Zacks Small-Cap Research

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Antares Pharma, Inc. (ATRS - NASDAQ)

Epinephrine Pen Ready to Go

Based on our DCF model and a 15% discount rate, ATRS is valued at approximately $3.75 per share. Our model applies a range of probabilities for development projects seeking ANDA and sANDA approval and eventual commercialization.

Current Price (8/17/2018)	$3.39
Valuation	**$3.75**

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 (%)	**10.8**
Beta	**-0.39**
Average Daily Volume (sh)	**998,781**
Shares Outstanding (mil)	**157.4**
Market Capitalization ($mil)	**533.5**
Short Interest Ratio (days)	**14.04**
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	**18.8**
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	$18.3 E	$63.2 E
2019					$137.8 E
2020					$198.2 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					$0.18 E
2020					$0.44 E

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What's New

FDA Approval of Teva Generic Epinephrine Pen

We amend our recent second quarter update to reflect the FDA approval of Teva's (NYSE: TEVA) epinephrine auto-injector for severe allergies. Both the 0.3 mg and the 0.15 mg (EpiPen Jr) were approved, receiving an AB equivalency rating. Teva did not provide details on timing or price, however, Teva has product ready to distribute and should only take only a short time (after printing up the package inserts) to stock the generic version in the drugstore. There are reported shortages of Mylan's branded and generic EpiPen which should allow for more rapid penetration of Teva's generic offering. We had assumed an 80% probability of approval and eventual sales in 2018, and now move this to 100%, raising our target price by $0.25 to $3.75.

2Q:18 Operational and Financial Results

Antares Pharma, Inc. (NASDAQ: ATRS) reported second quarter 2018 results on August 7, 2018, posting 5.6% topline growth and a loss of ($0.03) per share. Revenue growth was behind our forecast; however, earnings matched our estimate due to lower R&D expenses. Slower Otrexup growth and lower development revenue were partially offset by higher royalties relative to our numbers. Recent successes include the regulatory approval of Makena, progress on the sale of Zomajet and continued preparation for commercialization of Xyosted assuming an FDA approval.

Total revenues for 2Q:18 were $14.2 million, up from $13.4 million in 2Q:17. The Auto/Pen Injector Devices segment was the standout in the quarter due to contributions from Makena. Otrexup sales fell 4% on a GAAP basis due to rebates paid to PBMs despite a 3% increase in prescription volume. Absent this adjustment, Otrexup revenues would have increased 8%.

Sumatriptan market share declined by 6% in 2Q:18 due to Teva's loss of a price sensitive contract. However, revenues increased 16% to $2.7 million and the sumatriptan auto injector market as a whole rose 14%.[1] Total revenues of $2.7 million in 2Q:17 increased from $2.3 million. Pricing had been weakening as market share increased over the last few quarters; however, it appears that the environment has improved in 2Q:18 as Teva yielded market share in return for stronger pricing.

Needle-free Injector device sales surged to $1.4 million, expanding 44% compared to $1.0 million in 2Q:17. The Auto/Pen Injector category (excluding sumatriptan) rose to $3.3 million up 2,200% off of a small base. Total product sales, which are the combination of Otrexup, sumatriptan, Needle Free Injector devices and Auto/Pen Injectors, rose 120% in the second quarter of the year. Development revenue was down on a shift away from Makena development as first sales were recognized for this new product. Royalties rose 380% in the period to $1.3 million recognizing contributions from Makena.

Gross profit fell 8% in 2Q:18 to $7.2 million which represents a margin of 50.9% on total revenues. This compares to a 58.1% rate in 2Q:17 and 49.6% for the full year 2017. Product mix was cited as the cause of the contraction. Product sales margin was 39.8% in 2Q:18 vs. 28.0% in 2Q:17, while development revenue margin was 83.8% and 58.6% respectively.

R&D rose by 16% versus the prior year period due to new product investment and post-CRL activities for Xyosted. SG&A was up a modest 1% for the quarter on a year over year basis reflecting higher compensation and benefit expense offset by a reduction in legal expenses.

As of June 30, 2018, Antares held $28.8 million in cash on its balance sheet sequentially ahead due to funds received from the Zomajet sale more than offsetting cash burn. This is an increase in cash of $2.8 million compared to year end 2017. Cash burn of ($10.4) million over the first six months of the year is comprised of ($10.1) million of cash used in operating activities and ($0.3) million in capital expenditures. Cash received from sale of assets year to date has been $7.5 million from the Zomajet transaction.

