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Antares Pharma, Inc. (ATRS - NASDAQ)

Multiple New Launches Fire Up 2018

Based on our DCF model and a 15% discount rate, ATRS is valued at approximately $3.50 per share. Our model applies a range of probabilities for development projects seeking ANDA and sANDA approval and eventual commercialization.

Current Price (3/14/2018)	$2.60
Valuation	**$3.50**

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	**1.58**
One-Year Return (%)	**0.4**
Beta	**-0.47**
Average Daily Volume (sh)	**1,302,800**
Shares Outstanding (mil)	**156.8**
Market Capitalization ($mil)	**407.3**
Short Interest Ratio (days)	**1.29**
Institutional Ownership (%)	**37.1**
Insider Ownership (%)	**9.4**
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	**17.3**
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	$14.0 A	$54.5 A
2018					$74.6 E
2019					$126.9 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	-$0.02 A	-$0.11 A
2018					-$0.07 E
2019					$0.15 E

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What's New

2017 Full Year Operational and Financial Results

Antares Pharma, Inc. (NASDAQ: ATRS) reported 2017 full-year results on March 13, 2018, posting 10% topline growth and a loss of ($0.11) per share. Revenue growth fell short of our 11% forecast but earnings were a penny better. Impressive increases in Otrexup sales, were offset by a slowdown in sumatriptan and development revenue. Recent successes include the regulatory approval of Makena, progress on the sale of Zomajet and continued interaction with the FDA to get Xyosted across the finish line are positives we expect will drive performance as 2018 progresses.

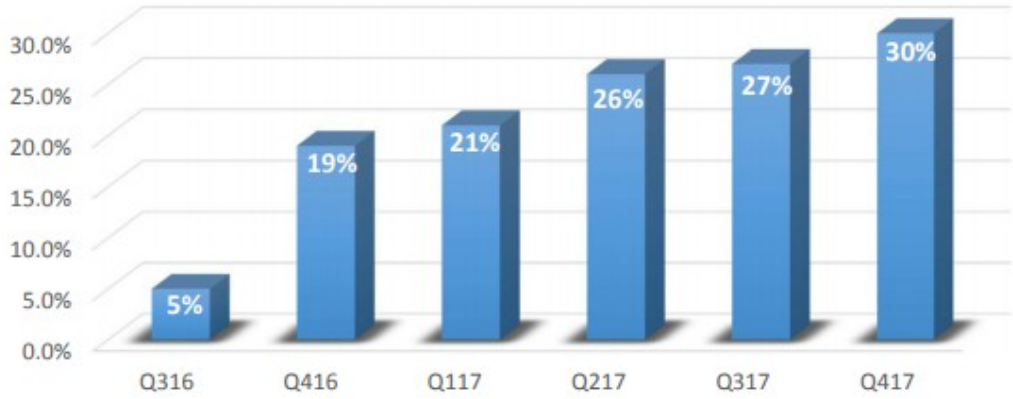
Total revenues for 2017 were $54.5 million, up from $49.5 million in 2016. Otrexup was a standout in the year and the quarter rising 18.5% and 17.4% respectively and comprising a third of total sales. Fourth quarter sales were $4.8 million, compared to $4.6 million in 3Q:17 and $4.1 million in 4Q:16.

Exhibit I – Otrexup Revenue Trends[1]



Antares' market share increase continued for sumatriptan, rising sequentially from 27% to 30%. Despite this increase in share, total revenues declined year over year from $2.7 million in 4Q:16 to $1.2 million in 4Q:17 due to pricing and timing effects. Pricing has weakened somewhat for the sumatriptan space and there has been a response with Endo withdrawing its Sumavel DosePro from the market in the first quarter. We believe that Teva will be wise balancing price and market share in coming quarters.

Exhibit II – Sumatriptan Auto Injector Market Share[2]



[1] Graphic sourced from Antares' 4Q:17 slide presentation.
[2] Data provided by Symphony Health Solutions and included in Antares' 4Q:17 slide presentation.

