Zacks Small-Cap Research

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Aralez Pharmaceuticals Inc. (ARLZ-NASDAQ)

ARLZ: NDA for YOSPRALA® Submitted; Approval Likely in the Fourth Quarter of 2016…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	02/26/2016
Current Price (03/22/16)	$3.99
Target Price	**$10.50**

UPDATE

On March 15, 2016, Aralez Pharmaceuticals, Inc. reported financial result for the fourth quarter and full year 2015 and provided financial guidance for 2016.

The company also announced that the New Drug Application (NDA) for YOSPRALA® has been submitted to the FDA, which we believe will lead to a likely approval in 4Q16. In addition, we continue to anticipate at least one accretive deal transpiring during 2016. Aralez has a strong management team with a proven track record in M&A, making the company a top pick in the specialty pharmaceutical sector.

SUMMARY DATA

52-Week High	**$12.44**
52-Week Low	**$3.72**
One-Year Return (%)	**-48.78**
Beta	**1.75**
Average Daily Volume (sh)	**734,108**
Shares Outstanding (mil)	**64**
Market Capitalization ($mil)	**$255**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**66**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/M**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/M**
P/E using 2016 Estimate	**13.6**

Risk Level	**Average**
Type of Stock	**Small-Growth**
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	11.2 E	11.5 E	11.9 E	15.1 E	49.7 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	-$0.53 E	-$0.32 E	-$0.36 E	-$0.36 E	-$1.56 E
2017					-$0.76 E
2018					-$0.26 E

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WHAT'S NEW

Financial Update

On March 15, 2016, Aralez Pharmaceuticals Inc. (ARLZ) reported financial results for the fourth quarter and full year 2015. The company provided the financial results for Pozen, Inc. and Tribute Pharmaceuticals Canada Inc. for the fourth quarter and full year 2015 as well as pro forma consolidated results for Aralez as of the end of 2015.

Pozen

Total revenues for the fourth quarter were $6.0 million and were composed entirely of royalties from the sale of Vimovo®. Total operating expenses for the fourth quarter of 2015 were $20.1 million, compared to $3.1 million for the corresponding time period of 2014. The increase in expenses were driven by $6.9 million of higher pre-commercialization costs associated with the planned launch of YOSPRALA®, $2.5 million in higher R&D costs, $4.2 million associated with new hires, and $3.1 million of merger-related costs. Net loss for the fourth quarter of 2015 was $13.3 million, or $0.40 per share.

For the full year 2015, Pozen had revenues of $21.4 million that were composed entirely of royalties from the sale of Vimovo®. Total operating expenses for the year ending Dec. 31, 2015 were $58.9 million, compared to $15.8 million for the year ending Dec. 31, 2014. The increase in expenses were driven by $10.4 million of higher pre-commercialization costs associated with the planned launch of YOSPRALA®, $2.8 million in higher R&D costs, $9.1 million associated with new hires (which included $4.1 million of non-cash stock-based compensation), and $20.7 million of transaction and severance-related costs. Net loss for 2015 was $37.8 million, or $1.16 per share.

As of Dec. 31, 2015, Pozen had cash and cash equivalents of $24.8 million. Subsequent to the end of the year and in conjunction with the merger between Pozen and Tribute, Aralez completed a transaction that provided $75 million from the issuance of equity, $75 million from the issuance of convertible debt, and access to $200 million of committed capital to fund future acquisitions.

Tribute (in Canadian dollars)

Total revenues for the year ending Dec. 31, 2015 were $30.3 million, compared to $16.9 million for the year ending Dec. 31, 2014. The increase in revenue was driven by a 173% increase in domestic product sales along with a 150% increase in international product sales. The company had a gross profit of $18.9 million. Total operating expenses for the full year 2015 were $21.8 million while non-operating expenses totaled $14.8 million. Net loss for the year ending Dec. 31, 2015 was $17.5 million, or $0.16 per share. Tribute exited 2015 with approximately $11.5 million in cash and cash equivalents.

Aralez (Pro Forma Consolidated)

For the year ending Dec. 31, 2015, Aralez had total revenues on a combined pro forma basis of $48.8 million, total operating expenses of $82.3 million, non-operating expenses of $8.5 million, and a net loss of $44.6 million, or $0.70 per share, based on approximately 63.4 million shares.

