Zacks Small-Cap Research

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Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: PDUFA Date for YOSPRALA® Set For September 14, 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 (05/16/16)	$3.53
Valuation	**$10.50**

OUTLOOK

On May 10, 2016, Aralez Pharmaceuticals, Inc. announced financial results for the first quarter of 2016. Total revenues for the quarter were $8.1 million. The company reported a net loss of $33.8 million, or $0.65 per share. Aralez exited the quarter with approximately $114 million in cash and cash equivalents.

During the quarter, the company filed the NDA for YOSPRALA® and was assigned a PDUFA date of September 14, 2016. Aralez has begun promoting Fibricor in the U.S. with a 25 person sales team, which will expand to appromately 110 individuals upon the approval of YOSPRALA®.

SUMMARY DATA

52-Week High	**$12.69**
52-Week Low	**$3.42**
One-Year Return (%)	**-47.39**
Beta	**1.21**
Average Daily Volume (sh)	**596.746**
Shares Outstanding (mil)	**64**
Market Capitalization ($mil)	**$226**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**35**
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	11.5 E	11.9 E	15.1 E	46.5 E
2017					88.8 E
2018					150.5 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	-$0.36 E	-$0.39 E	-$0.40 E	-$1.76 E
2017					-$0.84 E
2018					-$0.27 E

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WHAT'S NEW

Financial Update

On May 10, 2016, Aralez Pharmaceuticals, Inc. (ARLZ) reported financial results for the first quarter of 2016 ending Mar. 31, 2016. The financial results include net product revenues for Tribute Pharmaceuticals Canada Inc. for the period Feb. 5, 2016 to Mar. 31, 2016.

Total revenues for the first quarter of 2016 were $8.1 million, and consisted of $4.5 million in royalties from the sale of Vimovo® and $3.6 million in sales of other products from Tribute. The $4.5 million in royalty revenue was an increase of $0.1 million from the same time period of 2015. This increase is due to an increase in the royalty rate (10%) due to the company from sales of Vimovo by AstraZeneca, which was offset by a decrease in royalties from Horizon Pharma due to increased gross-to-net deductions incurred by Horizon.

Total operating expenses for the first quarter were $44.4 million, and consisted of $2.5 million in cost of goods sold, $37.5 million in SG&A expenses, and $4.4 million in R&D expenses. Included in the $37.5 million in SG&A expenses were $18.8 million in one-time transaction-related expenses, $3.9 million to build out the Aralez infrastructure, $3.7 million in pre-commercialization activities in preparation for the launch of YOSPRALA®, $1.0 million in severance and retention expenses, and $3.6 million in share-based compensation. The $4.4 million in R&D expenses included $0.7 million in one-time transaction related costs and $0.3 million in share-based compensation.

Interest expense for the quarter was $0.3 million due to the issuance of $75 million in principal of the 2.5% senior secured convertible notes in February 2016. Other income during the first quarter was $4.8 million, which was primarily due to the change in the fair value of the warrant liability acquired from Tribute due to the decrease in the company's share price during the first quarter.

As of Mar. 31, 2016, Aralez had cash and cash equivalents of $114 million. In addition, the company has access to a $200 million line of credit to fund future acquisitions.

Business Update

YOSPRALA®

On March 28, 2016, Aralez announced that the U.S. Food and Drug Administration (FDA) accepted the company's new drug application (NDA) for YOSPRALA® for the secondary prevention of cardiovascular disease in patients at-risk for aspirin-related gastric ulcers. The Prescription Drug User Fee Act (PDUFA) goal date for a decision is September 14, 2016.

As a reminder, the NDA for YOSPRALA® was originally filed in March 2013. On August 25, 2014, Pozen received a complete response letter (CRL) from the FDA, noting that deficiencies were found during an inspection of the facility that manufactures the active ingredient of YOSPRALA®. The supplier responded to the FDA and on June 30, 2014 the NDA was resubmitted. On December 17, 2014, Pozen received a second CRL, which contained identical wording to the first CRL. On December 28, 2015, Pozen announced that the NDA would move forward with a new supplier of the active pharmaceutical ingredient (API) for YOSPRALA®. During the first quarter, Aralez worked with the new supplier in preparation for a planned inspection by the FDA. There were no deficiencies noted during this inspection. Thus, we believe this will resolve the deficiencies noted in the previous CRLs and we anticipate YOSPRALA® being approved on or before the PDUFA date.