Needle-free Injector device sales declined 10% in 2017 to $4.9 million but rose in the fourth quarter by 4% to $1.2 million. For the first time, Antares separated sumatriptan revenues from Auto/Pen Injector Devices in the income statement. The Auto/Pen Injector category (now excluding sumatriptan in all periods) was down 50% for the year to $5.4 million while it rose 174% in the fourth quarter to $3.1 million. Total product sales, which is the combination of Otrexup, sumatriptan, Needle Free Injector devices and Auto/Pen Injectors, rose 11% for the year and 57% for the quarter. Development revenue was essentially flat for the year, but declined in the fourth quarter by 42% to $2.2 million on lower pen injector program revenue from Teva. Annual licensing revenues increased substantially to $1.1 million due to the recognition of deferred revenues in the second quarter. On a quarterly basis, licensing fell to half of its value last year at $19. Royalties saw a solid increase of 10% for 2017, and also rose in the fourth quarter by 28% to $834,000.

Gross profit for the year was $27.1 million which represents a margin of 49.6%, while fourth quarter levels were $6.9 million generating an associated margin of 49.4%. Full year product sales margin was 46.5%, up sharply from 2016's 36.4%. Fourth quarter product sales margins were even stronger at 48.7%, compared the 4Q:16 levels at 25.2%. Development revenue gross margins were down compared to the prior year, coming in at 49.0% for full year 2017 and are dependent on product mix. Contributions from Otrexup and higher licensing revenues helped drive the increase over prior year levels. R&D declined by 38% versus the prior year as efforts related to Xyosted and other programs tapered off and as the company lapped a $2 million NDA submission fee paid in 2016 that did not recur. SG&A was up 15% for the full year and up 19% in the fourth quarter on a year over year basis reflecting the preparation Antares had done for the Xyosted approval.

As of December 31, 2018, Antares held $31.6 million in cash on its balance sheet. We anticipate cash burn to be approximately $11 million in 2018, heavily weighted towards the earlier quarters in the year. We have increased our R&D estimates to reflect the new development initiatives that Antares will pursue in urology and neurology raising our estimate to $20 million. SG&A is expected to see a slight rise in 2018; however, when the Xyosted launch timing becomes clear, the model will need to be updated to reflect the timing of costs related to adding the sales force.

Makena Approval

On February 14, 2018 the FDA approved AMAG's Makena, subcutaneous injection for pre-term birth. Several benefits from the new method of administration are a faster injection with a less painful, concealed needle in the arm. The previous generation of Makena required a multi-step process involving a 21-gauge, 1.5 inch needle and a 60 second plus injection duration in the gluteus maximus. We expect that the simpler and less painful process for subcutaneous Makena, with no expected increase in price will result in a rapid switch over to the new product and limited resistance from payors. First sales are anticipated later this month, with the rapid changeover expected to limit any losses to potential generic competitors.

Sale of Zomajet

On October 10, Antares announced the sale of Zomajet to Ferring Pharmaceuticals for up to $14.5 million. As discussed in the release, Antares should continue to collect revenues from this product until year end 2018, and two payments totaling $4.75 million have already been received. This is a beneficial transaction for Antares as it divests a non-core business and provides capital to grow new products. Two additional payments of $4.75 and $5.0 million respectively are expected in the second and fourth quarter of 2018, at which time the transaction will be completed.

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.

During the Type A meeting on February 21, 2018 the company met with the FDA to discuss a resubmission plan in response to the CRL related to Xyosted. Notes are expected to be available 30 days following the meeting and management will hold back from making any commentary until the minutes are received to ensure they properly understand the FDA's input.

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.

Based on background work performed in a previous report 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.

