 180 days of marketing exclusivity
  - Teriparatide (Forteo) ANDA accepted by FDA
    - Teva may be considered first-to-file with 180 day exclusivity pending approval
    - Teva completed decentralized registration in EU & awaiting market authorization and patent clearance before commercialization
    - Approved in 17 EU countries
  - Epinephrine Pen
    - Launch expected early 2018
    - $20 million in devices sold to date
    - ANDA under active FDA review
- AMAG's subcutaneous Makena presented positive pharmacokinetic data
  - Anticipate first sales following expiration of IM exclusivity February 2018
  - Executing on purchase order for devices

Xyosted Receives CRL

The FDA delivered a complete response letter (CRL) to Antares on October 20 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) concerns, which suggests the remedies required can be accomplished in-house.

CRL have become increasingly common with many faulting the increased workload and strict time constraints on the agency which forces them to employ unorthodox methods to gain additional review time. 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 categorized as approved, approvable and not approved. The CRL was seen as "a more

consistent and neutral"[3] mechanism to communicate the FDA's rationale not to approve an application in its present form.[4] Since this change some analysis has been performed to examine the likelihood of a CRL being issued and the probability of 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.[5] 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.[6] 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 use of this product over many decades suggests that its safety should be well understood at this point suggesting that it will be approved when the FDA has its questions answered.

The normal process a company follows after the issuance of the CRL is to review the response, prepare a comprehensive briefing book, 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 and prepare briefing book
3) Request post-action meeting with FDA granted 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

We estimate the process outlined above will add approximately one year to our previous launch date. Prior to the CRL, 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 estimates the probability of ultimate commercialization at 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.

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 price target of $3.00 per share.

[3] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084143.htm
[4] https://www.healthcarelawinsights.com/wp-content/uploads/sites/278/2015/01/CRL_Whitepaper.pdf
[5] http://www.raps.org/focus-online/news/news-article-view/article/2761/
[6] 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

Sale of Zomajet

On October 10, Antares announced the sale of Zomajet to Ferring Pharmaceuticals for up to $14.5 million in a relationship that has continued since 2003. Antares has manufactured, through its partner Minnesota Rubber and Plastics, needle-free injector devices for Ferring and JCR to distribute in more than 30 countries. Revenues for the business line were $5.5 million in 2016, and we believe as royalties, the vast majority of revenues pass through to operating earnings. Sales in this segment were down 16% in the first nine months of 2017 from prior year levels. As discussed in the release, Antares should continue to collect revenues from this segment until year end 2018, however, the first payment of $2 million has already been received by Antares. This is a positive transaction in our opinion as it eliminates a non-core business from the portfolio and provides capital to grow new products.

Summary

Despite the CRL issued to Antares in late October, we continue to see substantial upside from current levels. The current quarter's performace was very strong with double digit overall growth. While some of the growth may be attributable to fluctuations in the supply chain or demand, the direction has been consistenly positive on a rolling basis. We continue to see an attractive portfolio of injectors and development pipeline and excluding the CRL, are satisfied to see progress and milestone achievement across the board. Several products are in the latest stages of approval and we anticipate a large jump in revenues next year as several new launches take place. Fixed cost leverage for currently marketed injectors offers another aveune for earnings growth as Otrexup and sumatriptan reach critical mass and begin to deliver attractive margins. We maintain our price target of $3.00 per share.

PROJECTED FINANCIALS

Antares Pharma, Inc. - Income Statement

Antares Pharma, Inc.	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
Total Revenues	**$52,222**	**$12,007**	**$13,416**	**$15,052**	**$14,380**	**$54,855**	**$74,119**	**$119,356**
Cost of Product Sales	$23,909	$5,448	$3,633	$7,600	$6,016	$22,697	$35,097	$48,870
Cost of Development Revenue	$4,908	$771	$1,983	$923	$1,210	$4,887	$2,640	$1,760
Gross Profit	$23,405	$5,788	$7,800	$6,529	$7,154	$27,271	$36,382	$68,725
Product Gross Margin	*44.8%*	*48.2%*	*58.1%*	*43.4%*	*49.8%*	*49.7%*	*49.1%*	*59.1%*
R&D	$21,127	$3,086	$3,160	$3,289	$2,500	$12,035	$10,000	$10,000
SG&A	$26,395	$7,467	$7,360	$8,186	$10,000	$33,013	$35,000	$36,050
Other expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($24,116)	($4,766)	($2,720)	($4,946)	($5,346)	($17,778)	($8,618)	$22,675
Operating Margin	*-46.2%*	*-39.7%*	*-20.3%*	*-32.9%*	*-37.2%*	*-32.4%*	*-11.6%*	*19.0%*
Total Other Income	($122)	$30	($120)	($507)	$0	($597)	$0	$0
Pre-Tax Income	($24,239)	($4,736)	($2,840)	($5,453)	($5,346)	($18,375)	($8,618)	$22,675
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)	($5,453)	($5,346)	($18,375)	($8,618)	$22,675
Reported EPS	**($0.16)**	**($0.03)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.12)**	**($0.05)**	**$0.14**
Shares Outstanding	154,992.1	155,215.0	155,926.1	156,400.7	157,354.7	156,224.2	158,880.0	161,580.9

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

© Copyright 2017, Zacks Investment Research. All Rights Reserved.