

# Ardelyx, Inc. (ARDX)

Positive Phase IIB Results Clouded by GI Side Effects

## MARKET DATA

Price	\$19.10
52-Week Range:	\$11.37 - \$35.48
Shares Out. (M):	17.1
Market Cap (\$M):	\$326.6
Average Daily Vol. (000):	133.0
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
	<b>FY</b>	<b>\$28.9</b>	<b>\$37.9</b>	<b>\$102.6</b>
EPS	1Q	--	(\$0.23)A	\$1.27
	2Q	--	\$0.18A	\$0.08
	3Q	--	\$0.00A	\$0.05
	4Q	--	\$0.13	\$1.48
	<b>FY</b>	<b>(\$0.50)</b>	<b>\$0.19</b>	<b>\$2.66</b>
	P/E	NM	NM	7.2x

Source: Company reports and JMP Securities LLC

## STOCK PRICE PERFORMANCE



**MARKET OUTPERFORM** | Price: \$19.10 | Target Price: \$32.00

## INVESTMENT HIGHLIGHTS

**Ardelyx announced top-line results today in a Phase IIB study of phosphate control in chronic kidney disease patients with unclear risk/benefit; we reiterate our Market Outperform rating and \$32 price target based on DCF and SOTP valuation methodologies.** The company today announced that tenapanor met its primary efficacy endpoint by decreasing serum phosphate in a dose dependent level to a high level of statistical significance ( $p=0.012$ ) in a Phase IIB study of 161 dialysis dependent patients conducted in partnership with AstraZeneca. Encouragingly, the company reports a dose dependent relationship with twice-daily dosing exceeding the pharmacodynamic of once daily and a safety profile as previously reported. 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. We remind investors that tenapanor exhibited exceptional efficacy and a better than standard of care tolerability for irritable bowel disease associated constipation.

**Safety and tolerability are as early trials suggested, albeit with a higher than expected rate of diarrhea.** It is unclear whether this risk-benefit profile is necessarily worrisome, as dosing regimens were varied from 1-30 mg, and previously the company had described the potential to leverage the high titratability of tenapanor in order to avoid the potential for diarrhea. We expect the effects of tenapanor to exceed responses seen with conventional phosphate binder treatments, but are wary of the tolerability due to greater than expected diarrhea. We look forward to the presentation of these data in a peer reviewed publication and or conference.

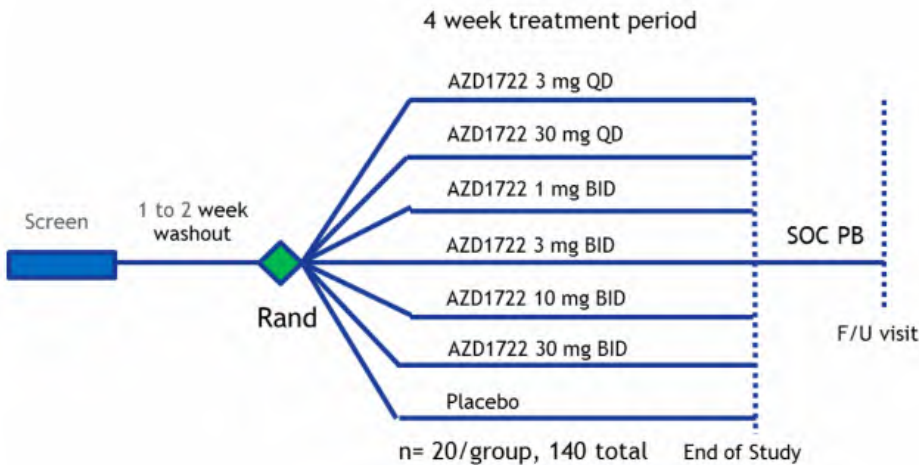
**Multiple potential markets for tenapanor.** As a reminder, Ardelyx is developing tenapanor- a non-absorbed inhibitor of sodium and phosphate uptake- with AstraZeneca. The mechanism of action of tenapanor results in exclusion of sodium and phosphate from the gut by inhibiting NHE, a transporter found 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. Figure 1 shows the currently reported Phase IIB randomized, placebo-controlled clinical trial design, with patients receiving either placebo, 3 or 30 mg tenapanor once daily, or 1, 3, 10, 30 mg twice daily. In line with the compound's effect on the absorption of solutes in the intestine, some degree of diarrhea has been seen in clinical trials with healthy volunteers, albeit at a lower rate than this current trial.

