Ardelyx, Inc. (ARDX)

Reports 4Q14 Results; Reiterate Market Outperform Rating and $32 Price Target

MARKET DATA

Price	$17.30
52-Week Range:	$11.37 - $35.48
Shares Out. (M):	15.7
Market Cap ($M):	$271.6
Average Daily Vol. (000):	70.0
Cash (M):	$107
Cash/Share:	$6.84
Enterprise Value (M):	$201
Float (M):	15.0
LT Debt (M):	$0
Short Interest:	1.5%

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014A	2015E	2016E
Revenue ($M)	1Q	$8.6	$13.3	$14.0
	2Q	$9.1	$14.0	$34.7
	3Q	$7.6	$34.7	$40.6
	4Q	$6.3	$40.6	$102.6
	FY	**$31.6**	**$102.6**	**$124.2**
EPS	1Q	($0.23)	$0.05	$0.01
	2Q	$0.18	$0.01	$1.15
	3Q	$0.00	$1.15	$1.40
	4Q	($0.21)	$1.40	$2.41
	FY	**($0.20)**	**$2.41**	**$2.72**
	P/E	NM	7.2x	6.4x
	Previous FY	$0.19	$2.66	NE

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $17.30 | Target Price: $32.00

INVESTMENT HIGHLIGHTS

Ardelyx Inc. reported 4Q14 and FY14 earnings results, highlighting a strong cash runway and an advancing development pipeline; we remain optimistic regarding upcoming potential catalysts, and reiterate our Market Outperform rating and $32 price target, based on our DCF and SOTP valuation methodologies. The highlight of the call was the advancement of the clinical development of tenapanor, a more relevant valuation metric than earnings, in our view. The company reported 4Q14 EPS of $(0.21) per basic and diluted share, compared with our estimate of $(0.13). ARDX ended the quarter with cash and cash equivalents of $107M, which we believe is sufficient to continue operations through 2015. Operating expenses were $10.3M, in line with our expectation of $10.5M. (Please refer to Figures 3 and 4 for our estimates and consensus, as well as changes to our model based on our expectations regarding operations costs.) While there has been recent stock weakness reflecting an increase in investor uncertainty following the results of the Phase IIB trial of tenapanor in chronic kidney disease-associated hyperphosphatemia (CKD-H), based upon a surprisingly higher incidence of diarrhea, we believe this weakness presents a favorable buying opportunity for shares of ARDX.

Top line results in CKD-H. The company recently detailed the results of its Phase IIB study of tenapanor, a selective inhibitor of sodium and phosphate uptake that was conducted in 161 dialysis dependent patients. The trial successfully met its primary efficacy endpoint by decreasing serum phosphate in a dose dependent manner to a high level of statistical significance (p=0.012). Although there was an unexpectedly high rate of diarrhea (as high as 68% in the 30mg BID cohort as compared to 12% in the placebo) in this trial, we remind investors that tenapanor exhibited exceptional efficacy, and we view the high incidence of diarrhea to be largely related to trial design issues (which did not allow for up- or down-titration). Of significance, current phosphate lowering treatments include sevelamer and ferric citrate – drugs that require an onerous 8-10 gram-sized pills per day, which correspondingly suffer from poor compliance. As ARDX explores an appropriate dosing regimen (currently studying a top dose of 30 mg once or twice daily), we remind investors that tenapanor has an extremely low pill burden (providing a market opportunity), and was able to achieve up to a 1.98mg/dL decrease in phosphate levels in the trial. These results compare favorably with previously reported phosphate decreases from Phase IIB trials of ferric citrate and sevelamer (Figure 1). As a reminder, 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.

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Multiple potential markets for Tenapanor. Recall that 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 NHE3, a transporter found in the intestinal cells whose primary responsibility is the uptake of sodium from the diet. That is, tenapanor flushes these salts through the gastrointestinal tract, thereby sparing kidneys and could aid patients with CKD and IBS. Tenapanor also affects the absorption of phosphate. These mechanistic attributes have led to the development of tenapanor in three key indications: dialysis dependent (CKD-H, diabetic nephropathy and IBS-C.

Upcoming potential catalysts. ARDX updated its expectations for final readouts of its Phase 2b trials: 1) results from the CKD-H are anticipated in 2Q15, which will be presented by AZN at the American Society of Nephrology in November in San Diego; and 2) final IBS-C results will be presented at the Digestive Disease Week in Washington, D.C. in May. Upon receipt of the final results, AZN will also determine the future development for tenapanor, which we await with optimism.

