Ardelyx, Inc. (ARDX)

Detailed Phase IIB Hyperphosphatemia Trial Results for Tenapanor

MARKET OUTPERFORM | Price: $15.78 | Target Price: $32.00

MARKET DATA

Price	$15.78
52-Week Range:	$11.37 - $35.48
Shares Out. (M):	17.1
Market Cap ($M):	$269.8
Average Daily Vol. (000):	82.0
Cash (M):	$112
Cash/Share:	$6.56
Enterprise Value (M):	$238
LT Debt (M):	$0

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013A	2014E	2015E
Revenue ($M)	1Q	--	$8.6A	$33.3
	2Q	--	$9.1A	$14.0
	3Q	--	$7.6A	$14.7
	4Q	--	$12.6	$40.6
	FY	**$28.9**	**$37.9**	**$102.6**
EPS	1Q	--	($0.23)A	$1.27
	2Q	--	$0.18A	$0.08
	3Q	--	$0.00A	$0.05
	4Q	--	$0.13	$1.48
	FY	**($0.50)**	**$0.19**	**$2.66**
	P/E	NM	83.1x	5.9x

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Ardelyx reported detailed results from the Phase IIB study of tenapanor and phosphate control in chronic kidney disease patients; we reiterate our Market Outperform rating and $32 price target based on DCF and SOTP valuation methodologies. In a recently released 8-K filing, ARDX included an investor presentation detailing the results from its Phase IIB study of tenapanor, a selective inhibitor of sodium and phosphate uptake, reiterating that tenapanor met its primary efficacy endpoint by decreasing serum phosphate in a dose dependent manner to a high level of statistical significance (p=0.012) (Figure 1). The results also provide more clarity on adverse events and safety/tolerability, specifically with reference to rates of diarrhea. We estimate the market potential for tenapanor in hyperphosphatemia and diabetic nephropathy to be greater than $600M and $1.4B by 2025 and about $1.79 and $3.60 in net present valuation on a per share basis, respectively. Due to the currently disclosed adverse event profile, we are reassessing our estimates pending further discussion with the company.

Serum phosphate lowering on par with binders, but in a smaller package. As a reminder to investors, AstraZeneca is currently developing tenapanor for the treatment of hyperphosphatemia. Current phosphate lowering treatments include sevelamer and ferric citrate- drugs that require 8-10 gram-sized pills per day, suffering from poor compliance. The value proposition of tenapanor is derived from its extremely low pill burden- studies are currently exploring a top dose of 30 mg once or twice daily. Results from this Phase IIB trial, illustrated in Figure 1, show dose dependent phosphate decreases of up to 1.98 mg/dL at the 30 mg twice-daily level. This compares favorably with previously reported phosphate decreases from Phase IIB trials of ferric citrate and sevelamer (Figure 2).

Adverse event profile could limit development. The company had previously noted that the rate of diarrhea had been larger than expected. In the current report, ARDX reports that the rate of diarrhea during the trial was as high as 68% in the 30 mg BID cohort as compared to 12% in the placebo (Figure 1). In the absence of phosphate control data (defined as a maintenance of phosphate below 5.5 mg/dL), we believe that to maintain control, a decrease in phosphate in the range of 1-2 mg/dL should be sufficient (assuming patients' phosphate levels are <8 mg/dL). Tenapanor accomplishes this between the 3-30 mg BID dose cohorts. These levels of diarrhea exceed the levels of diarrhea seen in competitive products (Figure 5) and may outweigh the compliance benefits afforded by the lower pill burden.

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Multiple potential markets for Tenapanor. As a reminder, Ardelyx is developing tenapanor- a non-absorbed inhibitor of sodium and phosphate uptake- with AstraZeneca. The mechanism of action of tenapanor results in exclusion of sodium and phosphate from the gut by inhibiting NHE, a transporter found in the intestinal cells whose primary responsibility is the uptake of sodium from the diet. Tenapanor also affects the absorption of phosphate. These mechanistic attributes have led to the development of tenapanor in three key indications: dialysis dependent chronic kidney disease-associated hyperphosphatemia, diabetic nephropathy and irritable bowel disease associated constipation. We remind investors that tenapanor exhibited exceptional efficacy and a better than standard of care tolerability for irritable bowel disease associated constipation.