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FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO JMP FACTS AND DISCLOSURES SECTION.

**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 offers 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.Overview of ESRD-Pi Phase IIB Trial Design



Primary endpoint: Change in serum phosphate levels  
Secondary endpoint: # patients achieving Pi goal <5.5 mg/dL;change from baseline of calcium x phosphate product safety/tolerability  
SOC PB: Standard-of-care phosphate binders

Source: Ardelyx company reports

FIGURE 2. Upcoming ARDX Milestones

Timing	Program	Catalyst
1H15	Tenapanor	Ph. IIB ESRD-Pi results expected (potential \$20MM milestone payment)
2H15	Tenapanor	Ph. IIA CKD-T2DM results expected
2H15	Tenapanor	Initiation of Ph. III trial in ESRD-Pi (triggers \$50 million milestone payment)

Source: Company Reports

FIGURE 3. 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
<b>Product Sales and Royalties</b>					-					-	-	-	2.9	28.8	97.6	192.3	272.2	333.4	378.9	412.1
Tenapanor - WW Royalties					-					-	-	-	2.9	28.8	97.6	192.3	272.2	333.4	378.9	412.1
<b>Total Sales and Royalties</b>	-	-	-	-	-	6.3	6.3	6.3	6.3	25.0	13.3	1.3	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	-	-	-	-	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 (reimbursement 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
<b>Total Revenues</b>	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																				
<b>Research and development</b>	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
<b>Selling, general and administrative</b>	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
<b>Total operating expenses</b>	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
<b>Operating Profit (Loss)</b>	(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%
<b>Other income (expense)</b>	(0.0)	(0.0)	(0.0)	-	(0.0)					-	-	-	-	-	-	-	-	-	-	-
<b>Total other income</b>	(0.0)	(0.0)	(0.0)	-	(0.0)					-	-	-	-	-	-	-	-	-	-	-
<b>Change in fair value of preferred stock warrant liability</b>	(2.6)	1.0			(1.6)															
<b>Pretax income</b>	(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
Provision 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%
<b>Net profit (loss) and comprehensive income</b>	(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%
<b>Net profit (loss) attributable to common stockholders</b>																				
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
<b>Basic GAAP EPS</b>	\$ (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	\$ 12.99	\$ 12.66	\$ 9.46	\$ 10.55	\$ 11.05
<b>Diluted GAAP EPS</b>	\$ (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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JMP Securities expects to receive OR intends to seek compensation for investment banking services from Ardelyx, Inc. in the next 3 months.

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Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

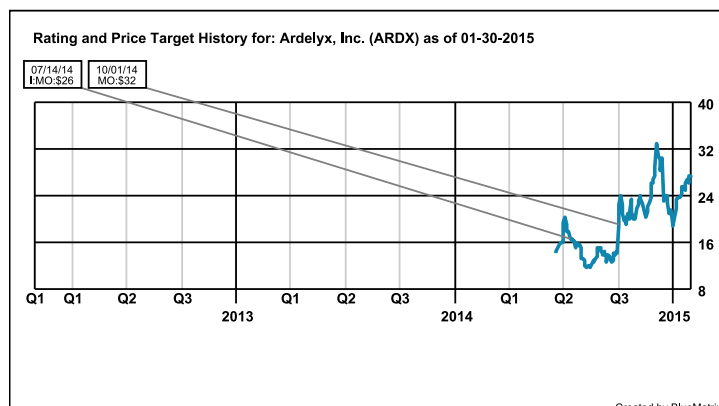
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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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	283	63.17%	Buy	283	63.17%	94	33.22%
MARKET PERFORM	Hold	154	34.38%	Hold	154	34.38%	20	12.99%
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%	116	25.89%

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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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