Ardelyx, Inc. (ARDX)

Presents Tenapanor Clinical Results at ASN Kidney Week

MARKET DATA

Price	$21.64
52-Week Range:	$11.37 - $25.23
Shares Out. (M):	17.1
Market Cap ($M):	$370.0
Average Daily Vol. (000):	20.0
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	NM	8.1x

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $21.64 | Target Price: $32.00

INVESTMENT HIGHLIGHTS

Ardelyx posters and presentations at ASN Kidney Week showcased tenapanor's potential in treating hyperphosphatemia; we remain optimistic regarding upcoming milestones, and reiterate our Market Outperform rating and $32 price target, based on our DCF and SOTP valuation methodologies. ARDX presented pre-clinical and early clinical data demonstrating the effects of tenapanor on phosphate and sodium levels in animal models of chronic kidney disease and in healthy volunteers. The results summarize previous reports, and provide a framework to understand tenapanor's potential clinical benefit.

Pre-clinical data supports the potential use of tenapanor to treat hyperphosphatemia and bone mineral disease. In a talk entitled, "Tenapanor Inhibits Phosphorous Absorption, and Protects against Vascular Calcification in Nephrectomized Rats," Dominique Charmot, outgoing CSO and Founder of Ardelyx and inventor of tenapanor, discussed the results in rats that supported the development of tenapanor. Tenapanor caused a dose dependent reduction in serum phosphate in rats fed a diet consisting of ^{33}P isotope-labeled phosphate. An interesting effect was demonstrated for vascular calcification in a 5/6th nephrectomized rat model of chronic kidney disease. Tenapanor was able to cause a dose dependent decrease in serum phosphate and FGF-23, two important biomarkers of bone mineral disease, while also showing a significant drop in circulating creatinine levels, suggestive of improved kidney function (Figures 1 and 2).

Tenapanor treatment exhibited dose dependent effects in line with its potential as a hyperphosphatemia treatment. Tenapanor caused a dose dependent increase in phosphate excretion in the gastrointestinal tract, while decreasing excretion in urine (Figures 3, 4, and 5). In both multiple ascending dose trials and dose regimen finding studies, stool phosphorus increased 4.3-7.1 mmol/day and 6.0-12.5 mmol/day, respectively. Interestingly, in a study in Japanese volunteers, the increase in stool phosphorus was dramatic, but less consistent at 0.8-14.2 mmol/day. It was suggested that since the Japanese study controlled diet only for sodium content, the phosphorus content was not standardized as in later studies, potentially contributing variation in the data. Another intriguing subset of data came from a comparison of sevelamer (Renagel) and tenapanor studies. Historical sevelamer has shown phosphate excretion in the stool of ~10mmol/day, which essentially only occurs at twice the therapeutic dose of sevelamer, 5 mg vs. a standard 2.4 mg dose (Figure 6). The urinary phosphorus effect is apparent in a dose dependent manner.