[1] Source: Symphony Health Solutions

Makena Approval

On February 14, 2018 the FDA approved AMAG's Makena, a subcutaneous (SC) 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 intra-muscular (IM) injection duration in the rear end. 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 were recognized in the last week in March and the product has been on the market for 13 weeks as of June 30. A rapid changeover from IM to SC is expected to limit any losses to potential generic competitors. The sales team takes from 3.5 to 4 months to cycle through the physicians covered, which suggests that the new product has been introduced to the targeted provider group by the date of second quarter reporting.

AMAG disclosed that 60% of patients enrolled in the Makena Care Connection program are using the auto-injector. Makena as a whole (IM & SC) comprise 51% of the market and total sales for AMAG were $105 million in 2Q:18. Antares' partner noted that several generic competitors have launched an IM alternative and AMAG itself will partner to provide an authorized generic option of Makena to patients. Our research found a generic IM version of Hydroxyprogesterone Caproate offered in late June 2018 by American Regent, a subsidiary of the Daiichi Sankyo Group focused on injectable products. Despite the competition, we see additional value added in the improved delivery of Makena and with the new product's price remaining constant with the old one AMAG should be able to convert a majority of addressable patients.

Exhibit I – Makena[2]





- ☑ Efficient
- ☑ Discreet
- ☑ Administration friendly

	Subcutaneous injection	Intramuscular injection
Injection location	Back of upper arm	Upper-outer quadrant of the gluteus maximus
Injection duration	~15 seconds	One minute or longer
Needle size	27-gauge, 0.5" SQ needle	21-gauge, 1.5" IM needle

Sale of Zomajet

On October 10, 2017 Antares announced the sale of Zomajet to Ferring Pharmaceuticals for $14.5 million. As discussed in the release, Antares will continue to collect revenues from this product until year-end 2018. Payments totaling $7.5 million have been received in 1H:18 and $9.5 million has been collected overall. This is a beneficial transaction for Antares as it divests a non-core business and provides capital to grow new products. A final installment of $5.0 million will be paid when Ferring receives the CE mark and inventory is transferred which is expected in the fourth quarter of 2018, at which time the transaction will be completed.

Xyosted Resubmits NDA with FDA

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) concerns, which suggests the remedies required can be accomplished in-house.

[2] Source: ATRS 1Q:18 Corporate Presentation

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.

Antares is in the process of ramping up for commercialization following the anticipated approval of Xyosted. They are making conditional offers to 60 sales reps with TRT marketing experience, which will become effective upon FDA approval. 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. Assuming approval comes on the target action date, first sales are expected before year end.

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 on the determined user fee goal date, and we adjust our valuation accordingly.

Pfizer Partnership

On August 6, 2018, Antares announced a development agreement with Pfizer to construct a rescue pen using Antares' quick shot system. Only limited information was provided about the project, however, the indication is characterized as an underserved area. Rescue medications are generally in the asthma, epilepsy, seizure, allergy, migraine and cardiovascular event market. We anticipate it will take a few years to get to first sales and that the product will traverse the 505(b)(2) approval process. However, as with other partnerships with Teva and AMAG, we anticipate development revenues and product revenues prior to the official launch.

Development Products

- QST receives CRL issued October 20, 2017
  - Resubmission of NDA – Late March 2018
  - Develop marketing plan - 2Q & 3Q 2018
  - PDUFA date – September 29, 2018
  - Hiring offers contingent on approval – 3Q:18
- 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
    - FDA approval granted August 16, 2018
    - Only AB rated alternative
    - Both 0.3 mg and 0.15 mg versions approved

- AMAG's subcutaneous Makena presented positive pharmacokinetic data
    - Approval granted February 14, 2018
    - First sales March 2018
    - Approval is first for QuickShot autoinjector
- New Products
    - Developing investigational new drug (IND) application for an undisclosed neurology candidate
    - Urology product to complement Xyosted salesforce
    - Pfizer partnership for rescue pen in underserved area

Summary

Despite the CRL issued to Antares last year, we continue to see upside from current levels. We adjust our estimates to reflect the approval of Teva's epinephrine pen and better sumatriptan performance. Estimates for royalty revenues increase to reflect the strong showing by Makena to date. The impact of these changes raises our target price to $3.75. Stronger than expected initial response to the generic epinephrine pen and success with Makena for both device sales and royalties are other positives which may support a net increase in revenue estimates if trends are confirmed for this product in future quarters.

