

Ardelyx, Inc. (ARDX)

Announces 2Q14 Earnings and Highlights Developmental Stage Programs

MARKET DATA	
Price	\$12.03
52-Week Range:	\$12.13 - \$21.60
Shares Out. (M):	17.1
Market Cap (\$M):	\$205.7
Average Daily Vol. (000):	17.0
Cash (M):	\$33
Cash/Share:	\$1.95
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	\$13.3			
	2Q		\$9.1A	\$34.0			
	3Q		\$12.1	\$14.7			
	4Q		\$12.6	\$40.6			
	FY	\$28.9	\$42.4	\$102.6			
EPS	1Q		(\$0.23)A	\$0.14			
	2Q		\$0.18A	\$1.29			
	3Q		\$0.18	\$0.09			
	4Q		\$0.16	\$1.53			
	FY	(\$0.50)	\$0.41	\$2.81			
	P/E	NM	29.3x	4.3x			
Previou	s FY	NC	\$0.02	\$2.24			
Source: Company reports and JMP Securities LLC							



MARKET OUTPERFORM | Price: \$12.03 | Target Price: \$26.00

INVESTMENT HIGHLIGHTS

Ardelyx 2Q earnings results highlighted strong cash runway and advancing development pipeline; we remain optimistic regarding upcoming milestones and reiterate our Market Outperform rating, with a year-end price target of \$26 based on our DCF and SOTP valuation methodologies. ARDX reported earnings of \$0.20 per basic share and \$0.18 per diluted share, better than our estimate of \$0.11 per share. The EPS increase over the same quarter last year was attributable to milestone payments from the company's ongoing partnership with AstraZeneca. We are updating our estimates to reflect incremental changes that have occurred in spending and in realization of milestone revenue. Our 2014 EPS estimate moves to \$0.41 from \$0.02 and our 2015 EPS estimate is now \$2.81 from \$2.24.

ARDX 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 proprietary cell culture system, ARDX 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. ARDX expects data from its Phase IIB trial of tenapanor in IBS-C in 4Q14, from its Phase IIB trial in hyperphosphatemia patients with end-stage renal disease (ESRD-Pi) in 1H15, and Phase IIA trial in patients with chronic kidney disease (CKD) in 2H15. ARDX also has research and development partnerships in place for its preclinical NaP2b inhibitor program with Sanofi, with potential milestones totaling \$198MM.

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 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.

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FIGURE 1. ARDX Milestones

4Q14 Tenapanor Ph. IIB IBS-C results expected 1H15 Tenapanor Ph. IIB ESRD-Pi results expected (potential \$20MM milestone payment) 2H15 Tenapanor Ph. IIA CKD-T2DM results expected	Timing	Program	Catalyst
	4Q14	Tenapanor	Ph. IIB IBS-C results expected
2H15 Tenapanor Ph. IIA CKD-T2DM results expected	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)	2H15	Tenapanor	Initiation of Ph. III trial in ESRD-Pi (triggers \$50 million milestone payment)

FIGURE 2. Changes to our Model

Changes to JMP Model	3Q	14E	4Q ²	14E	FY1	14E	FY1	15E	FY1	6E
(\$MM, except where noted)	OLD	NEW	OLD	NEW	OLD	NEW	OLD	NEW	OLD	NEW
License and milestone revenue	6.3	6.3	6.3	6.3	22.0	22.2	70.0	70.0	88.3	88.3
Total Revenues	12.1	12.1	12.6	12.6	44.8	42.4	102.6	102.6	124.2	124.2
Research and development	9.2	7.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Selling, general and administrative	1.7	1.3	1.8	1.5	6.4	5.4	9.4	7.4	2.4	1.9
Total operating expenses	10.9	9.0	12.0	9.9	41.8	34.4	61.2	50.7	75.6	64.1
Operating Profit (Loss)	1.1	3.0	0.6	2.7	2.9	8.0	41.3	51.9	48.6	60.1
Other Income (expense)	0.0	0.0	0.0	0.0	(0.0)	(0.0)	0.0	0.0	0.0	0.0
Pre-tax Income	1.1	3.0	0.6	2.7	0.3	6.4	41.3	51.9	48.6	60.1
Provision for income taxes										
% Tax Rate										
Net profit (Loss) allocable to common stockholders	1.1	3.0	0.6	2.7	0.3	6.4	41.3	51.9	48.6	60.1
% Net Margin										
Basic shares outstanding	17.1	17.1	17.1	17.1	15.7	15.7	17.1	17.1	17.2	17.2
Diluted shares outstanding	17.1	17.1	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	\$ 0.16	\$ 0.04	\$ 0.16	\$ 0.02	\$ 0.41	\$ 2.42	\$ 3.04	\$ 2.83	\$ 3.50
Diluted GAAP net loss per common share	\$ 0.04	\$ 0.16	\$ 0.04	\$ 0.16	\$ 0.02	\$ 0.41	\$ 2.24	\$ 2.81	\$ 2.61	\$ 3.23

