Zacks Small-Cap Research

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Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: Cuts 32% of the U.S. Sales Force as Part of Cost Reduction Measures…

Based on our financial model that uses a EV/revenue multiple of 5.0x based on projected 2021 revenues, with a 15% discount rate, ARLZ is valued at $6/share. Additional upside to this valuation is possible from increased sales of YOSPRALA® and/or accretive deals.

Current Price (04/06/17)	$1.77
Valuation	**$6.00**

OUTLOOK

On April 5, 2017, Aralez Pharmaceuticals Inc. (ARLZ) announced plans to reduce its U.S. Sales Force by 32% and to realign the company's resources behind the launch of Zontivity®, which will occur in mid-April 2017. In addition, the company has commenced cost reductions across the entire business. The reduction in sales force is expected to reduce the current annual run rate of operating expenses by approximately $7.5 million. In the second quarter of 2017, the company expects to incur a cash severance charge of approximately $0.6 million. The launch of YOSPRALA has not gone according to plan, however we are encouraged by the company's proactive approach to deal with the difficult conditions, and we anticipate hearing more about the overall cost savings plan during the next quarterly update.

SUMMARY DATA

52-Week High	**$6.26**
52-Week Low	**$1.77**
One-Year Return (%)	**-59.03**
Beta	**1.07**
Average Daily Volume (sh)	**2,145,165**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$116**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**44**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-3.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**-1.9**
P/E using 2018 Estimate	**-2.1**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	8.1 A	12.6 A	13.6 A	20.0 A	54.3 A
2017	18.7 E	19.0 E	21.6 E	26.1 E	85.4 E
2018					91.5 E
2019					105.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.65 A	-$0.27 A	-$0.32 A	-$0.55 A	-$1.67 A
2017	-$0.48 E	-$0.47 E	-$0.42 E	-$0.36 E	-$1.73 E
2018					-$1.64 E
2019					-$1.55 E

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WHAT'S NEW

Business Update

On April 5, 2017, Aralez Pharmaceuticals Inc. (ARLZ) announced a 32% reduction in the U.S. sales force and the commencement of a company-wide cost savings program. In addition, the company is going to be allocating additional resources to the launch of Zontivity® combined with a significant decrease in marketing for YOSPRALA®. We anticipate learning more about each of these initiatives during the next quarterly earnings call in May 2017.

The reduction in the sales force (from 110 representatives to 75) is being undertaken to preserve the company's financial flexibility, and is needed in light of YOSPRALA® sales coming in well under prior estimates. Total cost savings from the sales force reduction is expected to be approximately $7.5 million on an annual basis, however the company will take a $0.6 million cash severance charge in the second quarter of 2017 as a result of the reductions. Even with the reduction in sales force, the company is continuing to evaluate various accretive business development opportunities. As a reminder, Deerfield has made an additional $250 million available for any new business development deals.

Given that the company will be turning its focus on the launch of Zontivity®, we have provided an overview of the drug below.

Zontivity®

Zontivity® (vorapaxar) is an inhibitor of protease-activated receptor-1 (PAR-1), which is the primary receptor for thrombin. The drug inhibits thrombin receptor-activating peptide (TRAP)-induced platelet aggregation in a dose-dependent manner (Macauley *et al*., 2010), however it does not affect platelet aggregation induced by adenosine diphosphate (ADP), thromboxane A_2 (TXA_2), or collagen (Siller-Matula *et al*., 2010).

The FDA approved Zontivity® on May 5, 2014 based on data from the Thrombin Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events (TRA 2°P TIMI 50) Phase 3 clinical trial that enrolled 26,449 patients with a history of myocardial infarction, ischemic stroke, or peripheral artery disease (PAD) (Morrow *et al*., 2012). Patients were randomly assigned 1:1 to receive either vorapaxar (2.5 mg) (n=13,225) or placebo (n=13,244) once daily in addition to standard of care treatment (aspirin or clopidogrel therapy). The primary efficacy endpoint was a composite of cardiovascular death, myocardial infarction, stroke, or urgent coronary revascularization.

