Zacks Small-Cap Research

January 25, 2017
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Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: Aralez Attains Formulary Status for YOSPRALA™ from Express Scripts and CVS Caremark…

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 (01/25/17)	$4.23
Valuation	**$11.00**

OUTLOOK

Aralez Pharmaceuticals Inc. (ARLZ) enters 2017 with its attention fully focused on the successful launch of YOSPRALA™, highlighted by recent news of attaining formulary status with both Express Scripts and CVS Caremark. Aralez also recently announced that it has submitted a Marketing Authorization Application to the European Medicines Agency for PA10040 (YOSPRALA™) as the company seeks to maximize the worldwide opportunity for YOSPRALA™. Later in 2017, the company is planning to re-launch Zontivity®, which was acquired from Merck in September 2016. Based on the recent acquisition of Toprol-XL®, the company is likely to attain profitability in 2017 on an adjusted EBITDA basis, and will use the cash flow generated from Toprol-XL® ($81M in revenues for the first nine months of 2016) to support the launches of YOSPRALA™ and Zontivity®.

SUMMARY DATA

52-Week High	**$6.71**
52-Week Low	**$3.12**
One-Year Return (%)	**-36.96**
Beta	**1.17**
Average Daily Volume (sh)	**527,038**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**$277**
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 (%)	**-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					120.5 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	-$0.55 E	-$1.74 E
2017					-$1.87 E
2018					-$1.42 E

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WHAT'S NEW

YOSPRALA™ Update

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 of 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.

On September 15, 2016, Aralez 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. The company formally launched YOSPRALA™ on October 3, 2016 with a total of 110 sales representatives.

Formulary Status Update

Aralez has recently announced that it entered into rebate agreements with both CVS Caremark and Express Scripts Inc., which secures formulary status for YOSPRALA™ with both companies. Aralez has worked diligently to secure payor commitments to remove access barriers and broaden reimbursement for YOSPRALA™ and with the addition of both CVS Caremark and Express Scripts, Inc., Aralez estimates that approximately 80% of lives are now covered.

MAA to the EMA

On January 9, 2017, Aralez announced that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for PA10040 (YOSPRALA™) for the secondary prevention of cardiovascular disease in patients at-risk for aspirin-induced gastric ulcers. Aralez will seek a partner to commercialize PA10040 in the E.U., and we anticipate partnership talks accelerating as additional sales data from the launch of YOSPRALA™ in the U.S. is reported.

New Data Presented on YOSPRALA™

On November 14, 2016, Aralez announced new data for YOSPRALA™ was presented at the annual American Heart Association Scientific Sessions. The post-hoc analysis, titled "Efficacy and Safety of PA32540 (Enteric-Coated Aspirin 325 mg and Immediate-Release Omeprazole 40 mg) in Patients With a History of Myocardial Infarction: Analyses From Two Phase 3 Clinical Trials" found that YOSPRALA™ 325 mg/40 mg was associated with significantly lower rates of gastric ulceration compared to 325 mg of enteric-coated aspirin (2.3% vs. 7.5%; P=0.020) along with a lower rate of duodenal ulcers (2.3% vs. 9.5%; P=0.002). The study examined a subset of 411 patients from two double-blind Phase 3 clinical trials who were taking aspirin for prevention of a second heart attack. All patients in the study had been taking 325 mg of aspirin daily for at least three months and were expected to continue daily aspirin for at least six months. They also were at risk for aspirin-associated gastric ulceration, which was defined as being ≥55 years of age or 18-54 years old with a documented history of gastric or duodenal ulcer within five years before study enrollment. Endoscopy was performed at baseline and after one, three, and six months of treatment. These results further confirm that YOSPRALA™ may help patients stay on aspirin therapy due to a decreased risk of gastic ulcers, which an abundance of evidence suggests can help decrease the risk of having, or dying from, a major cardiovascular event.

Increased IP Protection

On January 11, 2017, Aralez announced that the U.S. Patent and Trademark Office (USPTO) has issued a patent entitled "Compositions and Methods for Delivery of Omeprazole Plus Acetylsalicylic Acid" that covers YOSPRALA™. The patent (U.S. patent number 9,539,214) has an expiry date of late 2032, with the potential for

patent term extension into early 2033. Following its listing in the 'Orange Book', Aralez will have a total of four listed patents for YOSPRALA™.