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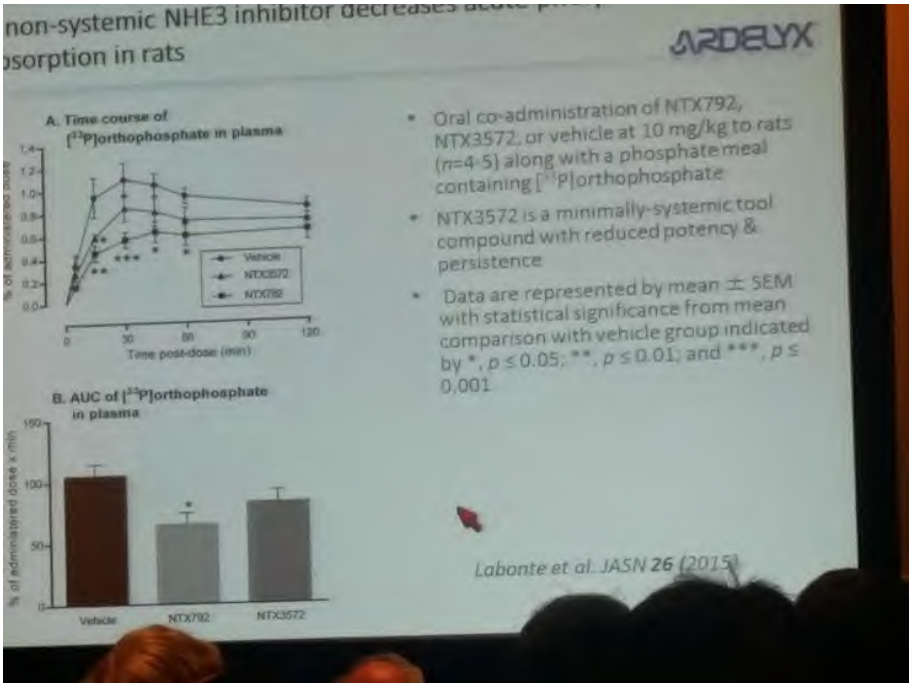
Tenapanor was tested in combination with sevelamer in order to gauge whether there was an additive or subtractive (due to interference) effect on stool and urinary sodium. Tenapanor alone caused an effect on stool urinary and stool phosphate that was unaffected by the therapeutic doses of sevelamer, suggesting that tenapanor is able to cause a therapeutic effect, rendering sevelamer unnecessary (Figure 7). We look forward to the results of the Phase IIa trials in patients with ESRD hyperphosphatemia, expected in 1H15 (Figures 8 and 9).

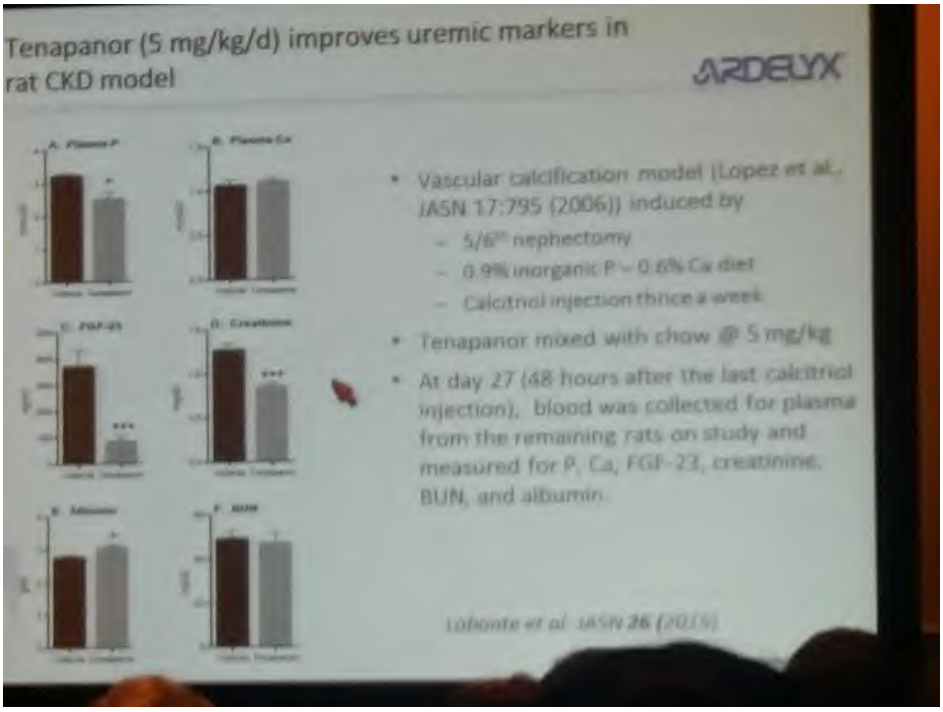
Tenapanor is poised to capture considerable market share by treating the symptoms of renal insufficiency, and also by creating a treatment regimen that leads to diet liberation and renal improvement. The various read-outs from multiple Phase II clinical studies offers attractive value inflection points that we believe can drive market valuation to the 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 the shares of ARDX.

