Zacks Small-Cap Research

March 16, 2017
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: 2016 Financial Results and Guidance for 2017…

Based on our financial model that uses a EV/revenue multiple of 5.0x based on projected 2021 revenues, with a 15% discount rate, ARLZ is valued at $6/share. Additional upside to this valuation is possible from increased sales of YOSPRALA® and/or accretive deals.

Current Price (03/16/17)	$2.37
Valuation	**$6.00**

OUTLOOK

On Mar. 13, 2017, Aralez Pharmaceuticals, Inc. (ARLZ) announced financial results for the fourth quarter and full year 2016. Total revenues in 2016 were $54.3 million. The company reported a net loss of $103 million and exited 2016 with $64.9 million in cash and cash equivalents. Aralez launched YOSPRALA® in October 2016 and thus far prescription uptake has been slower than expected, however the company is working diligently through delays in managed care coverage, building brand awareness, and decreasing switching at the pharmacist level. The company will be launching Zontivity in June 2016 following KOL advisory board meetings in March and April 2017 to create strategies for the launch and how best to develop the PAD market.

SUMMARY DATA

52-Week High	**$6.26**
52-Week Low	**$2.09**
One-Year Return (%)	**-43.44**
Beta	**1.12**
Average Daily Volume (sh)	**1,316,252**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$156**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**46**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-3.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**-1.9**
P/E using 2018 Estimate	**-2.1**

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)
2016	8.1 A	12.6 A	13.1 A	21.1 A	54.3 A
2017	18.7 E	19.0 E	21.6 E	26.1 E	85.4 E
2018					91.5 E
2019					105.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.65 A	-$0.27 A	-$0.32 A	-$0.55 A	-$1.67 A
2017	-$0.48 E	-$0.47 E	-$0.42 E	-$0.36 E	-$1.73 E
2018					-$1.64 E
2019					-$1.55 E

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Update

On March 13, 2017, Aralez Pharmaceuticals, Inc. (ARLZ) announced financial results for the fourth quarter and full year 2016. All prior year information is from the company's predecessor, Pozen, Inc. (POZN).

Total revenues in the fourth quarter of 2016 were $20.0 million, compared to $6.0 million for the fourth quarter of 2015. The revenues were comprised of:

- Net product revenue of $6.4 million, which primarily represented revenue from products acquired from Tribute Pharmaceuticals.
- Other revenues of $13.6 million, which was comprised of $8.6 million in net revenue from the acquisitions of Toprol-XL® and Zontivity® along with $5.0 million in VIMOVO® royalties.

Total revenues for the fully year 2016 were $54.3 million, compared to $21.4 million for the full year 2015. The revenues were comprised of:

- Net product reveue of $25.4 million, which primarily represent revenue from products acquired from Tribute Pharmaceuticals.
- Other revenues of $28.8 million, which was comprised of $8.8 million in net revenue from the acquisitions of Toprol-XL® and Zontivity® along with $20.0 million in VIMOVO® royalties.

GAAP SG&A expenses for the fourth quarter of 2016 were $32.9 million, compared to $16.7 million for the fourth quarter of 2015. The increase was driven primarily by increased commercialization costs for YOSPRALA®, costs to support the Aralez global corporate structure, product acquisition related expenses, and higher share compensation expense. GAAP R&D expenses for the fourth quarter of 2016 were $0.9 million, which was a decrease from $3.4 million in 2015. The decrease was due to higher costs related to YOSPRALA® in 2015.

For the full year 2016, GAAP SG&A expenses were $118.5 million, compared to $50.3 million for the full year 2015. The increase in SG&A expenses was driven primarily by increased commercialization costs related to the launch of YOSPRALA® in October 2016, costs to support the Aralez global corporate structure, excise tax equalization payments and product acquisition related expenses. GAAP R&D expenses in 2016 were $8.8 million compared to $8.5 milion in 2015.

Aralez exited 2016 with approximately $64.9 million in cash and cash equivalents. We believe the company has adequate resources to fund operations for at least the next 12 months. The company also has approximately $274 million in long term debt, which is comprised of $75 million in 2.5% senior secured convertible notes (due February 2022) and $200 million outstanding under a credit facility with Deerfield Management with an interest rate of 12.5%. The company will owe $26.9 million in interest in 2017.