FIGURE 1. Dose Response Results for Tenapanor Phase IIB in CKD Patients

	n	Change from Baseline	AE event rate due to diarrhea
1 mg BID	23	-0.47	26%
3 mg BID	21	-1.18	29%
10 mg BID	23	-1.7	48%
30 mg BID	24	-1.98	68%
3 mg QD	22	-0.56	18%
30 mg QD	21	-1.11	52%
Placebo	26	-0.54	12%
	Mean (treated)	-1.18	

Source: Company Reports

FIGURE 2. Results of Phosphate Binder Phase IIB trials

	Tenapanor	Sevelamer	Ferric Citrate
# Patients	134	48	146
Dosage	1-30 mg	0.76-7.4 g	1-8 g
Mean Pi change mg/dL	(-1.2)	~(-1.1)	(-1.3)

Source: JMP Securities LLC, Company Reports

FIGURE 3. Adverse Events: Gastrointestinal Disorders

Preferred Term	1 mg BID	3 mg BID	10 mg BID	30 mg BID	3 mg QD	30 mg QD	Placebo
n/group	23	21	23	25	22	21	26
Abdominal Distension		1					
Abdominal Pain				2	1		1
Abdominal Pain Upper			1				
Diarrhea	6	6	11	17	4	11	3
Diverticulum	1						
Dyspepsia		1					
Fecal Incontinence		1	2				2
Feces Soft		1					
GI Hypermotility					1		
GI Sounds Abnormal			1				
Hemorrhoids						1	
Nausea		1	1	1	2	1	1
Rectal Prolapse				1			
Steatorrhea			1				
Vomiting		1			1	2	

*Number of patients who had at least 1 AE in system organ class of gastrointestinal disorders

Source: Company Reports

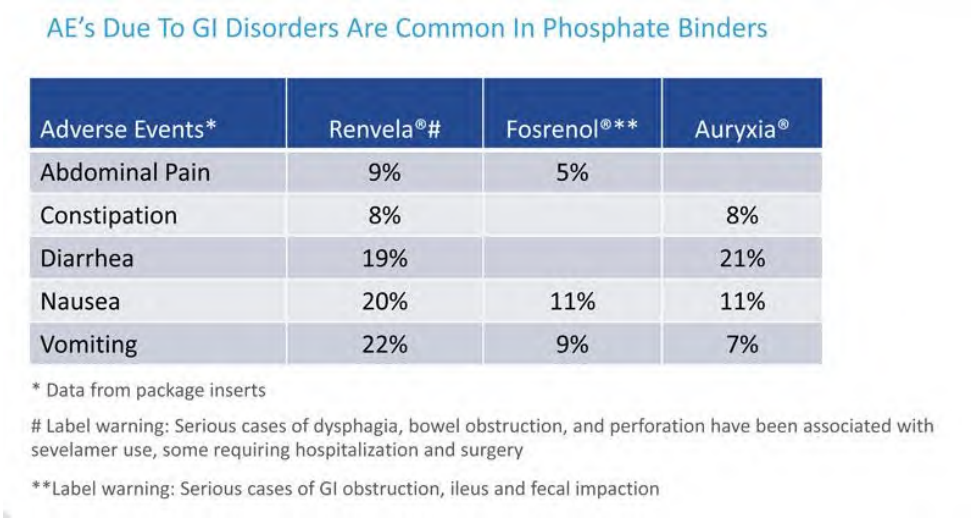
FIGURE 4. Discontinuations Due to Adverse Events

Adverse Event Term	1 mg BID	3 mg BID	10 mg BID	30 mg BID	3 mg QD	30 mg QD	Placebo
n/group	23	21	23	25	22	21	26
Discontinuations due to AE/group**	3	3	3	9	1	7	2
Abdominal Pain				1			
Diarrhea*	2	3	3	8		6	
Nausea						1	
Vomiting						1	
Serum Calcium Decrease					1		
Hyperphosphatemia	1				1		2
Dizziness						1	
Atherosclerosis		1					

*The term "diarrhea" also includes similar changes in stool form or bowel habits
**There may be multiple reasons for a single discontinuation

Source: Company Reports

FIGURE 5. Comparison of GI Events Across Phosphate Binder Treatments



Source: Company Reports

FIGURE 6. Upcoming ARDX Milestones

Timing	Program	Catalyst
2Q15	Tenapanor	Ph. IIA CKD-T2DM results expected
2H15	Tenapanor	Initiation of Ph. III trial in ESRD-Pi (triggers $50 million milestone payment)