Results from the trial showed that the primary endpoint had occurred in 1259 patients (11.2%) in the vorapaxar group compared to 1417 patients (12.4%) in the placebo group (HR=0.87, P<0.001). The rate of cardiovascular death or myocardial infarction was reduced from 8.2% to 7.3% for patients in the placebo and vorapaxar group, respectively (P=0.002). In patients with a qualifying diagnosis of myocardial infarction, treatment with vorapaxar reduced the relative risk of the primary endpoint by 20%.

Since Zontivity® is an anti-clotting agent there is a risk for severe bleeding to occur. In the TRA 2°P TIMI 50 trial, severe bleeding was seen in 438 vorapaxar-treated patients (4.2%) compared to 267 patients (2.5%) in the placebo group (P<0.001). During the trial, the data and safety monitoring board recommended that patients with a history of stroke discontinue vorapaxar due to excess occurrence of intracranial hemorrhage in those patients.

Zontivity® was approved to reduce the risk of heart attack, stroke, cardiovascular death, and urgent coronary revascularization in patients with a previous heart attack or PAD. Based upon the increased risk for bleeding, Zontivity® was approved with a "black box" warning indicating that the drug cannot be used in patients who had a stroke, transient ischemic attack, or intracranial hemorrhage due to the increased risk of intracranial hemorrhage in these patients.

Potential Market Opportunity

Heart disease is the number one cause of death in the U.S., claiming approximately 800,000 lives every year. Approximately 700,000 individuals in the U.S. suffer a heart attack each year, with approximately 500,000 of those being first time heart attacks and 200,000 being a recurrence.

Current standard of care for those who have suffered a heart attack includes dual antiplatelet therapy for a year (consisting of daily aspirin and a $P2Y_{12}$ inhibitor such as clopidogrel) followed by daily aspirin for life. The ability to add a third antiplatelet therapy for all patients following a heart attack will likely be challenging based on concerns related to cost and increased risk of bleeding associated with triple therapy. However, there are patients with high-risk of ischemic events in which physicians would likely consider adding Zontivity®, such as those with diabetes or recurrent spontaneous myocardial infarction.

A much larger opportunity may lie in patients with PAD, which is caused by narrowing or blockage of the arteries that carry blood from the heart to the legs. The CDC estimates that approximately 8.5 million individuals in the U.S. have PAD. In a secondary analysis from the TRA 2°P TIMI 50 trial, patients with PAD who received vorapaxar had decreased hospitalizations for acute limb ischemia (HR=0.58, *P*=0.006) and decreased need for peripheral artery revascularization (HR=0.84, *P*=0.017). Since current pharmacologic standard of care for PAD is monotherapy with either aspirin or clopidogrel, physicians may be more amenable to the addition of Zontivity®, particularly given its effectiveness in the TRA 2°P TIMI 50 trial.

Aralez is currently focused on access and reimbursement initiatives to ensure the appropriate wholesale acquisition cost (WAC) at the time of launch and to improve the products Tier position on formulary lists. The company is currently holding KOL advisory board meetings in order to learn more about the data compiled thus far for Zontivity® and particularly how the drug can best be positioned as a treatment for PAD. Aralez will begin promotion of Zontivity® in April 2017.

Conclusion and Valuation

Things are not yet proceeding according to plan for Aralez, but we are encouraged that management has identified the current challenges and is attempting to address them, beginning with reigning in costs as much as possible. We anticipate learning more about the steps the company is taking, particularly in regards to allocating additional resources behind the launch of Zontivity®, during the next earnings call in May 2017. In addition, since the PAD market represents potential upside for Zontivity®, we are looking forward to hearing how the company plans to proceed in that area.

Our valuation for Aralez is based on an enterprise value (EV)/revenues multiple of 5.0x on projected 2021 revenues of $199 million using a 15% discount rate. The company currently has $275 million in debt and approximately $65 million in cash at the end of 2016. This leads to a valuation of approximately $6 per share.