Development Products

- QST receives CRL issued October 20, 2017
  - Request for Type A Meeting – December 2017
  - Type A FDA Meeting – February 21, 2018
  - Type A Meeting Notes – Late March 2018
- Partner Teva
  - Exenatide
    - Settlement with AstraZeneca for exenatide in US
    - 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
    - Global sales for Forteo are $1.75 billion in 2017 and growing
  - Epinephrine Pen
    - Launch expected in 2018
    - ~$22 million in devices sold to date
    - ANDA under active FDA review
    - If approved, will be only AB rated alternative
- AMAG's subcutaneous Makena presented positive pharmacokinetic data
  - Approval granted February 14, 2018
  - Anticipate first sales March 2018
  - Approval is first for QuickShot autoinjector
- New Products
  - Developing investigational new drug (IND) application for an undisclosed candidate
  - May develop IND in Urology to complement Xyosted salesforce
  - May develop IND in Neurology specialty

Valuation

We update our model to reflect the approval of Makena in February and we increase our probability of successful commercialization for this product to 90%.[3] Estimates are reduced slightly for the epinephrine pen, and exenatide revenue lines for 2018 as we expect these to start a somewhat later in the year than previously forecast. Our target price benefits from a lower corporate tax rate in our NPV model as we reduce the blended federal and state rate[4] and we advance our NPV model by one year to reflect the end of 2017. The net result of these changes increases our target price from $3.00 to $3.50.

Summary

Despite the CRL issued to Antares in late October, we continue to see substantial upside from current levels. Success with Makena and accelerating growth for Otrexup combined with other anticipated launches this year create a confluence of positive factors that should drive topline and earnings growth. Near-term sales for Makena and likely launches for several Teva partnership products should add to this growth trend. As we move into 2018, we adjust our DCF model to reflect the changes we discuss above which increase to our valuation. The net of these changes increases our target price from $3.00 per share to $3.50 per share.

[3] After first sales are achieved, we will increase to 100%.

[4] Corporate tax rates were reduced from 34% to 21% as part of the Tax Cuts and Jobs Act of 2017. We lower our blended federal and state rate from just below 39% to 30%. We do not reduce the rate by the full 13% federal differential as we assume state rates will increase as flows of federal funds slow to states and local rates are increased to compensate. The decline also includes an adjustment to reflect the probability that federal rates may increase over the forecast period.

