Zacks Small-Cap Research

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Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: Acquires U.S. and Canadian Rights to Zontivity® From Merck…

Based on our financial model that uses a EV/revenue multiple of 5.0x based on projected 2020 revenues, with a 15% discount rate, ARLZ is valued at $11/share. Additional upside to this valuation is possible from attaining approval for YOSPRALA® in the E.U. and Canada and/or accretive deals.

Current Price (09/12/16)	$5.87
Valuation	**$10.50**

OUTLOOK

On September 7, 2016, Aralez Pharmaceuticals announced the acquisition of U.S. and Canadian rights to Zontivity® from Merck for $25 million in cash, graduated royalties, and potential sales-based milestones. Zontivity® is the only FDA approved protease-activated receptor-1 (PAR-1) inhibitor. PAR-1 is found on platelets and its inhibition can help prevent the formation of blood clots. Zontivity® is indicated for the reduction of thrombotic cardiovascular events in patients with a history of heart attack (myocardial infarction) or in patients with peripheral arterial disease (PAD).

Zontivity® is a very nice fit for Aralez, as the drug will be promoted to the same group of prescribing cardiologists as YOSPRALA®, which is currently pending FDA approval with a PDUFA date of Sep. 14, 2016.

SUMMARY DATA

52-Week High	**$10.04**
52-Week Low	**$3.12**
One-Year Return (%)	**-35.99**
Beta	**0.90**
Average Daily Volume (sh)	**872,923**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**$383**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**50**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-14.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**-2.0**
P/E using 2017 Estimate	**-4.2**

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)
2015	4.4 A	5.2 A	5.8 A	6.0 A	21.4 A
2016	8.1 A	12.6 A	12.7 E	15.8 E	49.1 E
2017					84.5 E
2018					136.8 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	$0.00 A	$0.50 A	-$0.25 A	-$0.40 A	-$1.16 A
2016	-$0.65 A	-$0.27 A	-$0.32 E	-$0.47 E	-$1.67 E
2017					-$1.04 E
2018					-$0.70 E

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WHAT'S NEW

Aralez Acquires U.S. and Canadian Rights to Zontivity®

On September 7, 2016, Aralez Pharmaceuticals, Inc. (ARLZ) announced the acquisition of U.S. and Canadian rights to Zontivity® from Merck. As an inhibitor of thrombin-induced platelet aggregation intended to reduce atherothrombotic events in patients with a history of heart attack, we believe Zontivity® will integrate seamlessly into the company's burgeoning cardiovascular pipeline that includes Fibricor® and YOSPRALA®, which is pending FDA approval with a PDUFA date of September 14, 2016.

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.

Sales of Zontivity® began in June 2014 and according to Symphony Reports the drug generated $2 million in revenue in 2015 and $2 million in revenue in the first half of 2016. Aralez acquired Zontivity® for an upfront payment of $25 million in cash along with graduated royalties and potential sales-based milestone payments. The company used a portion of the $93 million in cash that was available at the end of June 2016, and did not utilize the $200 million credit line that is currently in place with Deerfield management to avoid any future interest payments.

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.

Conclusion

Aralez's goal has always been to grow the company organically and through strategic business development opportunities that synergize with the company's anchor position in cardiovascular disease. Zontivity® certainly fits that descriptions, as it will be promoted to the same group of high prescribing cardiologists as YOSPRALA®. It is a revenue-generating product that has patent protection potentially extending to 2027. We currently estimate peak sales of $30-$35 million are possible, however this number may fluctuate as we learn more about the opportunity along with the sales and marketing strategy from the company in the coming months.

As a reminder, the PDUFA data for YOSPRALA® is September 14, 2016, and assuming the drug is approved we anticipate a formal launch in the fourth quarter of 2016 that will coincide with increasing the company's sales force to 110 individuals (from the 25 that are currently promoting Fibricor®). With the company's full efforts focused on the successful launch of YOSPRALA® later this year, we believe Zontivity® will be formally launched in 2017, with YOSPRALA® having first priority, Zontivity® second, and Fibricor® third.

We anticipated Aralez completing at least one business development transaction before the end of 2016, thus we are pleased to see that management is executing on the company's strategy. Following incorporation of Zontivity® into our financial model, we are increasing our valuation to $10.50 per share and believe that Aralez remains a top pick in the specialty pharmaceutical sector.

