Zacks Small-Cap Research

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Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: Third Times a Charm! FDA Approves YOSPRALA®; Will Launch the First Week of October 2016…

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 $10.50/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 (09/19/16)	$5.64
Valuation	**$10.50**

OUTLOOK

On September 15, 2016, Aralez Pharmaceuticals, Inc. (ARLZ) announced that the FDA has approved YOSPRALA® for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.

The company will hire 85 additional sales representatives (in addition to the 25 currently employed for the promotion of Fibricor) and will formally launch YOSPRALA® in the first week of October 2016. With the recent acquisition of Zontivity®, Aralez now has a full suite of complementary products in the cardiovascular space from which to build a leading specialty pharmaceutical company.

SUMMARY DATA

52-Week High	**$10.04**
52-Week Low	**$3.12**
One-Year Return (%)	**-42.51**
Beta	**0.90**
Average Daily Volume (sh)	**1,848,850**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**$368**
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

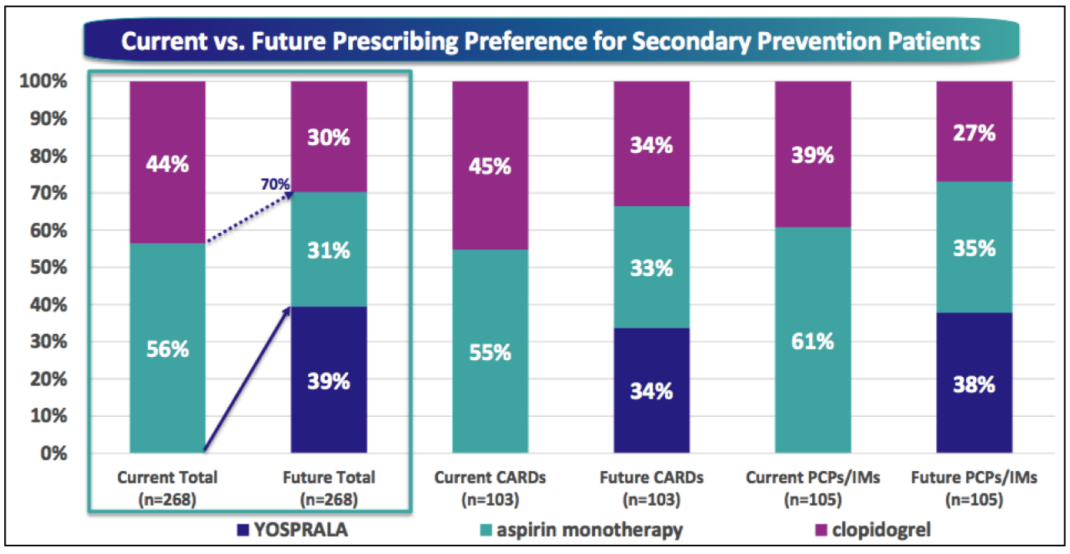
YOSPRALA® Approved by the FDA

On September 15, 2016, Aralez Pharmaceuticals, Inc. (ARLA) announced that the Food and Drug Administration (FDA) approved YOSPRALA® for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. In addition to announcing the approval of YOSPRALA®, the company confirmed the hiring of 85 additional sales representatives (in addition to the 25 that were already employed to promote Fibricor®) that will begin promoting YOSPRALA® the first week of October 2016.

YOSPRALA® is composed of a delayed-release aspirin (either 81 mg or 325 mg) and an immediate-release omeprazole (40 mg) intended for the secondary prevention of heart attack and stroke. For patients who have suffered a heart attack or stroke, taking daily aspirin has been shown to help prevent the occurrence a second heart attack or stroke. In the U.S., there are approximately 24 million secondary prevention patients, with approximately 70% of them taking daily aspirin. In addition, approximately 40% of prescribing physicians recommend that their patients take some form of gastric acid reducer. The reason for this is that daily use of nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin, is associated with an increased risk of developing gastric ulcers, thus the addition of an agent that decreases stomach acid production, such as the proton pump inhibitor (PPI) omeprazole, is intended to decrease the chance for the development of ulcers.