Tenapanor is poised to capture considerable market share by treating symptoms of IBS-C and renal insufficiency. The various readouts from multiple Phase II clinical studies offer attractive value inflection points that can drive market valuation to levels seen in companies with similar products that are approved or in development. The recent capital raise, along with collaboration fees and milestones received from partnerships with AstraZeneca and Sanofi make us bullish on shares of ARDX.

FIGURE 1. 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 2. Upcoming Potential Catalysts

Timing	Program	Catalyst
2Q15E	Tenapanor	Ph. IIA CKD-T2DM final results expected
2Q15E	Tenapanor	Presentation of final results of Ph. IIB IBS-C data at DDW (Washington, DC)
2H15E	Tenapanor	AZN go/no go decision
2H15E	Tenapanor	Initiation of Ph. III trial in ESRD-Pi (triggers $50 million milestone payment)
4Q15E	Tenapanor	Results of CKD data to be presented by AZ at ASN meeting (San Diego, CA)

Source: Company Reports

FIGURE 3. Estimates vs. Actuals

2014 JMP Estimates vs. Actual ($MM, except where noted)	4Q14A	4Q14 JMP Estimates	4Q14 Street	Actual vs. JMP Estimates	FY2014	FYQ14 JMP Estimates	FY14 Street Consensus	Actual vs. JMP Estimates
License and milestone revenue								
Total Revenues	6.3	12.6	9.6		31.6	37.9	35.2	
Research and development	7.4	8.5		1.1	25.9	27.0		1.1
Selling, general and administrative	2.9	2.0		0.9	7.3	6.4		0.9
Total operating expenses	10.3	10.5		0.2	33.2	33.4		0.2
Operating Profit (Loss)	(3.9)	2.2	0.1	(6.1)	(1.6)	4.5	3.9	(6.1)
Other Income (expense)	-	-	-		-	-	-	
Pre-tax Income	(4.0)	2.2	0.1	(6.2)	(3.2)	2.9	1.3	(6.1)
Provision for income taxes								
% Tax Rate								
Net profit (Loss) allocable to common stockholders			2.0	-			3.5	-
Basic shares outstanding	18.5	17.1		1.4	15.7	15.7		(0.0)
Diluted shares outstanding	18.5	17.1		1.4	15.7	15.7		(0.0)
Basic GAAP net loss per common share	$ (0.21)	$ 0.13		$ (0.34)	$ (0.20)	$ 0.19		$ (0.39)
Diluted GAAP net loss per common share	$ (0.21)	$ 0.13	$ 0.11	$ (0.34)	$ (0.20)	$ 0.19	$ 0.21	$ (0.39)

Source: JMP Securities LLC and Company Filings

FIGURE 4. Changes to Our Model

Changes to JMP Model ($MM, except where noted)	4Q14E		FY14E		FY15E		FY16E	
	OLD	NEW	OLD	NEW	OLD	NEW	OLD	NEW
License and milestone revenue	6.3	6.3	22.0	20.8	70.0	70.0	88.3	88.3
Total Revenues	12.6	12.6	44.8	37.9	102.6	102.6	124.2	124.2
Research and development	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Selling, general and administrative	1.8	2.0	6.4	6.4	9.4	10.2	2.4	2.7
Total operating expenses	12.0	10.5	41.8	33.4	61.2	53.5	75.6	67.7
Operating Profit (Loss)	0.6	2.2	2.9	4.5	41.3	49.1	48.6	56.5
Other Income (expense)	0.0	0.0	(0.0)	(0.0)	0.0	0.0	0.0	0.0
Pre-tax Income	0.6	2.2	0.3	2.9	41.3	49.1	48.6	56.5
Provision for income taxes								
% Tax Rate								
Net profit (Loss) allocable to common stockholders	0.6	2.2	0.3	2.9	41.3	49.1	48.6	56.5
% Net Margin								
Basic shares outstanding	17.1	17.1	15.7	15.7	17.1	17.1	17.2	17.2
Diluted shares outstanding	17.1	17.1	15.7	15.7	18.5	18.5	18.6	18.6
Basic GAAP net loss per common share	$ 0.04	$ 0.13	$ 0.02	$ 0.19	$ 2.42	$ 2.87	$ 2.83	$ 3.29
Diluted GAAP net loss per common share	$ 0.04	$ 0.13	$ 0.02	$ 0.19	$ 2.24	$ 2.66	$ 2.61	$ 3.03