FIGURE 1. Tenapanor Effect on Phosphate Absorption in Rats



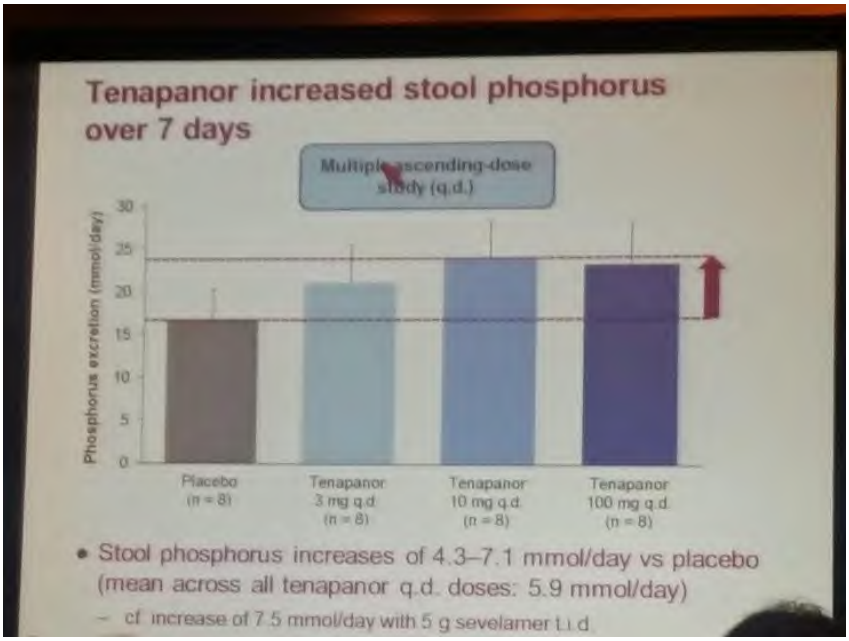
Source: JMP Securities LLC

FIGURE 2. Vascular Calcification Biomarker Improvement in Rat CKD Model



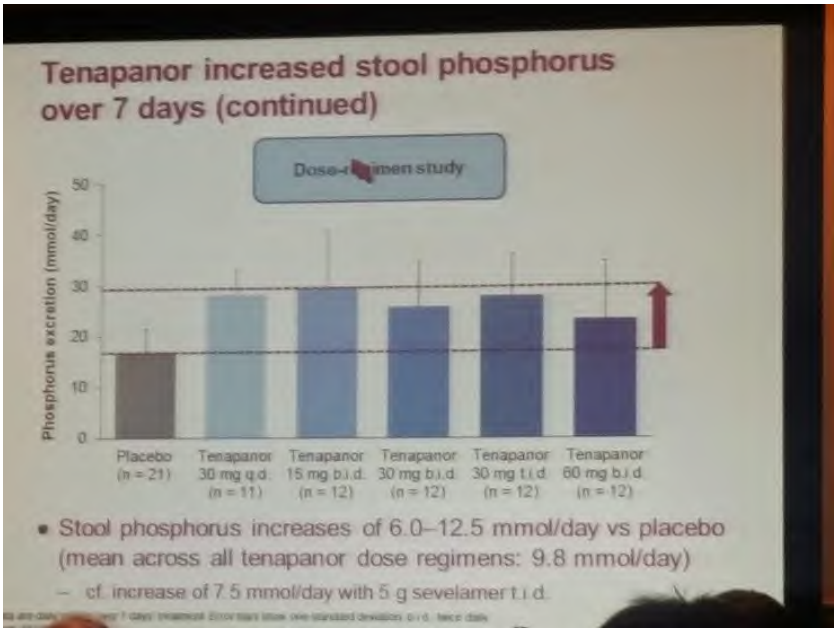
Source: JMP Securities LLC

FIGURE 3. Tenapanor MAD Study - Effect on Phosphorus Excretion



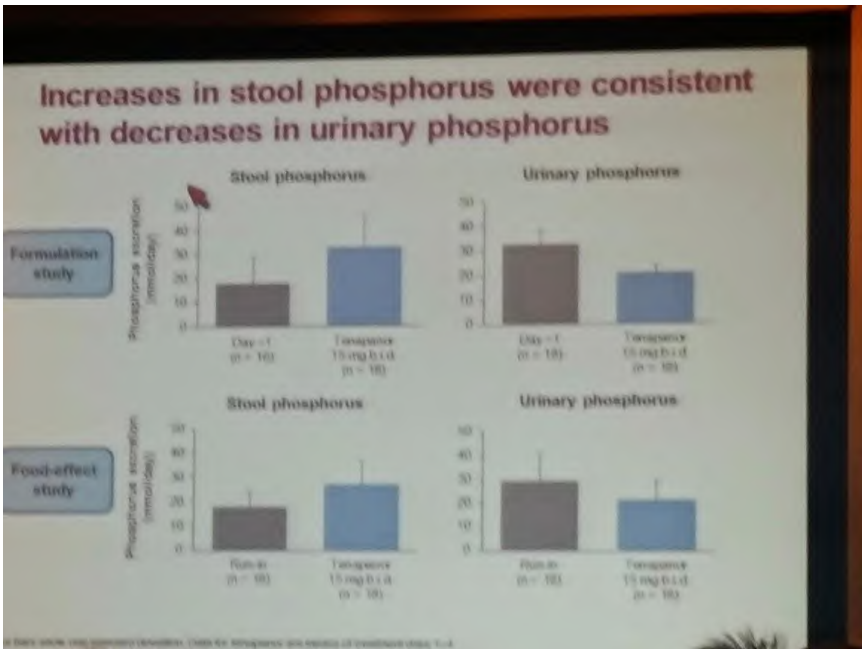
Source: JMP Securities LLC

FIGURE 4. Tenapanor Dose Regimen Study - Effect on Phosphorus Excretion



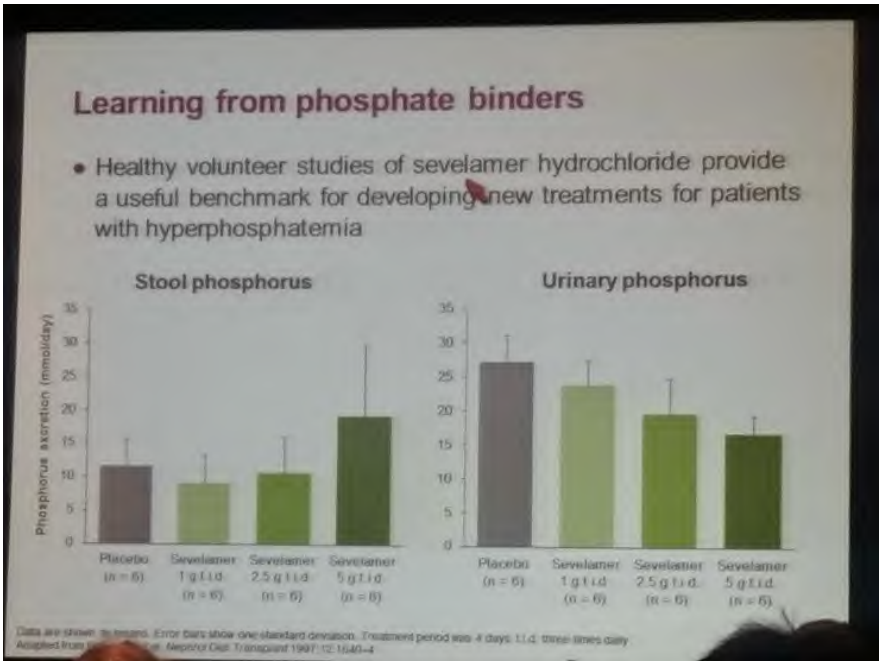
Source: JMP Securities LLC

FIGURE 5. Paired Decreases in Urinary and Stool Phosphorus Levels