Previously disclosed data showed that patients taking YOSPRALA® develop significantly fewer gastric ulcers than patients taking enteric-coated aspirin after six months of treatment (Whellan *et al*., 2014). While the two components of YOSPRALA® are available separately, a meta-analysis showed that a fixed-dose combination regimen reduces the risk of non-compliance by 24%-26% compared to administering the drug components separately (Bangalore *et al*., 2007). The dangers of non-compliance are well documented, as aspirin users who are non-adherent to therapy have a three-fold higher risk of a major cardiovascular event (Biondi-Zoccai *et al*., 2006). Following a gastrointestinal bleeding event, aspirin discontinuation is associated with a seven-fold increase in the risk of a cardiovascular event or death (Derogar *et al*., 2013).

To gain better insight into how YOSPRALA® may be received by physicians, Aralez conducted a survey with cardiologists (CARDs), primary care physicians (PCPs), and internal medicine (IMs) specialists about their prescribing preferences for secondary prevention patients. The following graphic shows the breakdown of patients on either aspirin monotherapy or clopidogrel (Plavix®) and how the surveyed physicians might utilize YOSPRALA® following its launch. The results show that those physicians would prescribe YOSPRALA® for up to 39% of their secondary prevention patients, representing a sizeable market opportunity for Aralez and indicative of the fact that YOSPRALA® could gain appreciable market share following its launch.



Source: Aralez Pharmaceuticals Inc.

Aralez has taken a practical approach to pricing YOSPRALA® that is designed to remove barriers to access and make the drug affordable by targeting a patient copay of less than $1 per day for those with private health insurance. At launch, YOSPRALA® will have a Wholesale Acquisition Cost (WAC) of $150 per 30-count bottle. To help ensure patient access to the drug, Aralez will be working to secure formulary access, initiate an active and passive copay mitigation program at the point of sale, and establish a mail order pharmacy to provide patients with access to the drug at a reasonable out-of-pocket cost. To help ensure a successful launch, a coordinated campaign consisting of flyers, copay cards, patient brochures, and journal advertisements will be utilized to increase patient and physician awareness of YOSPRALA® as quickly as possible.

In addition to the upcoming launch of YOSPRALA® in the U.S., the company will be submitting for regulatory approval of the drug in Europe in the fourth quarter of 2016 and in Canada in the first half of 2017.

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®.

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 gross revenue in 2015 and $2 million in gross 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

The approval of YOSPRALA® is a major milestone for Aralez, as the pathway to approval has been a long, winding road for both shareholders and the company (going back to Aralez's predecessor POZEN). Now that its approved, we believe the market opportunity for YOSPRALA® is significant: for 2017 and 2018 we model for revenues of $30 and $75 million, respectively, with the total continuing to rise to a peak of $250 million in 2022. With an estimated 6.3 million patients taking daily aspirin and a PPI, there is likely upside to that peak revenue value depending upon what percentage of those patients can be converted to YOSPRALA®.

Aralez has built a solid foundation from which to build a leading specialty pharmaceutical company. From the beginning, management has continually stressed that the company will grow both organically (i.e., the approval of YOSPRALA®) and through strategic business development (i.e., the acquisition of Zontivity®). We would not be surprised to see additional business development activity through the rest of 2016 and into 2017, as management has indicated they are "actively involved" in examining a number of different potential opportunities. However, this will not take away from other areas of the company, as management has stressed the company is fully focused on the successful launch of YOSPRALA®.

We are glad to see the company executing according to the business plan laid out when Aralez was first formed. Our financial model, which is derived using an enterprise value (EV)/revenues multiple based on forecasted 2020 revenue, leads to a valuation of $10.50 per share and we continue to believe that Aralez is 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 and Other	($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)
Avg. Weighted Shares Outstanding	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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