PROJECTED FINANCIALS

Aralez Pharmaceuticals Inc.
Income Statement

Aralez Pharmaceuticals, Inc.	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Vimovo (royalty)	**$20.3**	**$3.5**	**$3.5**	**$3.5**	**$3.5**	**$14.0**	**$12.0**	**$11.0**
YOY Growth		-	-	-	-	*-30.9%*	*-14.3%*	*-8.3%*
Yosprala	**$0.0**	**$0.4**	**$0.6**	**$0.9**	**$1.2**	**$3.1**	**$10.0**	**$20.0**
YOY Growth	-	-	-	-	-	-	-	-
Zontivity	**$0.6**	**$0.6**	**$0.6**	**$0.8**	**$0.9**	**$2.9**	**$3.5**	**$8.0**
YOY Growth	-	-	-	-	-	-	-	-
Toprol XL	**$8.0**	**$9.0**	**$9.0**	**$11.0**	**$15.0**	**$44.0**	**$44.0**	**$44.0**
YOY Growth	-	-	-	-	-	-	-	-
Other Products	**$25.4**	**$5.2**	**$5.3**	**$5.4**	**$5.5**	**$21.4**	**$22.0**	**$22.0**
Total Revenues	$54.3	$18.7	$19.0	$21.6	$26.1	$85.4	$91.5	$105.0
YOY Growth	-	-	-	-	-	*57.4%*	*7.1%*	*14.8%*
Cost of Goods Sold	$11.8	$3.5	$3.6	$4.0	$4.9	$16.0	$17.0	$19.0
Gross Income	$42.5					$69.4	$74.5	$86.0
Product Gross Margin	*78.3%*	*81.3%*	*81.1%*	*81.5%*	*81.2%*	*81.3%*	*81.4%*	*81.9%*
SG&A	$107.0	$25.0	$23.9	$23.2	$23.2	$95.3	$98.0	$103.0
% SG&A	*197.1%*	*133.5%*	*125.8%*	*107.4%*	*88.9%*	*111.6%*	*107.1%*	*98.1%*
SG&A Stock Based Compensation	$11.6	$3.5	$3.5	$3.5	$3.5	$14.0	$15.0	$15.0
R&D	$8.5	$0.7	$0.6	$0.5	$0.5	$2.3	$2.0	$2.0
% R&D	*15.7%*	*3.7%*	*3.2%*	*2.3%*	*1.9%*	*2.7%*	*2.2%*	*1.9%*
R&D Stock Based Compensation	$0.3	$0.1	$0.1	$0.1	$0.1	$0.2	$0.2	$0.3
EBITDA	($84.9)	($14.0)	($12.7)	($9.7)	($6.1)	($42.4)	($40.7)	($34.3)
Operating Margin	*-156.4%*	*-74.9%*	*-66.6%*	*-44.7%*	*-23.2%*	*-49.6%*	*-44.5%*	*-32.7%*
Interest, Income Net and Other	($5.5)	($8.5)	($8.5)	($8.5)	($8.5)	($34.0)	($34.0)	($34.0)
Amortization Expense	($12.6)	($8.0)	($8.0)	($8.0)	($8.0)	($32.0)	($30.0)	($30.0)
Pre-Tax Income	($103.0)	($30.5)	($29.2)	($26.2)	($22.6)	($108.4)	($104.7)	($98.3)
Taxes	($0.1)	$1.2	$1.2	$1.2	$1.2	$4.8	$3.0	$5.0
Net Income	($103.0)	($31.7)	($30.4)	($27.4)	($23.8)	($113.2)	($107.7)	($103.3)
YOY Growth	-	-	-	-	-	*9.9%*	*-4.8%*	*-4.1%*
Net Margin	*-189.7%*	*-169.5%*	*-159.7%*	*-126.6%*	*-91.0%*	*-132.5%*	*-117.7%*	*-98.4%*
Reported EPS	($1.67)	($0.48)	($0.45)	($0.40)	($0.33)	($1.66)	($1.54)	($1.45)
Avg. Weighted Shares Outstanding	61.8	65.5	67.0	69.0	71.0	68.1	70.0	71.0

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