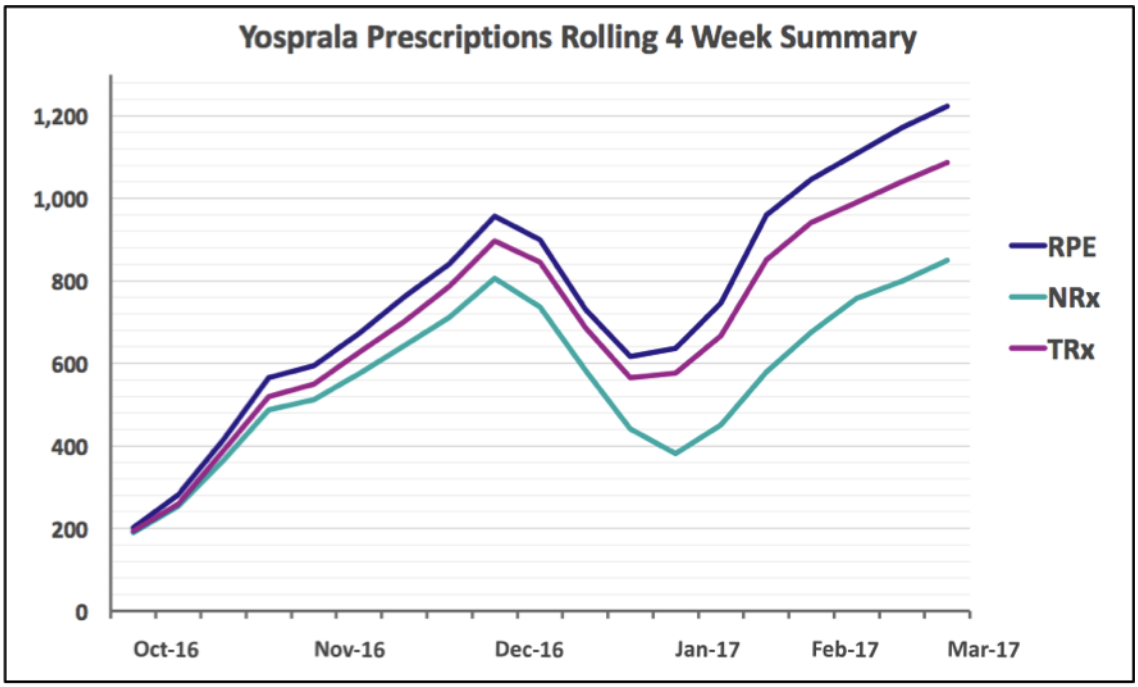
Aralez provided financial guidance for 2017 and currently expects 2017 net revenues of $80 to $100 million and adjusted EBITDA of $(25) to $(10) million. The revenue numbers are quite below our previous estimate of $120 million for 2017, and we believe this is due in part to slower than expected prescription uptake for YOSPRALA®. For this reason we have reduced our estimate for 2017 YOSPRALA® revenues from $20 million to $3.1 million, however we note there may be some upside to this number if momentum in prescriptions begins to accelerate.

YOSPRALA® Update

During the conference call to discuss results for 2016, management provided both some qualitative and quantitate feedback on how the launch of YOSPRALA® is progressing thus far. Qualitatively, it appears that physician's are open to the key concepts behind YOSPRALA®, namely that it can help improve patient compliance for those taking daily aspirin by decreasing adverse gastrointestinal side effects. Quantitatively, there have been approximately 60,000 calls since the launch to approximately 16,000 healthcare practitioners and sales reps have distributed approximately 54,000 sample bottles. However, prescription uptake has not been as high as the company had expected at this point. Over 600 physicians have written prescriptions since the launch, with 61% of those written by primary care physicians and 25% written by cardiologists.

There appears to be some pushback from cardiologists regarding YOSPRALA®, however it doesn't appear to have anything to do with YOSPRALA's® properties, but rather making cardiologists feel comfortable prescribing the product and to continually do so.

The following chart shows prescription growth for YOSPRALA® since its launch in October 2016. We attribute the decrease in the Dec. timeframe to be due to the holiday season, and are encouraged by the uptick since the first of the year.



Source: Aralez Pharmaceuticals, Inc.

Given the slow uptake seen thus far in YOSPRALA®, we have significantly decreased our projected revenue numbers over the next couple of years, however there may be upside to our new projections if prescription numbers begin to pick up. We now are estimating $3.1 million in 2017 YOSPRALA® revenues and $10 million in 2018. We will continue to monitor uptake over the next year and make adjustments to our model accordingly.

Zontivity® Update

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.

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 is currently focused on access and reimbursement initiatives to ensure the appropriate wholesale acquisition cost (WAC) at the time of launch and to improve the products Tier position on formulary lists. The company is currently holding KOL advisory board meetings in order to learn more about the data compiled thus far for Zontivity® and particularly how the drug can best be positioned as a treatment for PAD. Aralez will begin promotion of Zontivity® in June 2017.

Toprol-XL® Update

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 $95 million for 2014, 2015, and 2016, respectively. The uptick in 2016 revenues was due in part to a contract that AstraZeneca signed with the Veterans Administration (VA) for the branded drug. However, we anticipate revenues to decrease in future years due to generic competition, which could end up impacting the VA contract. Aralez will record revenues net of cost of sales during the transition period until the company takes full control of the drug from AstraZeneca.

Conclusion and Valuation

We are disappointed by the struggles in the early launch of YOSPRALA® and we have adjusted our model accordingly. For 2017 and 2018, we now model for revenues of $3.1 million and $10 million, respectively. We will continue to monitor prescription growth and adjust these numbers as time goes on. We continue to call for mid single digit revenues for Zontivity® over the next few years, however we view the PAD market as something that offers potential upside, and we look forward to more clarity from the company on this in the future.