On a pro forma basis, Aralez reported cash and cash equivalents of $152 million, which includes the cash and cash equivalents from Pozen and Tribute as of the end of 2015 along with adjustments of $118.9 million made in relation to the merger. Those adjustments are as follows:

Proceeds from Aralez Financing(i)	$	149,201,793
Repayment of Tribute SWK Loan, including fees(ii)		(13,271,978)
Repayment of Tribute debenture, including redemption fee(iii)		(9,461,681)
Transaction expenses to be incurred by Pozen(iv)		(7,225,182)
Aralez Financing issuance costs to be incurred by Pozen(v)		(326,441)
Pro forma adjustment to cash and cash equivalents		118,916,511

Source: Aralez Pharmaceuticals Inc.

2016 Guidance

The company has guided for total revenues in 2016 of $48 to $58 million, non-GAAP G&A expenses of $85 to $100 million, and non-GAAP R&D expenses of $8 to $12 million. On a GAAP basis, the company is guiding for G&A expenses of $121 to $139 million, which includes $11 to $12 million of stock-based compensation, $14 to $15 million in merger-related expenses, and $11 to $12 million in excise tax equalization payments. For R&D expenses, the company is anticipating $0.1 to $0.2 million of stock based compensation and $0.15 to $0.25 million in merger-related expenses.

Business Update

On February 5, 2015, Aralez Pharmaceuticals Inc. (ARLZ) announced that the planned merger between Pozen, Inc. and Tribute Pharmaceuticals Canada, Inc. was complete following approval by the shareholders of each company. The combined company will continue operations as Aralez Pharmaceuticals Inc. and will be headquartered in Canada, with additional operations in the U.S. and Ireland.

The strategy behind Aralez is that the company will become a cardiovascular focused specialty pharmaceutical company with support from a pain-focused franchise. We expect that the company will be centered on YOSPRALA®, once it is approved, which we believe will occur in 2016 (discussed further below). In the run-up to the launch of YOSPRALA®, the company will focus its efforts on increasing sales of Fibricor® in the U.S., which Tribute purchased from Sun Pharma in mid-2015 and Aralez will begin promoting in April 2016.

In conjunction with the completion of the merger, a group of leading healthcare investors, led by Deerfield Management, has committed up to $350 million in capital for Aralez to fund the anticipated commercial launch of YOSPRALA® and for "future acquisitions". The investment in Aralez consisted of $75 million in equity and $75 million in 2.5% convertible senior secured notes due in six years.

In addition to the $150 million that was invested in Aralez at closing, another $200 million in senior secured debt is available to the company to "fund future acquisitions". We believe this will translate into a number of deals that will transpire in 2016 and beyond to build Aralez into a company with a cardiovascular-based and North American focused portfolio of products. These deals are likely to focus on products that are already approved or very near approval that the company views as low-risk, high-value assets.