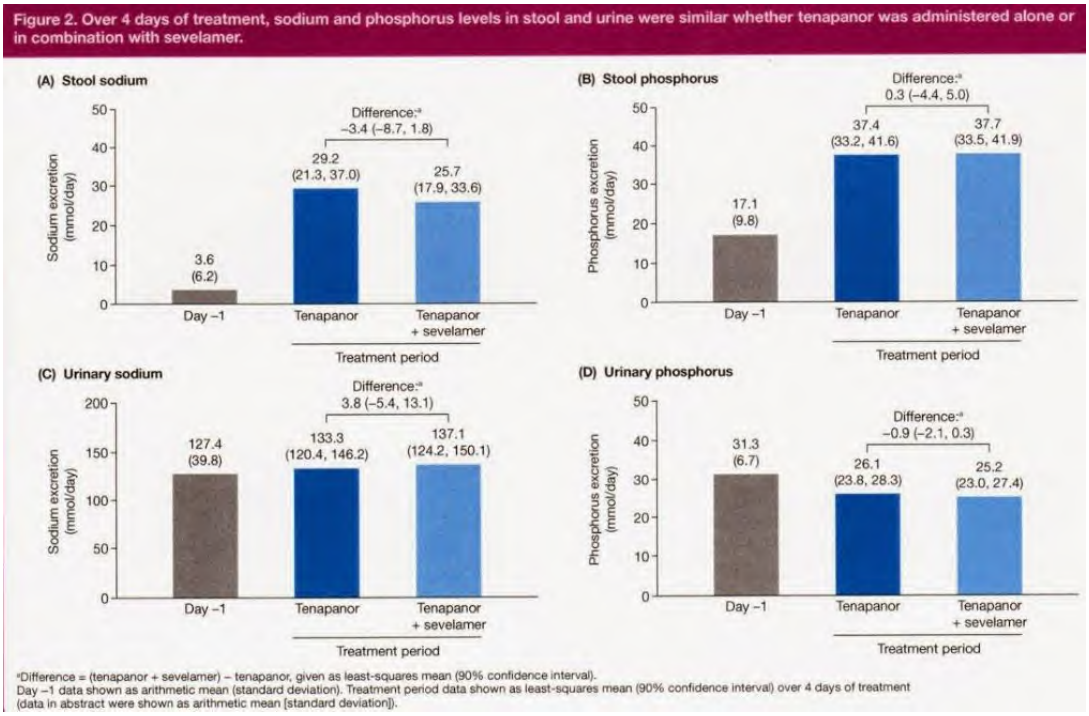
Source: JMP Securities LLC

FIGURE 6. Historical Outcomes of Sevelamer Studies in Patients



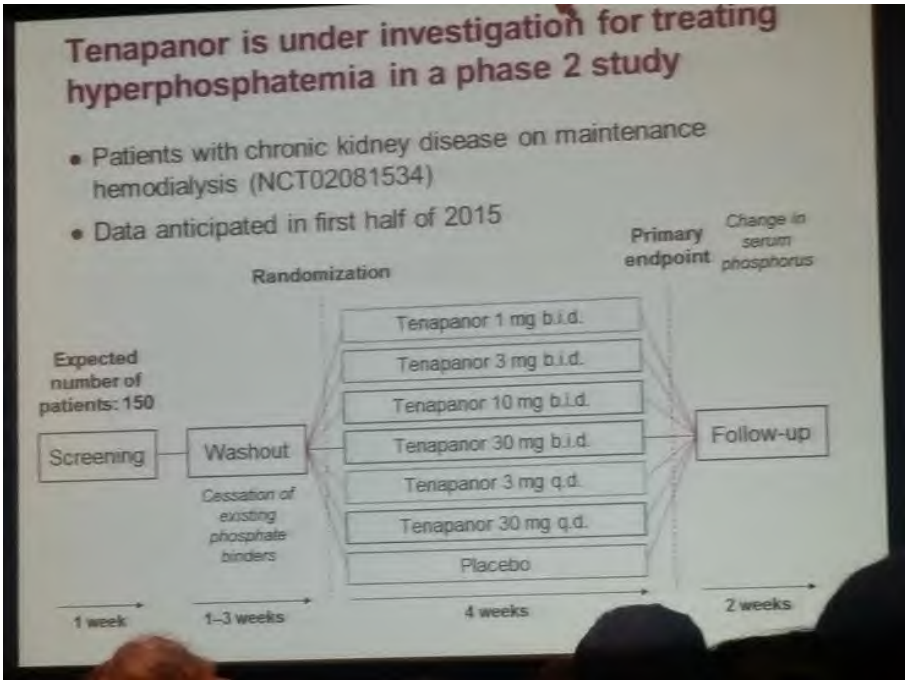
Source: JMP Securities LLC

FIGURE 7. Tenapanor in Combination with Sevelamer



Source: JMP Securities LLC

FIGURE 8. Tenapanor Phase II Trial Design for Hyperphosphatemia



Source: JMP Securities LLC

FIGURE 9. ARDX Milestones

Timing	Program	Catalyst
1H15E	Tenapanor	Ph. IIB ESRD-Pi results expected (potential $20M milestone payment)
2H15E	Tenapanor	Ph. IIA CKD-T2DM results expected
2H15E	Tenapanor	Initiation of Ph. III trial in ESRD-Pi (triggers $50M milestone payment)