FIGURE 7. Income Statement

Ardelyx Income Statement	1Q14A	2Q14A	3Q14A	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties																				
Tenapanor - WW Royalties					-					-	-	-	2.9	28.8	97.6	192.3	272.2	333.4	378.9	412.1
Total Sales and Royalties	-	-	-	-	-					-	-	-	2.9	28.8	97.6	192.3	272.2	333.4	378.9	412.1
Licensing revenue (amortization of upfront payments)	3.2	6.5	4.8	6.3	20.8	6.3	6.3	6.3	6.3	25.0	13.3	1.3	-	-	-	-	-	-	-	-
Milestones	-	-	-	-	-	20.0	-	-	25.0	45.0	75.0	65.0	117.5	130.0	225.0	106.8	70.0	-	-	-
Collaborative development revenue (reimbursment from AZN)	5.3	2.6	2.8	6.4	17.2	7.0	7.7	8.5	9.3	32.6	35.9	46.6	65.3	78.3	86.1	90.4	90.4	90.4	90.4	90.4
Total Revenues	8.6	9.1	7.6	12.6	37.9	33.3	14.0	14.7	40.6	102.6	124.2	112.9	185.7	237.1	408.8	389.5	432.7	423.8	469.3	502.5
% change																				
Research and development	7.6	5.2	5.7	8.5	27.0	9.3	10.3	11.3	12.4	43.3	54.4	73.8	88.2	106.1	114.9	121.1	128.7	138.3	150.3	165.2
Selling, general and administrative	1.4	1.20	1.82	2.01	6.4	2.21	2.43	2.67	2.94	10.2	13.3	16.0	17.6	19.3	21.3	23.4	25.7	28.3	31.1	34.2
Total operating expenses	9.0	6.4	7.5	10.5	**33.4**	**11.5**	**12.7**	**14.0**	**15.4**	**53.5**	**67.7**	**89.8**	**105.7**	**125.5**	**136.2**	**144.5**	**154.5**	**166.6**	**181.4**	**199.5**
Operating Profit (Loss)	(0.5)	2.8	0.1	2.2	**4.5**	**21.7**	**1.3**	**0.8**	**25.2**	49.1	56.5	23.1	79.9	111.7	272.6	245.0	278.2	257.2	287.9	303.1
Margin(%)											*45.5%*	*20.4%*	*43.0%*	*47.1%*	*66.7%*	*62.9%*	*64.3%*	*60.7%*	*61.4%*	*60.3%*
Other income (expense)	(0.0)	(0.0)	(0.0)		(0.0)															
Total other income	(0.0)	(0.0)	(0.0)	-	(0.0)					-	-	-	-	-	-	-	-	-	-	-
Change in fair value of preferred stock warrant liability	(2.6)	1.0			(1.6)															
Pretax income	(3.1)	3.8	0.1	2.2	**2.9**	**21.7**	**1.3**	**0.8**	**25.2**	49.1	56.5	23.1	79.9	111.7	272.6	245.0	278.2	257.2	287.9	303.1
Provsion for income taxes					-					-	-	-	-	-	13.6	24.5	55.6	90.0	100.8	106.1
% Tax Rate															*5.0%*	*10.0%*	*20.0%*	*35.0%*	*35.0%*	*35.0%*
Net profit (loss) and comprehensive income	(3.1)	3.8	0.1	2.2	**2.9**	**21.7**	**1.3**	**0.8**	**25.2**	49.1	56.5	23.1	79.9	111.7	258.9	220.5	222.6	167.2	187.1	197.0
After Tax Margin(%)											*45.5%*	*20.4%*	*43.0%*	*47.1%*	*63.3%*	*56.6%*	*51.4%*	*39.4%*	*39.9%*	*39.2%*
Net profit (loss) attributable to common stockholders																				
Basic		0.5																		
Diluted		0.7																		
Basic shares outstanding	13.3	2.6	18.4	17.1	15.7	17.1	17.1	17.1	17.1	17.1	17.2	17.2	17.3	17.4	17.4	17.5	17.6	17.7	17.7	17.8
Diluted shares outstanding	13.3	3.9	17.1	17.1	15.7	17.1	17.1	17.1	17.1	18.5	18.6	18.7	18.8	18.9	19.0	19.1	19.3	19.4	19.5	19.6
Basic GAAP EPS	$ (0.23)	$ 0.20	$ 0.00	$ 0.13	$ 0.19	$ 1.27	$ 0.08	$ 0.05	$ 1.48	$ 2.87	$ 3.29	$ 1.34	$ 4.62	$ 6.43	$ 14.85	$ 12.59	$ 12.66	$ 9.46	$ 10.55	$ 11.05
Diluted GAAP EPS	$ (0.23)	$ 0.18	$ 0.00	$ 0.13	$ 0.19	$ 1.27	$ 0.08	$ 0.05	$ 1.48	$ 2.66	$ 3.03	$ 1.23	$ 4.25	$ 5.90	$ 13.60	$ 11.52	$ 11.56	$ 8.63	$ 9.60	$ 10.04

