Zacks Small-Cap Research

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Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: YOSPRALA™ Hits the Market and the Acquisition of Toprol-XL® is Complete…

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 (11/10/16)	$4.40
Valuation	**$11.00**

OUTLOOK

On November 7, 2016, Aralez Pharmaceuticals, Inc. announced financial results for the third quarter of 2016. The company reported $13.6 million, which consisted of $8.1 million in revenue from products acquired in Tribute acquisition and $5.5 million in Vimovo® royalties. Net loss for the quarter was $20.6 million, or $0.32 per share.

The company officially launched YOSPRALA™ on Oct. 3, 2016 and reported 190 new prescriptions (48/wk average) since that date, which compares reasonably well with other cardiovascular products launched in the past few years. New financial guidance for 2016 calls for revenues of $54 to $62 million (up from $48 to $58 million) and Non-GAAP SG&A expenses of $78 to $86 million (down from $85 to $100 million).

SUMMARY DATA

52-Week High	**$8.11**
52-Week Low	**$3.12**
One-Year Return (%)	**-34.38**
Beta	**0.96**
Average Daily Volume (sh)	**505,290**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**$288**
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	13.1 A	21.1 E	55.4 E
2017					145.5 E
2018					175.5 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 A	-$0.41 E	-$1.60 E
2017					-$1.18 E
2018					-$1.03 E

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WHAT'S NEW

Financial Update

On November 7, 2016, Aralez Pharmaceuticals, Inc. (ARLZ) announced financial results for the third quarter of 2016. The company reported revenues of $13.6 million, which was slightly ahead of our estimate of $12.7 million. This was due to better than expected revenue from products acquired in the Tribute acquisition of $8.1 million. Royalties derived from the sale of Vimovo® were $5.6 million, compared to $5.8 million in the third quarter of 2015. The decrease was due to a decrease in U.S. net sales of Vimovo® primarily due to lower net pricing by Horizon Pharma.

Total operating expenses for the third quarter were $33.3 million, and consisted of $3.4 million in cost of goods sold, $2.4 million in amortization, $25.4 million in SG&A expenses, and $2.0 million in R&D expenses. The $25.4 million in SG&A compared to $12.2 million for the same time period in 2015, with the increase primarily driven by $7.0 million of commercialization costs incurred in the U.S., $3.3 million of expenses related to the company's Canadian operation, and $4.2 million of additional expenses related to the company's global corporate structure. The $2.0 million in R&D expenses was a slight increase of $0.2 million from the same time period in 2015.

The company issued updated guidance for 2016 revenues and Non-GAAP SG&A and R&D expenses. Aralez now expects net revenues of $54 million to $62 million, while the original guidance was for net revenues of $48 million to $58 million. The increase in expected revenues is due to the acquisition of both Zontivity® and Toprol-XL®, as revenues from those products will be recognized net of related cost of product revenues and fees. Non-GAAP SG&A expenses are now expected to be $78 million to $86 million, which is down from original guidance of $85 million to $100 million. This decrease was due to the company carefully managing expenses and the timing of expenses, for instance through the timing of the hiring of the additional 85 sales representatives following the approval of YOSPRALA™. Non-GAAP R&D expenses are still expected to be $8 million to $10 million.

Aralez exited the third quarter of 2016 with $56.5 million in cash and cash equivalents following the payment of $25 million for the acquisition of Zontivity®. On October 31, 2016, the company drew down $25 million from the existing $200 million credit facility with Deerfield Management to replenish the $25 million upfront payment made for the Zontivity® acquisition and also drew down the remaining $175 million to finance the upfront cash cost for Toprol-XL®. An additional $250 million credit line has been established with Deerfield to fund any additional transactions.

Business Update

YOSPRALA™

On September 15, 2016, Aralez Pharmaceuticals, Inc. (ARLZ) 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.