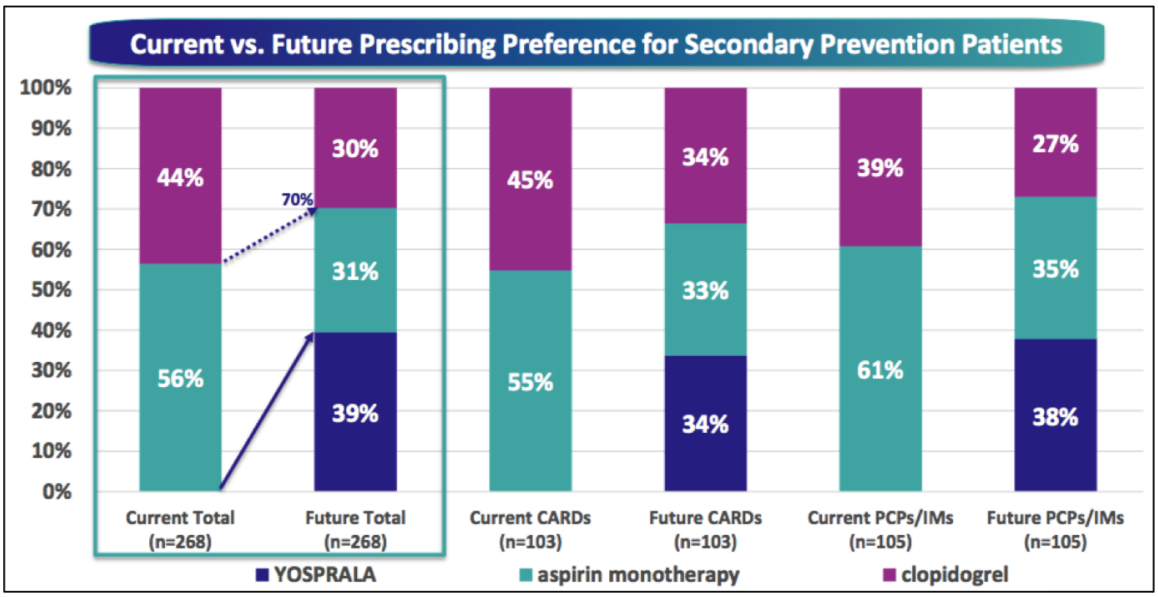
Yosprala®

On March 15, 2016, Aralez announced that the New Drug Application (NDA) for YOSPRALA® has been resubmitted to the U.S. Food and Drug Administration (FDA) for the secondary prevention of cardiovascular disease in patients at-risk for aspirin-related gastric ulcers. 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 previously announced secondary provider of the active pharmaceutical ingredient (API) for YOSPRALA®, thus the NDA will likely receive a Class-2 (six month) review. Now that the NDA has be resubmitted, the FDA is expected to issue correspondence to Aralez within 30 days as to whether all the deficiencies identified in the CRL have been addressed. If the NDA is accepted, the FDA will also assign a new Prescription Drug User Fee Act (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).

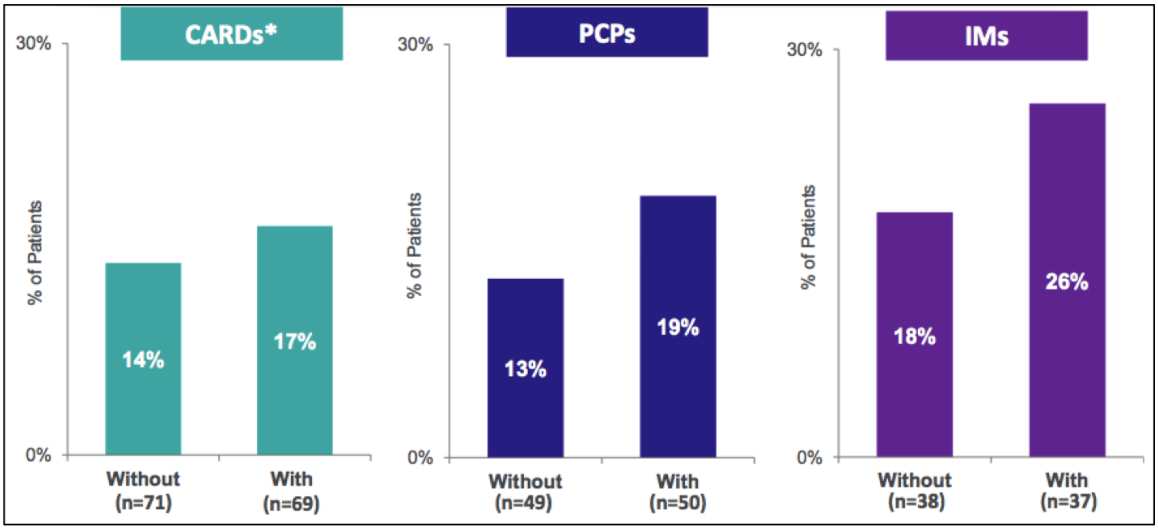
To gain better insight into how YOSPRALA® may be received by physicians, Aralez conducted a survey with cardiologists (CARDs), primary care physicians (PCPs), and internal medicine (IMs) specialists about their

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 that had been hired 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 third 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 beginning in April 2016. One of the key aspects in launching Fibricor® will be to begin to build relationships ahead of the launch of YOSPRALA®. Following approval of YOSPRALA®, Aralez intends to promote the two drugs together in order to help drive U.S. sales of Fibricor®.