We continue to model for gross margins to be near 80% in 2017 and slowly rise to the mid-to-upper 80's by 2020. We model for $101 million in GAAP G&A expenses and $2.5 million in GAAP R&D expenses in 2017, which includes approximately $14 million in non-cash, share-based compensation. Our model calls for a GAAP net loss in 2017 of approximately $105 million, which is in line with the company's guidance.

Our valuation is based on an enterprise value (EV)/revenues multiple of 5.0x on projected 2021 revenues of $199 million using a 15% discount rate. The company currently has $274 million in debt and approximately $65 million in cash at the end of 2016. This leads to a valuation of approximately $6 per share. This is significantly lower than our previous target price, however it is the result of having to significantly lower our projections of YOSPRALA® revenue based on how the drug is selling now.

PROJECTED FINANCIALS

Aralez Pharmaceuticals Inc.
Income Statement

Aralez Pharmaceuticals, Inc.	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Vimovo (royalty)	**$20.3**	**$3.5**	**$3.5**	**$3.5**	**$3.5**	**$14.0**	**$12.0**	**$11.0**
YOY Growth		-	-	-	-	*-30.9%*	*-14.3%*	*-8.3%*
Yosprala	**$0.0**	**$0.4**	**$0.6**	**$0.9**	**$1.2**	**$3.1**	**$10.0**	**$20.0**
YOY Growth	-	-	-	-	-	-	-	-
Zontivity	**$0.6**	**$0.6**	**$0.6**	**$0.8**	**$0.9**	**$2.9**	**$3.5**	**$8.0**
YOY Growth	-	-	-	-	-	-	-	-
Toprol XL	**$8.0**	**$9.0**	**$9.0**	**$11.0**	**$15.0**	**$44.0**	**$44.0**	**$44.0**
YOY Growth	-	-	-	-	-	-	-	-
Other Products	**$25.4**	**$5.2**	**$5.3**	**$5.4**	**$5.5**	**$21.4**	**$22.0**	**$22.0**
Total Revenues	$54.3	$18.7	$19.0	$21.6	$26.1	$85.4	$91.5	$105.0
YOY Growth	-	-	-	-	-	*57.4%*	*7.1%*	*14.8%*
Cost of Goods Sold	$11.8	$3.5	$3.6	$4.0	$4.9	$16.0	$17.0	$19.0
Gross Income	$42.5					$69.4	$74.5	$86.0
Product Gross Margin	*78.3%*	*81.3%*	*81.1%*	*81.5%*	*81.2%*	*81.3%*	*81.4%*	*81.9%*
SG&A	$107.0	$25.0	$25.0	$25.0	$25.0	$100.0	$105.0	$110.0
% SG&A	*197.1%*	*133.5%*	*131.6%*	*115.7%*	*95.8%*	*117.1%*	*114.8%*	*104.8%*
SG&A Stock Based Compensation	$11.6	$3.5	$3.5	$3.5	$3.5	$14.0	$15.0	$15.0
R&D	$8.5	$0.7	$0.6	$0.5	$0.5	$2.3	$2.0	$2.0
% R&D	*15.7%*	*3.7%*	*3.2%*	*2.3%*	*1.9%*	*2.7%*	*2.2%*	*1.9%*
R&D Stock Based Compensation	$0.3	$0.1	$0.1	$0.1	$0.1	$0.2	$0.2	$0.3
EBITDA	($84.9)	($14.0)	($13.8)	($11.5)	($7.9)	($47.1)	($47.7)	($41.3)
Operating Margin	*-156.4%*	*-74.9%*	*-72.4%*	*-53.0%*	*-30.1%*	*-55.1%*	*-52.1%*	*-39.3%*
Interest, Income Net and Other	($5.5)	($8.5)	($8.5)	($8.5)	($8.5)	($34.0)	($34.0)	($34.0)
Amortization Expense	($12.6)	($8.0)	($8.0)	($8.0)	($8.0)	($32.0)	($30.0)	($30.0)
Pre-Tax Income	($103.0)	($30.5)	($30.3)	($28.0)	($24.4)	($113.1)	($111.7)	($105.3)
Taxes	($0.1)	$1.2	$1.2	$1.2	$1.2	$4.8	$3.0	$5.0
Net Income	($103.0)	($31.7)	($31.5)	($29.2)	($25.6)	($117.9)	($114.7)	($110.3)
YOY Growth	-	-	-	-	-	*14.5%*	*-2.7%*	*-3.8%*
Net Margin	*-189.7%*	*-169.5%*	*-165.5%*	*-135.0%*	*-97.9%*	*-138.0%*	*-125.4%*	*-105.0%*
Reported EPS	($1.67)	($0.48)	($0.47)	($0.42)	($0.36)	($1.73)	($1.64)	($1.55)
Avg. Weighted Shares Outstanding	61.8	65.5	67.0	69.0	71.0	68.1	70.0	71.0

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2017, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.