The company formally launched YOSPRALA™ on October 3, 2016 and has a number of clearly defined objectives to achieve in order to make the launch successful, including generating awareness among doctors on the dangers of discontinuing aspirin therapy, the need to protect patients from gastrointestinal-related side effects due to aspirin

therapy, and building brand awareness with consumers. Since the launch, the company reports there have been 190 new prescriptions (averaging 48 per week), which puts YOSPRALA™ on par with other cardiovascular drugs launched in the past few years, including Brilinta®, Eliquis®, and Xarelto®. The sales team has reached approximately 8,000 physicians and 17,000 sample bottles have been distributed.

In regards to payor coverage, YOSPRALA™ is currently reimbursed for approximately 50% of patients when looking at all payors, with half being reimbursed without restrictions and the other half requiring pre-authorization. For commercial payors, approximately 60% of patients are covered with 40% of those requiring pre-authorization. The company is set to hold clinical and financial presentations with large payors in the near future to help secure favorable coverage. In addition, the company will continue to work for YOSPRALA™ inclusion in electronic prescription platforms.

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

On September 6, 2016, Aralez 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®, YOSPRALA™, and Toprol-XL®.

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, drawn from the company's cash balance, along with graduated royalties and potential sales-based milestone payments. The company drew down $25 million from the previously committed debt facility with Deerfield Management to replenish cash reserves following payment of the upfront fee.

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 Acquires U.S. Rights to Toprol-XL®

On October 31, 2016, Aralez announced the completion of the acquisition of the U.S. rights to Toprol-XL® and its authorized generic. Toprol-XL® is a cardiovascular beta-blocker indicated for treating patients with hypertension, angina pectoris, and stable, symptomatic heart failure. The acquisition further broadens the company's cardiovascular portfolio and will begin generating meaningful cash, which will move Aralez to profitability on an adjusted basis in 2017.

Toprol-XL®

Toprol-XL® (metoprolol succinate) is a selective β1-receptor blocker, otherwise known as a "beta blocker". This class of drugs is composed of competitive antagonists that block endogenous epinephrine and norepinephrine binding on adrenergic beta receptors. Toprol-XL® is a beta blocker that is selective for β1 receptors, which are mainly located on the heart and kidneys. The drug is formulated to provide a controlled and predictable release of metoprolol succinate from controlled release pellets such that only one dose of drug is required per day.

The FDA originally approved Toprol-XL® in 1992. The MERIT-HF study was a double blind, placebo controlled Phase 3 clinical trial of Toprol-XL® that included 3991 patients (1990 to Toprol-XL®) with NYHA Class II-IV heart failure (MERIT-HF Study Group). The trial was terminated early due to a statistically significant reduction in all-cause mortality (34%, *P*=0.00009). The risk of all-cause mortality plus all-cause hospitalization was reduced by 19% (P=0.00012).

Peak sales of Toprol-XL® were $1.6 billion in 2006, at which point patent protection expired. Sales of both Toprol-XL® and its authorized generic in the U.S. were $91 million, $89 million, and $81 million for 2014, 2015, and the first nine months of 2016, respectively. The uptick in 2016 revenues through the first nine months of the year was due in part to a contract that AstraZeneca signed with the Veterans Administration for the branded drug.

Aralez acquired the U.S. rights to Toprol-XL® for a $175 million upfront payment and could potentially pay $48 million in milestone payments along with a 15% royalty on net sales. As mentioned previously, the upfront payment was financed through the previously committed debt facility with Deerfield Management.

Conclusion and Valuation

We have built a detailed financial model for Aralez that takes into account potential future revenues from YOSPRALA™, Toprol-XL®, Zontivity®, other product revenues, and royalty income for Vimovo®.

For YOSPRALA™, we are encouraged to see that the launch is similar to other cardiovascular products from the past few years. We continue to model for minimal revenues in 2016. For 2017 and 2018, we conservatively estimate revenues of $20 and $55 million, respectively, with the total continuing to rise to a peak of $225 million in 2022. However, these numbers will be entirely dependent on YOSPRALA™ uptake and prescription growth and will likely be modified further in the future.

Our model calls for gross margins to be near 80% in 2016 and slowly rise to the mid-to-upper 80's by 2020. We model for $118.6 million in GAAP G&A expenses and $9.4 million in GAAP R&D expenses in 2016, both of which are in line with the company's updated guidance. The G&A expenses include approximately $12 million in stock-

based compensation, $15 million in merger-related expenses, and $11 million in excise tax payments. We anticipate G&A expenses increasing in 2017 with the relaunch of Zontivity®.

