

# Ardelyx, Inc. (ARDX)

Reports 3Q14 Earnings

MARKET DATA	
Price 52-Week Range:	\$24.01 \$11.37 - \$25.23
Shares Out. (M):	17.1
Market Cap (\$M):	\$410.6
Average Daily Vol. (000):	16.0
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	9.0x				
Previou	ıs FY	NC	\$0.41	\$2.81				
Source: Company reports and JMP Securities LLC								



MARKET OUTPERFORM | Price: \$24.01 | Target Price: \$32.00

#### **INVESTMENT HIGHLIGHTS**

Ardelyx Inc. reports 3Q14 earnings results, highlighting a strong cash runway and advancing development pipeline; we remain optimistic regarding upcoming catalysts and reiterate our Market Outperform rating with a year-end price target of \$32 based on our DCF and SOTP valuation methodologies. During the quarter, ARDX reported an advancing pipeline with strong tenapanor clinical results, a more relevant valuation metric than earnings, in our view. The company reported EPS of \$0.00 per basic and diluted share, better than our estimate of (\$0.16) per share. The company ended the quarter with cash and cash equivalents of \$112MM. We expect this level of cash to be sufficient to continue operations through 2015. Operating expenses were \$7.2MM, less than our expectations of \$9MM. Please see Figures 2 and 3 for our estimates and consensus and changes to our model based on our expectations regarding operating costs.

The company highlighted recent Phase IIb tenapanor results and expected ASN clinical results. As we have previously reported, top-line results of tenapanor in Phase IIb for constipation associated with irritable bowel syndrome met its primary efficacy endpoint of an increase in the complete spontaneous bowel movement (CSBM) responder endpoint at the 50 mg twice daily dose (60.7% vs. 33.7% p<0.001) in this 371-patient, mid-stage trial. Encouragingly, there was a statistically significant result for the dual composite responder endpoint of CBSM/abdominal pain (50% vs 23.6%, p<0.001). This compares favorably with the Week 6 responder data reported for the current IBS-C market leader Linzess (33.6% responder rate vs. 21% placebo).

**Future clinical read-outs.** ARDX updated its expectations for data read-outs from its Phase IIb trial in hyperphosphatemia patients with end-stage renal disease (ESRD-Pi) to 1Q15, earlier than previous guidance of 1H15, and its Phase IIa trial in patients with chronic kidney disease (CKD) in 2H15.

We believe Tenapanor is poised to capture considerable market share by treating 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 offer attractive value inflection points that could drive market valuation to levels seen in companies with similar products that are approved or are in development, in our view. The recent capital raise, along with collaboration fees and milestones received from partnerships with AstraZeneca and Sanofi, makes us bullish on shares of ARDX.

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## **FIGURE 1. ARDX Milestones**

Timing	Program	Catalyst
1Q15	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)

## FIGURE 2. Estimates vs. Actuals

2014 JMP Estimates vs. Actual (\$MM, except where noted)	3Q14 Actual	3Q14 JMP Estimates	3Q14 Street	Actual vs. JMP
License and milestone revenue				
	7.0	40.4	0.0	
Total Revenues	7.6	12.1	9.0	
Research and development	5.7	7.7		2.0
Selling, general and administrative	1.8	1.3		0.5
Total operating expenses	7.5	9.0		(1.5)
Operating Profit (Loss)	0.1	3.0	1.0	(2.9)
Other Income (expense)	-	-	-	
Pre-tax Income	0.1	3.0	1.3	(2.9)
Provision for income taxes				
% Tax Rate				
Net profit (Loss) allocable to common stockholders			3.0	-
Particular of the Par	40.4	47.4		
Basic shares outstanding	18.4	17.1		1.3
Diluted shares outstanding	17.1	17.1		0.0
Basic GAAP net loss per common share	\$ 0.00	\$0.18		\$ (0.17)
Diluted GAAP net loss per common share	\$ 0.00	\$0.18	\$ 0.15	\$ (0.17)

Source: JMP Securities LLC, Company reports, Thomson Reuters

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FIGURE 3. Changes to Our Model

Changes to JMP Model	4	Q14	E		FY1	14E		FY15E			FY16E				
(\$MM, except where noted)	OLD		NEW	•	OLD	NI	EW	C	DLD	N	EW	O	LD	N	IEW
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	1	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	\$ 0.0	4 \$	0.13	\$	0.02	\$	0.19	\$	2.42	\$	2.87	\$	2.83	\$	3.29
Diluted GAAP net loss per common share	\$ 0.0	4 \$	0.13	\$	0.02	\$	0.19	\$	2.24	\$	2.66	\$	2.61	\$	3.03

Source: JMP Securities LLC

## FIGURE 4. Updated Income Statement

Ardelyx Income Statement	1Q14A	2Q14A	3Q14A	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties																1
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	25.0	13.3	1.3	_	_	-	-	-	-	-	-
Milestones	-		-	-	-	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	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	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	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	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	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	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	0.4	0.0	(1.6)	40.4	50.5	00.4	70.0	444.7	070.0	045.0	070.0	057.0	207.0	200.4
Pretax income	(3.1)	3.8	0.1	2.2	2.9	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	(2.4)	2.0	0.4	2.2	2.9	49.1	FC F	22.4	70.0	444.7	5.0%	10.0%	20.0%	35.0%	35.0%	35.0% 197.0
Net profit (loss) and comprehensive income	(3.1)	3.8	0.1	2.2	2.9	49.1	56.5	23.1	79.9	111.7	258.9	220.5	222.6	167.2	187.1	_
After Tax Margin(%)  Net profit (loss) attributable to common stockholders							45.5%	20.4%	43.0%	47.1%	63.3%	56.6%	51.4%	39.4%	39.9%	39.2%
1 1 /		0.5														
Basic Diluted		0.5 0.7														1
Basic shares outstanding	13.3	2.6	18.4	17.1	15.7	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 Diluted shares outstanding	13.3	3.9	17.1	17.1	15.7	18.5	18.6	18.7	18.8	18.9	17.4	17.5	17.6	17.7	17.7	19.6
Basic GAAP EPS	\$ (0.23)	\$ 0.20	\$ 0.00	\$ 0.13	\$ 0.19		\$ 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	\$ 2.66	\$ 3.03	\$ 1.23	\$ 4.02	\$ 5.90	\$ 13.60	\$ 11.52	\$ 11.56	\$ 8.63	\$ 9.60	\$ 10.04
DIMON OFFICE LIST	* (0.23)	¥ 0.10	Ψ 0.00	¥ 0.13	¥ 0.15	₩ 2.00	4. 2.02	ψ. 1.ZJ	TICJ	ψ. J.50	Ψ. 10.00	⊕ 11.JZ	<b>⊕</b> 11,20	Ψ 0.03	₩ J.00	¥ 10.04

Source: JMP Securities LLC, 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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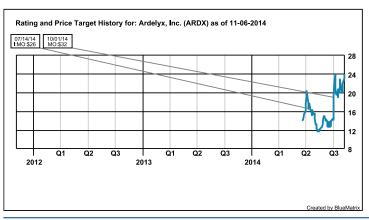
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							# Co's Receiving IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	286	61.37%	Buy	286	61.37%	105	36.71%
MARKET PERFORM	Hold	140	30.04%	Hold	140	30.04%	15	10.71%
MARKET UNDERPERFORM	Sell	2	0.43%	Sell	2	0.43%	0	0%
COVERAGE IN TRANSITION		36	7.73%		36	7.73%	0	0%
TOTAL:		466	100%		466	100%	122	26.18%

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#### Ardelyx, Inc. (ARDX)



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