Source: JMP Securities LLC

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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JMP Securities currently makes a market in the security of Ardelyx, Inc.

JMP Securities was manager or co-manager of a public offering of securities for Ardelyx, Inc. (ARDX) in the past 12 months, and received compensation for doing so.

JMP Securities expects to receive OR intends to seek compensation for investment banking services from Ardelyx, Inc. in the next 3 months.

JMP Securities Investment Opinion Definitions:

Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.
Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.
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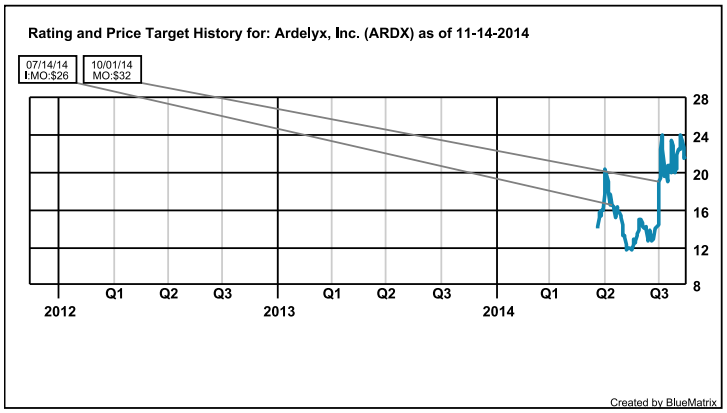
JMP Securities Research Ratings and Investment Banking Services: (as of November 17, 2014)

JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	285	*60.90%*	Buy	285	*60.90%*	103	*36.14%*
MARKET PERFORM	Hold	142	*30.34%*	Hold	142	*30.34%*	15	*10.56%*
MARKET UNDERPERFORM	Sell	2	*0.43%*	Sell	2	*0.43%*	0	*0%*
COVERAGE IN TRANSITION		36	*7.69%*		36	*7.69%*	0	*0%*
TOTAL:		468	*100%*		468	*100%*	120	*25.64%*

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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