Our valuation is based on an enterprise value (EV)/revenues multiple of 5.0x on projected 2020 revenues of $304 million using a 15% discount rate. The company currently has $275 million in debt and we estimate approximately $81 million in cash (end of Q3 cash of $56 million plus $25 million from credit facility taken in October 2016). This leads to a valuation of $11 per share. We note potential upside to the model exists based on better than anticipated sales of the company's products and any additional accretive deals. We continue to 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 A	Q4 E	2016 E	2017 E	2018 E
Vimovo (royalty)	**$21.4**	**$4.5**	**$5.2**	**$5.6**	**$5.3**	**$20.6**	**$17.0**	**$15.0**
YOY Growth		-	-	-	-	*-3.9%*	*-17.3%*	*-11.8%*
Yosprala	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$1.5**	**$1.5**	**$20.0**	**$55.0**
YOY Growth	-	-	-	-	-	-	-	-
Zontivity	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.8**	**$0.8**	**$4.0**	**$6.0**
YOY Growth	-	-	-	-	-	-	-	-
Toprol XL	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$8.0**	**$8.0**	**$80.0**	**$75.0**
YOY Growth	-	-	-	-	-	-	-	-
Other Products	**$27.4**	**$3.6**	**$7.4**	**$8.1**	**$5.5**	**$24.5**	**$24.5**	**$24.5**
Total Revenues	$48.8	$8.1	$12.6	$13.6	$21.1	$55.4	$145.5	$175.5
YOY Growth	-	-	-	-	-	*13.4%*	*162.8%*	*20.6%*
Cost of Goods Sold	$10.7	$2.5	$3.4	$3.4	$3.3	$12.6	$35.0	$42.0
Product Gross Margin	*78.0%*	*68.5%*	*73.3%*	*75.3%*	*84.4%*	*77.3%*	*75.9%*	*76.1%*
SG&A	$54.5	$37.5	$22.7	$25.4	$33.0	$118.6	$138.0	$150.0
% SG&A	*111.6%*	*464.9%*	*180.7%*	*186.7%*	*156.4%*	*214.3%*	*94.8%*	*85.5%*
R&D	$8.5	$4.4	$1.5	$2.0	$1.5	$9.4	$8.5	$8.8
% R&D	*17.4%*	*54.8%*	*11.7%*	*14.9%*	*7.1%*	*17.0%*	*5.8%*	*5.0%*
EBITDA	($24.9)	($36.4)	($15.0)	($17.2)	($16.7)	($85.3)	($36.0)	($25.3)
Operating Margin	*-51.1%*	*-451.2%*	*-119.2%*	*-126.3%*	*-79.1%*	*-154.0%*	*-24.7%*	*-14.4%*
Interest, Income Net and Other	($8.5)	$4.5	($0.9)	($0.7)	($6.5)	($3.5)	($27.0)	($27.0)
Amortization Expense	($8.6)	($1.3)	($2.1)	($2.4)	($3.0)	($8.8)	($12.0)	($12.0)
Pre-Tax Income	($42.0)	($33.1)	($18.0)	($20.3)	($26.2)	($97.6)	($75.0)	($64.3)
Taxes	$2.6	$0.7	($0.5)	$0.3	$0.5	$0.9	$3.0	$5.0
Net Income	($44.6)	($33.8)	($17.5)	($20.6)	($26.7)	($98.6)	($78.0)	($69.3)
YOY Growth	-	-	-	-	-	*120.9%*	*-20.9%*	*-11.2%*
Net Margin	*-91.4%*	*-419.4%*	*-138.9%*	*-151.2%*	*-126.5%*	*-178.0%*	*-53.6%*	*-39.5%*
Reported EPS	($0.70)	($0.65)	($0.27)	($0.32)	($0.41)	($1.60)	($1.18)	($1.03)
Avg. Weighted Shares Outstanding	63.4	52.2	64.4	65.2	65.4	61.8	66.0	67.0

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

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