Source: JMP Securities LLC

FIGURE 5. Updated Income Statement

Ardelyx Income Statement	1Q14A	2Q14A	3Q14A	4Q14A	2014A	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	3.9	18.4	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	2.5	13.2	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	6.3	31.6	13.3	14.0	34.7	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	7.4	25.9	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	2.88	7.3	3.17	3.49	3.84	4.22	14.7	19.1	23.0	25.3	27.8	30.6	33.6	37.0	40.7	44.8	49.2
Total operating expenses	9.0	6.4	7.5	10.3	**33.2**	**12.5**	**13.7**	**15.1**	**16.6**	**58.0**	**73.6**	**96.8**	**113.4**	**133.9**	**145.5**	**154.7**	**165.7**	**179.0**	**195.0**	**214.5**
Operating Profit (Loss)	(0.5)	2.8	0.1	(3.9)	**(1.6)**	**0.8**	**0.2**	**19.6**	**24.0**	44.6	50.6	16.1	72.2	103.2	263.2	234.8	267.0	244.8	274.3	288.1
Margin(%)											*40.8%*	*14.2%*	*38.9%*	*43.5%*	*64.4%*	*60.3%*	*61.7%*	*57.8%*	*58.4%*	*57.3%*
Other income (expense)	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)															
Total other income	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)					-	-	-	-	-	-	-	-	-	-	-
Change in fair value of preferred stock warrant liability	(2.6)	1.0			(1.6)															
Pretax income	(3.1)	3.8	0.1	(4.0)	**(3.2)**	**0.8**	**0.2**	**19.6**	**24.0**	44.6	50.6	16.1	72.2	103.2	263.2	234.8	267.0	244.8	274.3	288.1
Provsion for income taxes					-					-	-	-	-	-	13.2	23.5	53.4	85.7	96.0	100.8
% 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	(4.0)	**(3.2)**	**0.8**	**0.2**	**19.6**	**24.0**	44.6	50.6	16.1	72.2	103.2	250.1	211.3	213.6	159.1	178.3	187.2
After Tax Margin(%)											*40.8%*	*14.2%*	*38.9%*	*43.5%*	*61.2%*	*54.3%*	*49.4%*	*37.5%*	*38.0%*	*37.3%*
Net profit (loss) attributable to common stockholders																				
Basic		0.5		*(0.2)*																
Diluted		0.7		*(0.2)*																
Basic shares outstanding	13.3	2.6	18.4	18.5	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	18.5	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**	**$ (0.21)**	$ (0.20)	$ 0.05	$ 0.01	$ 1.15	$ 1.40	$ 2.61	$ 2.95	$ 0.93	$ 4.17	$ 5.94	$ 14.34	$ 12.07	$ 12.14	$ 9.01	$ 10.05	$ 10.51
Diluted GAAP EPS	**$ (0.23)**	**$ 0.18**	**$ 0.00**	**$ (0.21)**	$ (0.20)	$ 0.05	$ 0.01	$ 1.15	$ 1.40	$ 2.41	$ 2.72	$ 0.86	$ 3.84	$ 5.45	$ 13.14	$ 11.04	$ 11.09	$ 8.21	$ 9.14	$ 9.54

Source: JMP Securities LLC and Company Filings

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

Potential risks to our price target include, but are not limited, to clinical and regulatory, partnering, reimbursement & commercial and competitive factors.

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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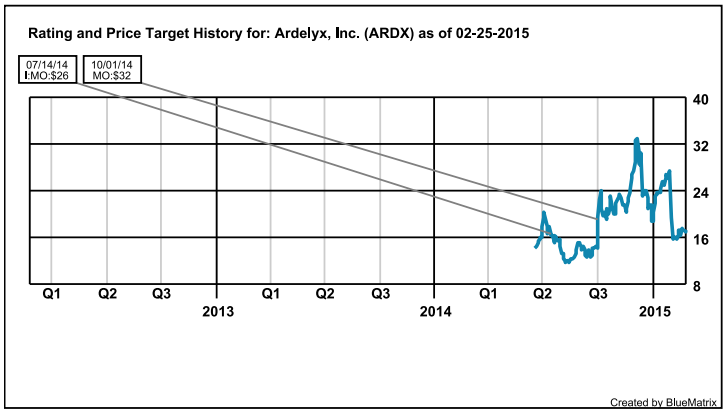
MARKET OUTPERFORM	Buy	282	*62.95%*	Buy	282	*62.95%*	90	*31.91%*
MARKET PERFORM	Hold	155	*34.60%*	Hold	155	*34.60%*	22	*14.19%*
MARKET UNDERPERFORM	Sell	8	*1.79%*	Sell	8	*1.79%*	0	*0%*
COVERAGE IN TRANSITION		1	*0.22%*		1	*0.22%*	0	*0%*
TOTAL:		448	*100%*		448	*100%*	114	*25.45%*

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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