Additional Corporate Updates

In addition to the recent news regarding YOSPRALA™, Aralez has also recently announced additional corporate updates, including:

On December 19, 2016, the company announced the commercial launch of BLEXTEN™ in Canada for the treatment of Seasonal Allergic Rhinitis and Chronic Spontaneou Urticaria. BLEXTEN™ is a second-generation antihistamine drug that works through selective antagonism of the H1 receptor, with effectiveness comparable to cetirizine (Zyrtec®) and desloratadine (Clarinex®). Sales of BLEXTEN™ should help drive organic growth of the company's Canadian business.

On December 19, 2016, Aralez announced that it had been added to the NASDAQ Biotechnology Index (NBI) effective as of the opening of trading that day. The NASDAQ Biotechnology Index contains securities of NASDAQ-listed companies classified as either Biotechnology or Pharmaceutical that also meet certain eligibility requirements, including minimum market capitalization and average daily trading volume.

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 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 $122.2 million in GAAP G&A expenses and $10.4 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 $61 million in cash at the end of 2016. This leads to a valuation of approximately $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**	**$55.0**	**$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	$120.5	$175.5
YOY Growth	-	-	-	-	-	*13.4%*	*117.7%*	*45.6%*
Cost of Goods Sold	$10.7	$2.5	$3.4	$3.4	$3.3	$12.6	$25.0	$42.0
Gross Income	$38.1					$42.8	$95.5	$133.5
Product Gross Margin	*78.0%*	*68.5%*	*73.3%*	*75.3%*	*84.4%*	*77.3%*	*79.3%*	*76.1%*
SG&A	$54.5	$33.9	$20.1	$22.8	$33.0	$109.8	$135.0	$140.0
% SG&A	*111.6%*	*420.5%*	*159.8%*	*167.2%*	*156.4%*	*198.3%*	*112.0%*	*79.8%*
SG&A Stock Based Compensation		$3.6	$2.6	$2.7	$3.5	$12.4	$14.0	$15.0
R&D	$8.5	$4.1	$1.5	$2.0	$2.5	$10.1	$8.0	$8.3
% R&D	*17.4%*	*50.7%*	*11.7%*	*14.9%*	*11.8%*	*18.2%*	*6.6%*	*4.7%*
R&D Stock Based Compensation		$0.3	$0.0	$0.0	$0.0	$0.3	$0.5	$0.5
EBITDA	($24.9)	($36.4)	($15.0)	($17.2)	($21.20)	($89.8)	($62.0)	($30.3)
Operating Margin	*-51.1%*	*-451.2%*	*-119.2%*	*-126.3%*	*-100.5%*	*-162.1%*	*-51.5%*	*-17.3%*
Interest, Income Net and Other	($8.5)	$4.5	($0.9)	($0.7)	($6.5)	($3.5)	($34.0)	($34.0)
Amortization Expense	($8.6)	($1.3)	($2.1)	($2.4)	($6.0)	($11.8)	($30.0)	($30.0)
Pre-Tax Income	($42.0)	($33.1)	($18.0)	($20.3)	($33.7)	($105.1)	($126.0)	($94.3)
Taxes	$2.6	$0.7	($0.5)	$0.3	$2.0	$2.4	$3.0	$5.0
Net Income	($44.6)	($33.8)	($17.5)	($20.6)	($35.7)	($107.6)	($129.0)	($99.3)
YOY Growth	-	-	-	-	-	*141.0%*	*19.9%*	*-23.0%*
Net Margin	*-91.4%*	*-419.4%*	*-138.9%*	*-151.2%*	*-169.2%*	*-194.3%*	*-107.1%*	*-56.6%*
Reported EPS	($0.70)	($0.65)	($0.27)	($0.32)	($0.55)	($1.74)	($1.87)	($1.42)
Avg. Weighted Shares Outstanding	63.4	52.2	64.4	65.2	65.4	61.8	69.0	70.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*
**Pro Forma Aralez Combined*

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