PROJECTED FINANCIALS

Aralez Pharmaceuticals Inc.
Income Statement

Aralez Pharmaceuticals, Inc.	2015 A*	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E	2018 E
Vimovo (royalty)	**$21.4**	**$4.5**	**$5.2**	**$5.3**	**$5.3**	**$20.3**	**$20.0**	**$20.0**
YOY Growth		-	-	-	-	*-5.1%*	*-1.5%*	*0.0%*
Yosprala	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$3.0**	**$3.0**	**$30.0**	**$75.0**
YOY Growth	-	-	-	-	-	-	-	-
Zontivity	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$4.0**	**$6.0**
YOY Growth	-	-	-	-	-	-	-	-
Other Products	**$27.4**	**$3.6**	**$7.4**	**$7.4**	**$7.5**	**$25.8**	**$26.5**	**$26.8**
Total Revenues	$48.8	$8.1	$12.6	$12.7	$15.8	$49.1	$80.50	$127.80
YOY Growth	-	-	-	-	-	*0.7%*	*63.8%*	*58.8%*
Cost of Goods Sold	$10.7	$2.5	$3.4	$2.8	$3.3	$12.0	$17.0	$27.0
Product Gross Margin	*78.0%*	*68.5%*	*73.3%*	*78.0%*	*79.1%*	*75.6%*	*78.9%*	*78.9%*
SG&A	$54.5	$37.5	$22.7	$26.0	$38.0	$124.2	$110.0	$125.0
% SG&A	*111.6%*	*464.9%*	*180.7%*	*204.7%*	*240.5%*	*252.8%*	*136.6%*	*97.8%*
R&D	$8.5	$4.4	$1.5	$1.5	$1.5	$8.9	$8.5	$8.8
% R&D	*17.4%*	*54.8%*	*11.7%*	*11.8%*	*9.5%*	*18.1%*	*10.6%*	*6.9%*
EBITDA	($24.9)	($36.4)	($15.0)	($17.6)	($27.0)	($95.9)	($55.0)	($33.0)
Operating Margin	*-51.1%*	*-451.2%*	*-119.2%*	*-138.6%*	*-170.9%*	*-195.3%*	*-68.3%*	*-25.8%*
Interest Income / Net	($8.5)	$4.5	($0.9)	($0.9)	($0.9)	$1.8	($2.5)	($3.0)
Amortization Expense	$8.6	$1.3	$2.1	$2.1	$2.1	$7.6	$8.0	$8.0
Pre-Tax Income	($42.0)	($33.1)	($18.0)	($20.6)	($30.0)	($101.7)	($65.5)	($44.0)
Taxes	$2.6	$0.7	($0.5)	$0.5	$0.5	$1.1	$3.0	$3.0
Net Income	($44.6)	($33.8)	($17.5)	($21.1)	($30.5)	($102.9)	($68.5)	($47.0)
YOY Growth	-	-	-	-	-	*130.5%*	*-33.4%*	*-31.4%*
Net Margin	*-91.4%*	*-419.4%*	*-138.9%*	*-166.1%*	*-193.0%*	*-209.3%*	*-85.1%*	*-36.8%*
Reported EPS	($0.70)	($0.65)	($0.27)	($0.32)	($0.47)	($1.67)	($1.04)	($0.70)
Fully Diluted Shares	63.4	52.2	64.4	65.0	65.4	61.7	66.0	67.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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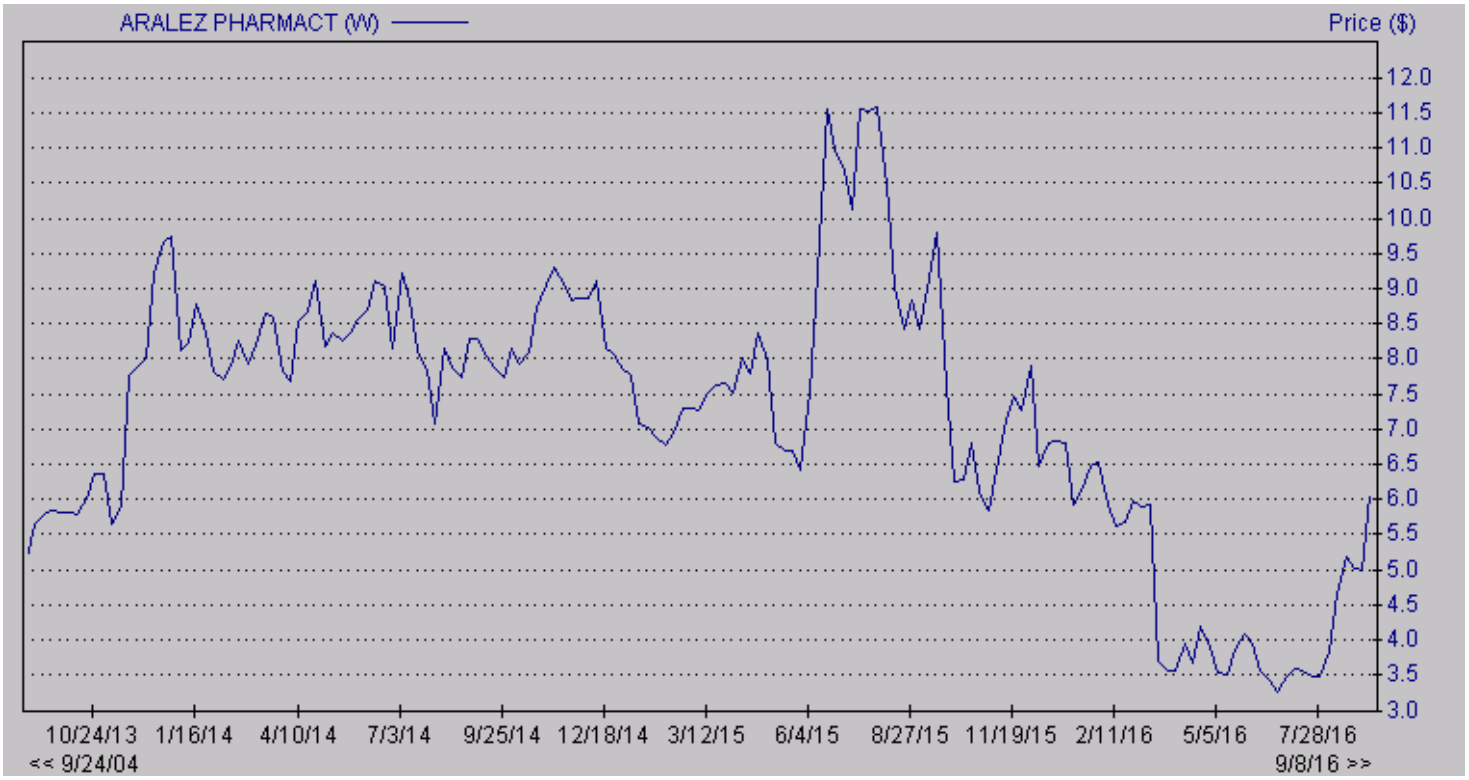
HISTORICAL STOCK PRICE



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