Valuation and Recommendation

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 just over $20 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 $125 million in GAAP G&A expenses and $11.7 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 target price is derived using an enterprise value (EV)/revenues multiple based on forecasted 2020 revenue. We view this as an appropriate methodology for a company with increasing revenue transitioning to sustained profitability. Applying a 5.0x multiple to projected 2020 revenues of $249 million yields a target EV of approximately $1.2 billion. Discounting back 4 years with a 15% discount rate yields a net present EV of $712 million. Taking into account the company's net debt and cash yields a net present market cap of $784 million, and when divided by the fully diluted share count of 75 million results in a fair value of approximately $10.50 per share and we are maintaining a 'Buy' rating on the shares. Additional upside to our model 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.

Lastly, we remind investors that four out of the last five companies where Adrian Adams, the current CEO of Aralez, worked as CEO were acquired for an average premium of 39%. Long term it would not surprise us to see a similar outcome for Aralez.

Dates	Position	Company	Outcome	Premium
Dec. 2011 - Jan. 2015	CEO/President	Auxillium Pharmaceuticals, Inc.	Acquired by Endo Pharmaceuticals, Inc.	47%
Sep. 2011 - Nov. 2011	CEO/Chairman	Neurologix, Inc.	Filed for Ch. 7 Bankruptcy	N/A
Feb. 2010 - May 2011	CEO/President	Inspire Pharmaceuticals, Inc.	Acquired by Merck	26%
Mar. 2007 - Feb. 2010	CEO/President	Sepracor, Inc.	Acquired by Dainippon Sumitomo Pharma Co.	28%
2002 - Dec. 2006	CEO/President	Kos Pharmaceuticals, Inc.	Acquired by Abbott Laboratories	56%

Source: Zacks SCR

PROJECTED FINANCIALS

Aralez Pharmaceuticals Inc.
Income Statement

Aralez Pharmaceuticals, Inc.	2015 A*	Q1 E	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
Fibricor	**$2.0**	**$0.7**	**$0.8**	**$0.8**	**$0.8**	**$3.1**	**$3.3**	**$3.5**
YOY Growth	-	-	-	-	-	-	-	-
Vimovo (royalty)	**$21.4**	**$5.7**	**$5.7**	**$5.8**	**$5.8**	**$23.0**	**$24.0**	**$25.0**
YOY Growth		-	-	-	-	*7.5%*	*4.3%*	*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**	**$4.8**	**$5.0**	**$5.3**	**$5.5**	**$20.6**	**$21.5**	**$22.0**
Total Revenues	$48.8	$11.2	$11.5	$11.9	$15.1	$49.7	$88.8	$150.5
YOY Growth	-	-	-	-	-	*1.7%*	*78.9%*	*69.5%*
Cost of Goods Sold	$10.7	$2.0	$2.2	$2.3	$2.8	$9.3	$14.0	$22.0
Product Gross Margin	*78.0%*	*82.1%*	*80.8%*	*80.7%*	*81.5%*	*81.3%*	*84.2%*	*85.4%*
SG&A	$54.5	$40.0	$26.0	$28.0	$31.0	$125.0	$110.0	$125.0
% SG&A	*111.6%*	*357.1%*	*227.1%*	*235.3%*	*205.3%*	*251.8%*	*123.9%*	*83.1%*
R&D	$8.5	$2.5	$2.7	$3.2	$3.3	$11.7	$7.0	$5.0
% R&D	*17.4%*	*22.3%*	*23.6%*	*26.9%*	*21.9%*	*23.6%*	*7.9%*	*3.3%*
EBITDA	($24.9)	($33.3)	($19.5)	($21.6)	($22.0)	($96.4)	($42.2)	($1.5)
Operating Margin	*-51.1%*	*-297.3%*	*-169.9%*	*-181.5%*	*-145.7%*	*-194.1%*	*-47.5%*	*-1.0%*
Interest Income / Net	($8.5)	($0.5)	($0.5)	($0.6)	($0.6)	($2.1)	($2.5)	($3.0)
Amortization Expense	$8.6	$2.2	$2.3	$2.5	$2.5	$9.5	$10.0	$11.0
Pre-Tax Income	($42.0)	($36.0)	($22.3)	($24.7)	($25.1)	$108.0	($54.7)	($15.5)
Taxes	$2.6	$0.8	$0.8	$1.0	$1.0	$3.6	$4.0	$5.0
Net Income	($44.6)	($36.8)	($23.1)	($25.7)	($26.1)	($111.6)	($58.7)	($20.5)
YOY Growth	-	-	-	-	-	*150.0%*	*-47.4%*	*-65.1%*
Net Margin	*-91.4%*	*-328.6%*	*-201.3%*	*-215.5%*	*-172.5%*	*-224.7%*	*-66.1%*	*-13.6%*
Reported EPS	($0.70)	($0.53)	($0.32)	($0.36)	($0.36)	($1.56)	($0.76)	($0.26)
Fully Diluted Shares	63.4	70.0	71.0	72.0	73.0	71.5	77.0	80.0