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**	**$137,824**	**$198,179**
Cost of Product Sales	$22,317	$6,536	$6,677	$7,313	$7,943	$25,804	$59,290	$76,804
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	$76,294	$119,136
Product Gross Margin	*49.6%*	*43.4%*	*50.9%*	*53.7%*	*54.0%*	*54.4%*	*57.0%*	*61.2%*
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)	$29,735	$72,631
Operating Margin	*-30.2%*	*-44.2%*	*-27.6%*	*-13.2%*	*-7.9%*	*-17.8%*	*21.6%*	*36.6%*
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)	$29,735	$72,631
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)	$29,735	$72,631
Reported EPS	**($0.11)**	**($0.04)**	**($0.03)**	**($0.01)**	**($0.01)**	**($0.07)**	**$0.18**	**$0.44**
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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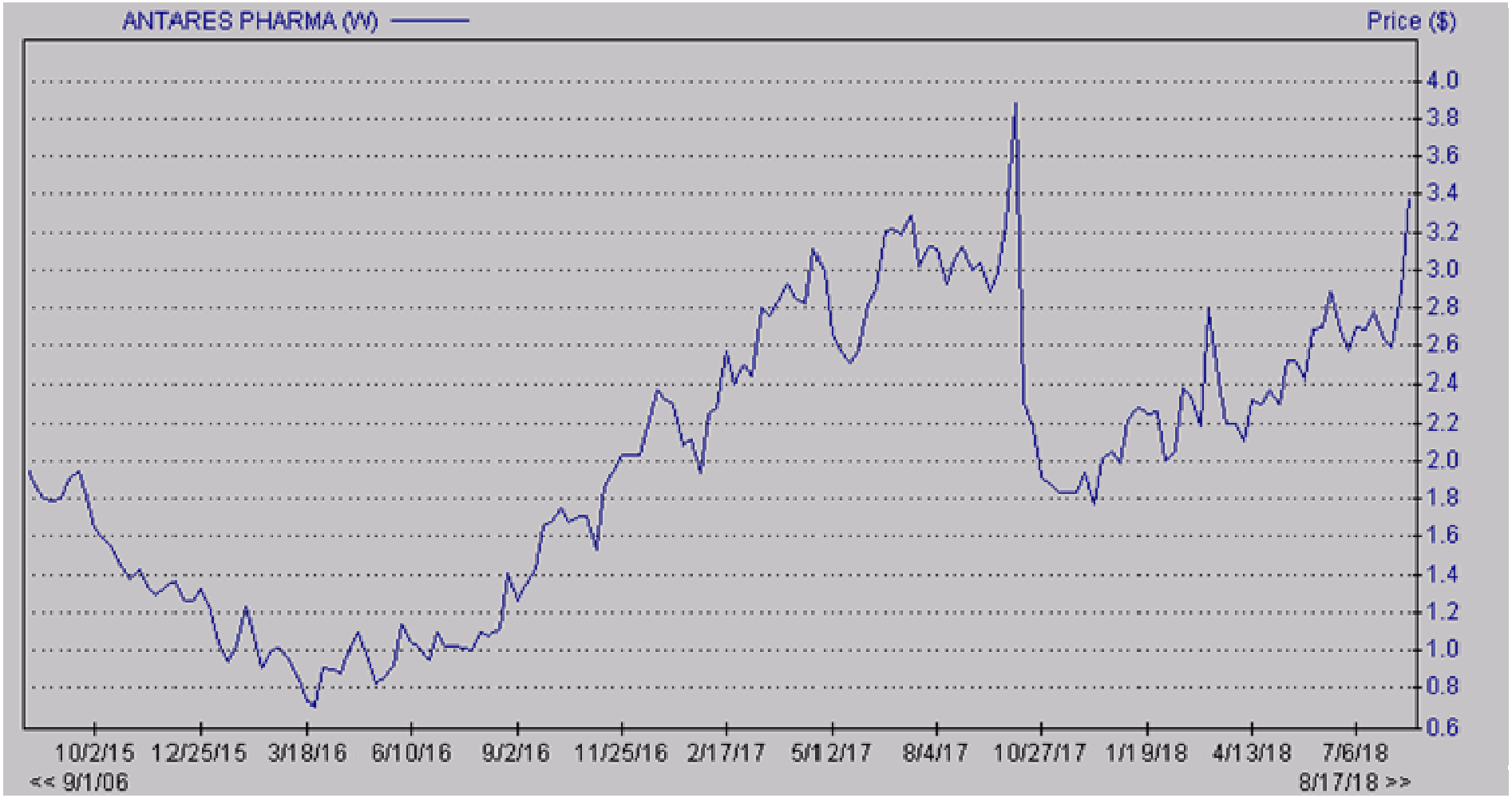
HISTORICAL STOCK PRICE

Antares Pharma, Inc. – Share Price Chart



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