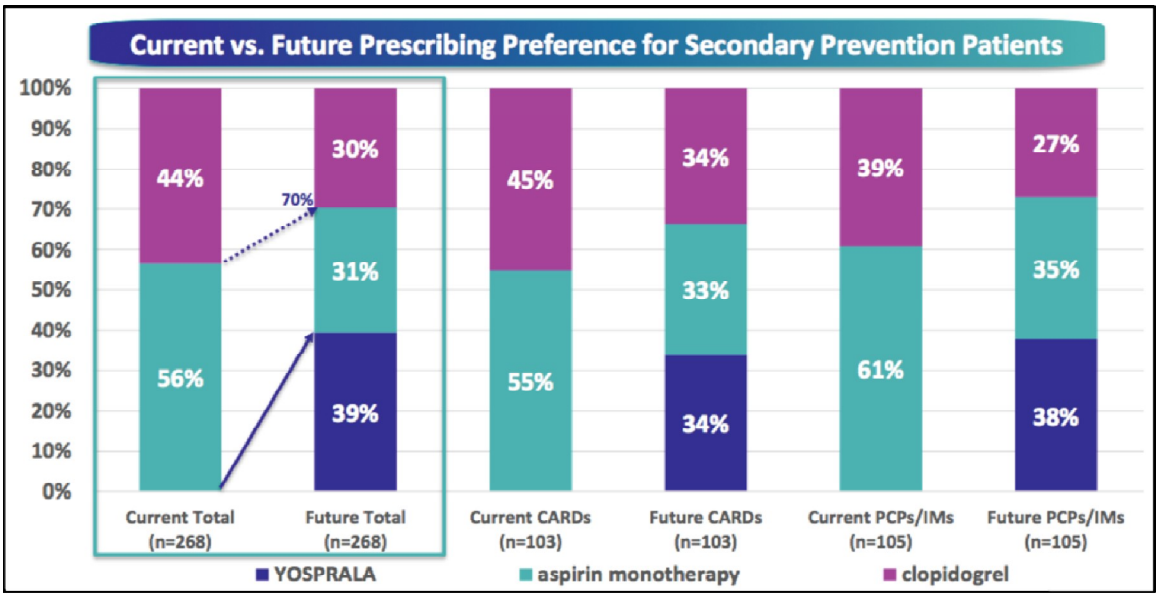
YOSPRALA® is composed of a delayed-release aspirin and an immediate-release omeprazole intended for the secondary prevention of heart attack and stroke. For patients who have suffered a heart attack or stroke, taking daily aspirin has been shown to help prevent the occurrence a second heart attack or 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. Pozen has previously shown that patients taking YOSPRALA® develop significantly fewer gastric ulcers than patients taking enteric-coated aspirin after six months of treatment (Whellan *et al*., 2014).

In April 2016, the U.S. Preventive Services Task Force (USPTF) stated that people in their 50's with risk factors for cardiovascular disease (i.e., high blood pressure, high cholesterol, or a history of smoking) may benefit from taking daily aspirin for at least a decade. This is in addition to guidelines published in the Journal of the American College of Cardiology that includes the use of aspirin in every instance of Dual Antiplatelet therapy (DAPT). Aralez is poised to benefit from these guidelines and the increasing awareness of the cardioprotective aspects of daily aspirin.