Source: JMP Securities LLC and Company Reports

Company Description

Ardelyx is a biopharmaceutical company focused on the development of therapies for the treatment of various cardiovascular, renal, and digestive disorders. By leveraging its unique platform combining non-systemic small molecule inhibitors and a proprietary cell culture system, Ardelyx has advanced tenapanor, an innovative candidate for the treatment of kidney disease and irritable bowel syndrome (IBS-C) in partnership with AstraZeneca. In addition to demonstrating preclinical and clinical efficacy in reducing the absorption of dietary sodium and phosphate, tenapanor has been shown to be safe and well-tolerated, having completed Phase I safety. Ardelyx expects data from its Phase IIB trial of tenapanor in IBS-C in 4Q2014, from its Phase IIB trial in hyperphosphatemia patients with end-stage renal disease (ESRD-Pi) in 1H2015, and its Phase IIA trial in patients with chronic kidney disease (CKD) in 2H15. Ardelyx also has research and development partnerships in place for its preclinical NaP2b inhibitor program with Sanofi.

Investment Risks

Clinical and regulatory. If tenapanor is not able to meet any of its primary outcomes or suffers from safety and tolerability issues, Ardelyx and AstraZeneca may choose to end development in any of its current indications. Additionally, if the FDA and EMEA do not approve tenapanor, Ardelyx's stock price would likely suffer.

Partnering. Ardelyx has partnered with AstraZeneca in the development of tenapanor and with Sanofi in the development of RDX002. AstraZeneca is responsible for the continued clinical and commercial development of tenapanor and may decide to end development for one or more indications. Additionally, Sanofi may not exercise its option to license RDX002 for clinical development. If it were necessary for Ardelyx to develop and market any of its programs due to the loss of or inability to retain a partner, it may be difficult to develop an internal commercial structure. Management has limited experience in commercial and marketing activities.

Reimbursement and commercial. The reimbursement landscape for dialysis drugs has shifted dramatically in recent years. In 2010, CMS introduced requirements for the fixed reimbursement "bundle" that have forced negative pricing pressure on injectables, such as erythropoietin-stimulating agents (e.g., EPO). The Protecting Access to Medicare Act of 2014 places ESRD oral therapeutics into the bundle beginning in 2024. The potential lack of separate reimbursement under Part D could make tenapanor unprofitable if these impacts on revenue are outpaced by rising costs of manufacture and marketing.

Competitive. There are a number of marketed and OTC therapies for several indications that Ardelyx is pursuing. There are several prescribed phosphate binders approved (Renagel/Renvela, PhosLo/Phoslyra, and Fosrenol), and in development (Zerenex, Alfaren, and Velphoro) for hyperphosphatemia. Sevlamer, the active ingredient in Renagel, goes off patent in 2014. Additionally, the IBS-C market has a number of OTC competitors (Miralax, Metamucil, Fibercon, Ex-lax) and several recently approved therapeutics (Linzess and Amitza). The CKD market is populated by a number of generic Angiotensin-converting enzyme (ACE) inhibitors and Angiotensin II receptor blockers (ARBs) that have similar minor efficacy in type 2 diabetic patients with moderately increased albuminuria.

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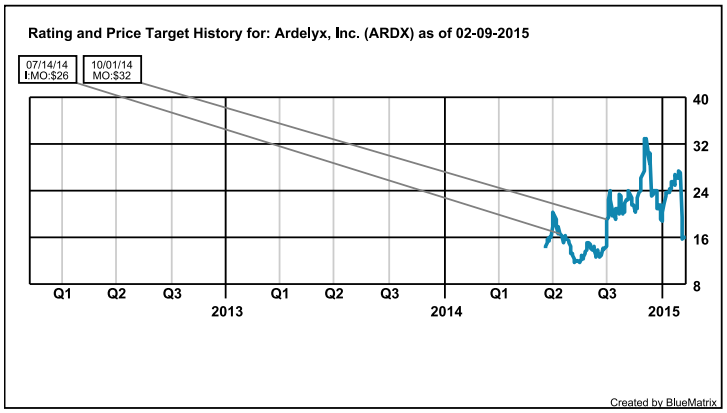
MARKET OUTPERFORM	Buy	282	*63.09%*	Buy	282	*63.09%*	90	*31.91%*
MARKET PERFORM	Hold	154	*34.45%*	Hold	154	*34.45%*	21	*13.64%*
MARKET UNDERPERFORM	Sell	8	*1.79%*	Sell	8	*1.79%*	0	*0%*
COVERAGE IN TRANSITION		1	*0.22%*		1	*0.22%*	0	*0%*
TOTAL:		447	*100%*		447	*100%*	113	*25.28%*

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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