PROJECTED FINANCIALS

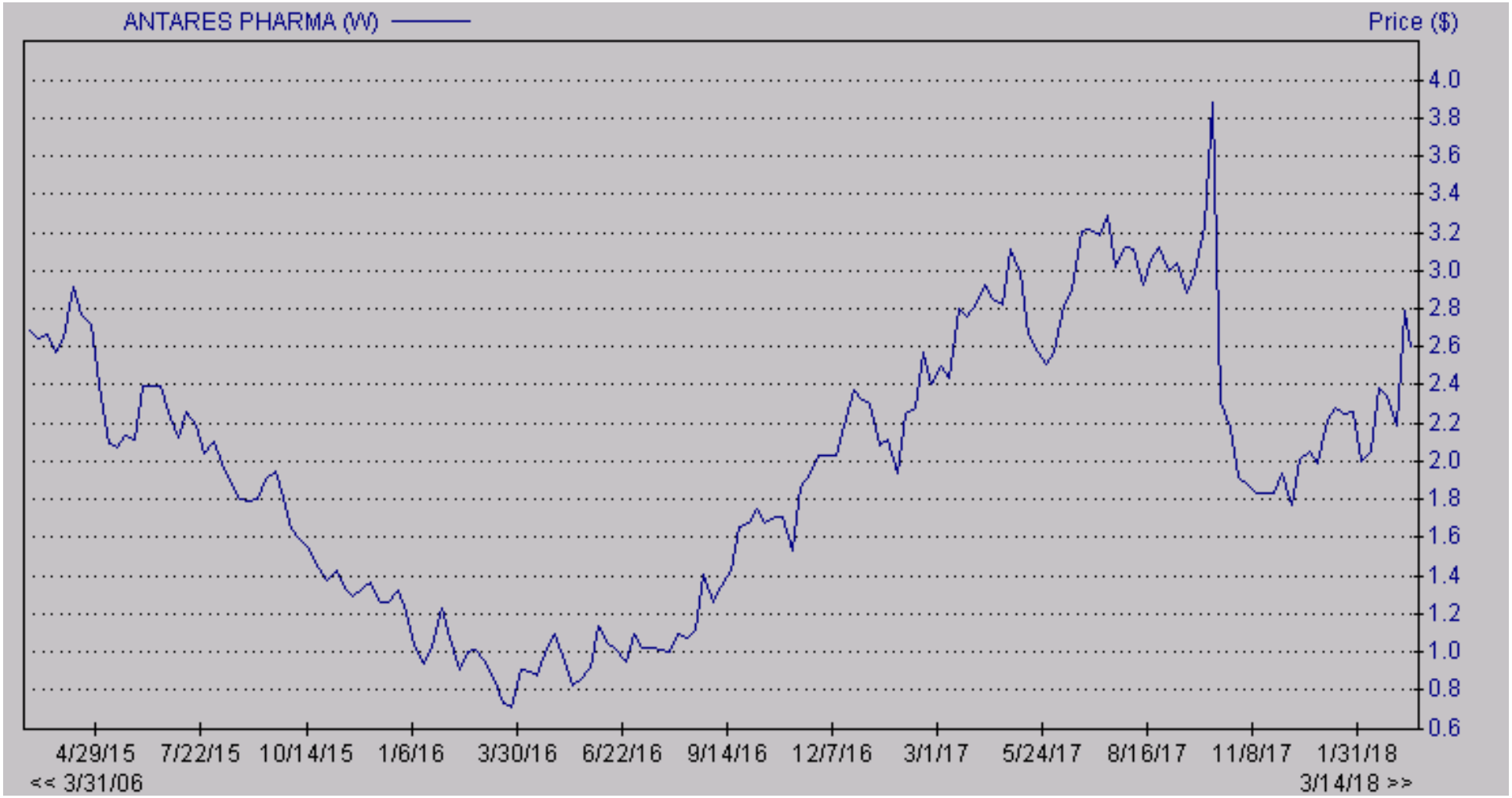
Antares Pharma, Inc. - Income Statement

Antares Pharma, Inc.	2016 A	Q1 A	Q2 A	Q3 A	Q4 A	2017 A	2018 E	2019 E
Total Revenues	**$49,485**	**$12,007**	**$13,416**	**$15,052**	**$14,040**	**$54,515**	**$74,589**	**$126,884**
Cost of Product Sales	$23,909	$5,448	$3,633	$7,600	$5,635	$22,317	$31,855	$54,367
Cost of Development Revenue	$4,908	$771	$1,983	$923	$1,472	$5,149	$3,000	$2,240
Gross Profit	$20,668	$5,788	$7,800	$6,529	$6,933	$27,050	$39,734	$70,277
Product Gross Margin	*41.8%*	*48.2%*	*58.1%*	*43.4%*	*49.4%*	*49.6%*	*53.3%*	*57.2%*
R&D	$21,127	$3,086	$3,160	$3,289	$3,612	$13,147	$20,000	$15,000
SG&A	$26,395	$7,467	$7,360	$8,186	$7,340	$30,353	$30,620	$31,539
Other expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($26,853)	($4,766)	($2,720)	($4,946)	($4,019)	($16,451)	($10,886)	$23,738
Operating Margin	*-54.3%*	*-39.7%*	*-20.3%*	*-32.9%*	*-28.6%*	*-30.2%*	*-14.6%*	*18.7%*
Total Other Income	($122)	$30	($120)	($507)	$305	($292)	$0	$0
Pre-Tax Income	($26,976)	($4,736)	($2,840)	($5,453)	($3,714)	($16,743)	($10,886)	$23,738
Taxes & Other	$100	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($27,076)	($4,736)	($2,840)	($5,453)	($3,714)	($16,743)	($10,886)	$23,738
Reported EPS	**($0.17)**	**($0.03)**	**($0.02)**	**($0.03)**	**($0.02)**	**($0.11)**	**($0.07)**	**$0.15**
Shares Outstanding	154,992.1	155,215.0	155,926.1	156,400.7	156,655.0	156,054.1	158,707.0	161,405.0

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

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HISTORICAL STOCK PRICE



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