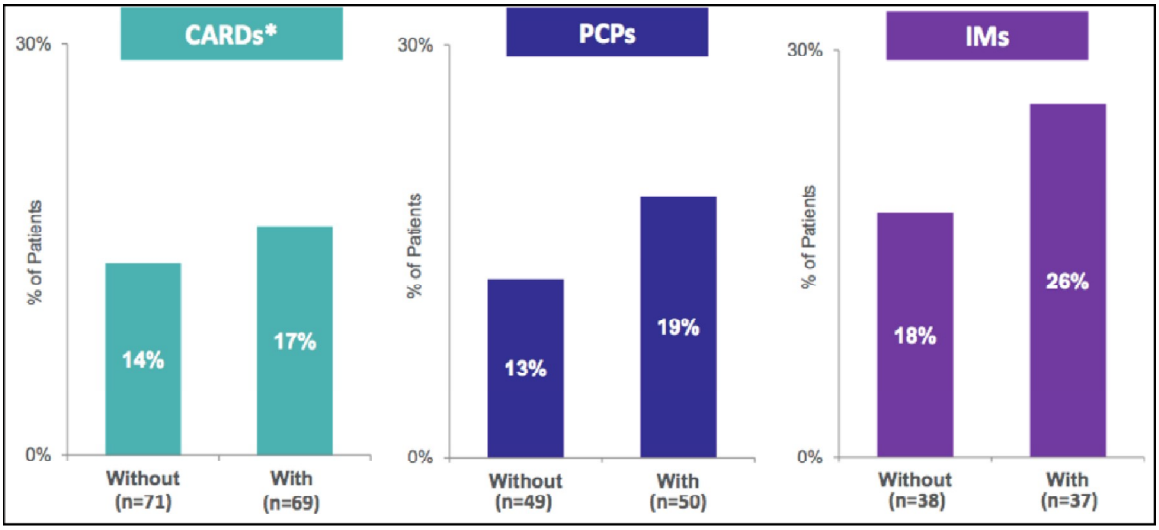
Aralez has developed an educational campaign titled "Hole in Aspirin Therapy" that will feature such things as advertisements in medical journals. The company is hoping to raise awareness of the gastrointestinal side effects of aspirin therapy (i.e., bleeding), which can lead to non-adherence and discontinuation of treatment. YOSPRALA® is designed to decrease the chances for these side effects. Discontinuing daily aspirin is reported to increase the risk of major cardiovascular events by three fold, thus avoiding the major reason for discontinuation of treatment could have a profound impact on patient healthcare outcomes.

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® once it is approved. 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 approval.



***Source*: Aralez Pharmaceuticals Inc.**

In addition, Aralez's market research indicates that educational initiatives can help to drive physician support of YOSPRALA®. The following figure shows that physicians intend to use YOSPRALA® in approximately 14-18% of their aspirin/proton pump inhibitor patients without educational initiatives, but this increases to approximately 17-26% for physicians that are supplied with educational materials.



Source: Aralez Pharmaceuticals Inc.

Aralez has indicated that upon FDA approval, the company will launch YOSPRALA® with approximately 110 sales representatives (25 of which are already employed to promote Fibricor®). The company estimates that this will allow them to reach 29% of secondary prevention specialists, or approximately 15,000 physicians. The company will likely expand this sales force to approximately 300 individuals that will reach 40% of the defined market, or close to 35,000 physicians.

Aralez will file for approval of YOSPRALA® in Europe in the fourth quarter of 2016, however the company has not indicated whether the rights to the drug will be licensed or if the company will promote it in that region.

Fibricor®

Fibricor® is a unique formulation of fenofibric acid and is indicated as an adjunctive therapy to diet for the treatment of severe hypertriglyceridemia (triglycerides ≥ 500 mg/dL), to reduce elevated LDL cholesterol, total cholesterol, triglycerides, apolipoprotein B (Apo B), and to increase HDL cholesterol. Fenofibrate was originally sold by Abbott Labs (now AbbVie Pharmaceuticals) as TriCor, with peak sales in excess of $1 billion. AbbVie brought a blockbuster next-generation product, Trilipix (fenofibric acid) to the market as a follow-on to TriCor, but now 80% of the market for fenofibrate and fenofibric acid is generic. As a reminder, Tribute acquired Fibricor® from Sun Pharma in May 2015. Tribute paid $10 million for the rights to the product, which included $5 million upfront, $2 million due in November 2015, and $3 million due in May 2016. Fibricor® had U.S. net sales of $2 million in 2015 with no promotion. Aralez has assembled a 25 person sales team to promote Fibricor® to approximately 3,500 cardiologists and primary care physicians, which began promoting the drug in April 2016.

One of the key aspects in launching Fibricor® will be to begin to build relationships ahead of the launch of YOSPRALA®. In addition, the company's commercialization strategy is designed to educate healthcare practicioners on the benefits of Fibricor® and how to maximize effectiveness through prescribing practices. Lastly, the company is planning to utilize a new copay program to leverage affordability of both the branded drug and the authorized generic. Following approval of YOSPRALA®, Aralez intends to promote the two drugs together in order to help drive U.S. sales of Fibricor®.

Conclusion and Valuation

We have built a detailed financial model for Aralez that takes into account potential future revenues from YOSPRALA®, Fibricor®, the other assets acquired from Tribute, and royalty income for Vimovo®.

For YOSPRALA®, we continue to anticipate approval of the drug in the fourth quarter of 2016, leading to minimal revenues this year. For 2017 and 2018 we model for revenues of $40 and $100 million, respectively, with the total continuing to rise to a peak of $250 million in 2022.