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

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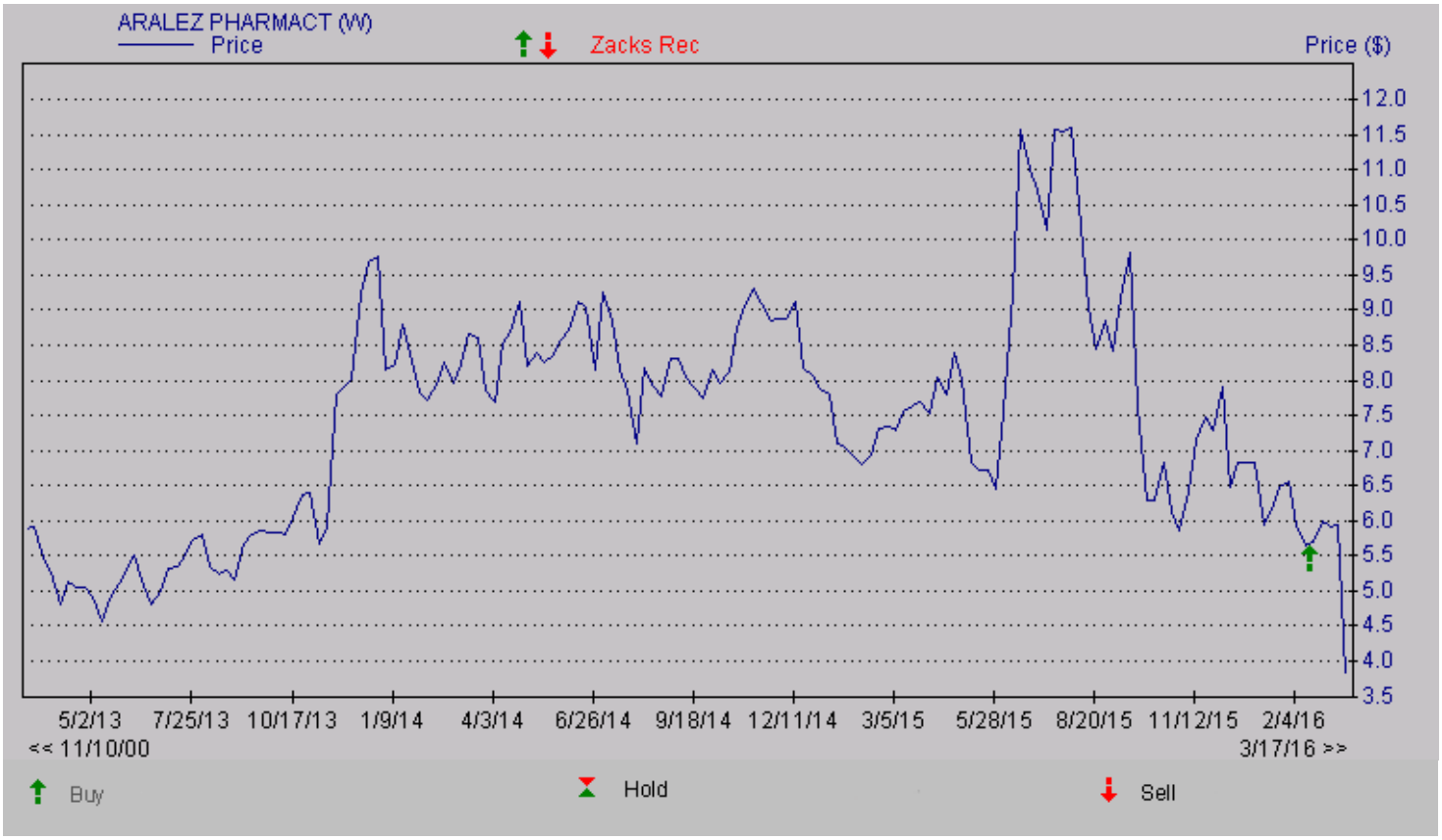

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