For Fibricor and the company's other assets, we model for just over $3 million in revenue for Fibricor and approximately $19 million in revenue for the rest of the portfolio in 2016, with revenues growing in the mid-single digits in the following years.

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 operating expenses in 2016 of approximately $146 million, which includes $123 million in GAAP G&A expenses and $14 million in GAAP R&D expenses, both of which are in line with the company's guidance. Additionally, 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. Operating expenses will decrease slightly in 2017 before rising in 2018 due to expansion of the sales force promoting YOSPRALA®.

Our valuation is based on an enterprise value (EV)/revenues multiple of 5.0x on projected 2020 revenues using a 15% discount rate, which yields a fair value of approximately $10.50. We note that additional upside to this valuation is possible from the company attaining approval for YOSPRALA® in Canada and the E.U., better than anticipated sales of products from the company's portfolio, and of course any accretive deals, at least one of which we anticipate occurring before the end of 2016.

PROJECTED FINANCIALS

Aralez Pharmaceuticals Inc.
Income Statement

Aralez Pharmaceuticals, Inc.	2015 A*	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
Fibricor	**$2.0**	**$0.5**	**$0.8**	**$0.8**	**$0.8**	**$2.9**	**$3.3**	**$3.5**
YOY Growth	-	-	-	-	-	-	-	-
Vimovo (royalty)	**$21.4**	**$4.5**	**$5.7**	**$5.8**	**$5.8**	**$21.8**	**$24.0**	**$25.0**
YOY Growth		-	-	-	-	*1.9%*	*10.1%*	*4.2%*
Yosprala	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$3.0**	**$3.0**	**$40.0**	**$100.0**
YOY Growth	-	-	-	-	-	-	-	-
Other Products	**$25.4**	**$3.1**	**$5.0**	**$5.3**	**$5.5**	**$18.9**	**$21.5**	**$22.0**
Total Revenues	$48.8	$8.1	$11.5	$11.9	$15.1	$46.5	$88.8	$150.5
YOY Growth	-	-	-	-	-	*-4.7%*	*90.9%*	*69.5%*
Cost of Goods Sold	$10.7	$2.5	$2.2	$2.3	$2.8	$9.8	$14.0	$22.0
Product Gross Margin	*78.0%*	*68.5%*	*80.8%*	*80.7%*	*81.5%*	*78.8%*	*84.2%*	*85.4%*
SG&A	$54.5	$37.5	$26.0	$28.0	$31.0	$122.5	$110.0	$125.0
% SG&A	*111.6%*	*464.9%*	*227.1%*	*235.3%*	*205.3%*	*263.3%*	*123.9%*	*83.1%*
R&D	$8.5	$4.4	$3.0	$3.2	$3.3	$13.9	$7.0	$5.0
% R&D	*17.4%*	*54.8%*	*26.2%*	*26.9%*	*21.9%*	*29.9%*	*7.9%*	*3.3%*
EBITDA	($24.9)	($36.35)	($19.8)	($21.6)	($22.0)	($99.7)	($42.2)	($1.5)
Operating Margin	*-51.1%*	*-451.2%*	*-172.5%*	*-181.5%*	*-145.7%*	*-214.4%*	*-47.5%*	*-1.0%*
Interest Income / Net	($8.5)	$4.5	($0.5)	($0.6)	($0.6)	$2.9	($2.5)	($3.0)
Amortization Expense	$8.6	$1.3	$2.3	$2.5	$2.5	$8.6	$10.0	$11.0
Pre-Tax Income	($42.0)	($33.1)	($22.6)	($24.7)	($25.1)	$105.4	($54.7)	($15.5)
Taxes	$2.6	$0.7	$0.7	$0.8	$1.0	$3.2	$4.0	$5.0
Net Income	($44.6)	($33.8)	($23.3)	($25.5)	($26.1)	($108.5)	($58.7)	($20.5)
YOY Growth	-	-	-	-	-	*143.2%*	*-45.9%*	*-65.1%*
Net Margin	*-91.4%*	*-419.4%*	*-203.1%*	*-213.9%*	*-172.5%*	*-233.4%*	*-66.1%*	*-13.6%*
Reported EPS	($0.70)	($0.65)	($0.36)	($0.39)	($0.40)	($1.76)	($0.84)	($0.27)
Fully Diluted Shares	63.4	52.2	64.0	65.0	65.0	61.5	70.0	75.0

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

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WEEKLY PRICE CHART



Source: Stockcharts.com

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