Source: JMP Securities LLC

FIGURE 3. Updated Income Statement

Ardelyx Income Statement	1Q14A	2Q14A	3Q14E	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	6.3	6.3	22.2	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	5.8	6.4	20.1	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	12.1	12.6	42.4	13.3	34.0	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	7.7	8.5	29.0	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	1.32	1.46	5.4	1.60	1.76	1.94	2.13	7.4	9.7	11.6	12.8	14.0	15.4	17.0	18.7	20.5	22.6	24.8
Total operating expenses	9.0	6.4	9.0	9.9	34.4	10.9	12.0	13.2	14.5	50.7	64.1	85.4	100.9	120.2	130.4	138.0	147.4	158.8	172.9	190.1
Operating Profit (Loss)	(0.5)	2.8	3.0	2.7	8.0	2.3	22.0	1.5	26.1	51.9	60.1	27.4	84.7	117.0	278.4	251.4	285.3	265.0	296.5	312.4
Margin(%)											48.4%	24.3%	45.6%	49.3%	68.1%	64.6%	65.9%	62.5%	63.2%	62.2%
Other income (expense)	(0.0)	(0.0)			(0.0)															
Total other income	(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	3.0	2.7	6.4	2.3	22.0	1.5	26.1	51.9	60.1	27.4	84.7	117.0	278.4	251.4	285.3	265.0	296.5	312.4
Provsion for income taxes					-					-	-	-	-	-	13.9	25.1	57.1	92.7	103.8	109.4
% Tax Rate															5.0%	10.0%	20.0%	35.0%	35.0%	35.0%
Net profit (loss) and comprehensive income	(3.1)	3.8	3.0	2.7	6.4	2.3	22.0	1.5	26.1	51.9	60.1	27.4	84.7	117.0	264.5	226.3	228.2	172.2	192.7	203.1
After Tax Margin(%)											48.4%	24.3%	45.6%	49.3%	64.7%	58.1%	52.7%	40.6%	41.1%	40.4%
Net profit (loss) attributable to common stockholders																				
Basic		0.5																		
Diluted		0.7																		
Basic shares outstanding	13.3	2.6	17.1	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	\$ 0.18	\$ 0.16	\$ 0.41	\$ 0.14	\$ 1.29	\$ 0.09	\$ 1.53	\$ 3.04	\$ 3.50	\$ 1.59	\$ 4.90	\$ 6.73	\$ 15.16	\$ 12.92	\$ 12.98	\$ 9.75	\$ 10.86	\$ 11.40
Diluted GAAP EPS	\$ (0.23)	\$ 0.18	\$ 0.18	\$ 0.16	\$ 0.41	\$ 0.14	\$ 1.29	\$ 0.09	\$ 1.53	\$ 2.81	\$ 3.23	\$ 1.47	\$ 4.50	\$ 6.18	\$ 13.90	\$ 11.82	\$ 11.85	\$ 8.89	\$ 9.88	\$ 10.35

Source: JMP Securities LLC, 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 nonsystemic small molecule inhibitors and 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 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 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.

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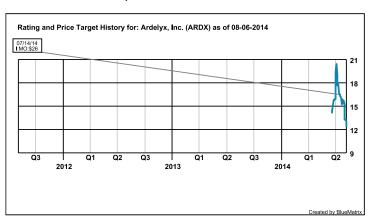
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							# Co's	
							Receiving	
							IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	266	60.05%	Buy	266	60.05%	98	36.84%
MARKET PERFORM	Hold	137	30.93%	Hold	137	30.93%	18	13.14%
MARKET UNDERPERFORM	Sell	4	0.90%	Sell	4	0.90%	0	0%
COVERAGE IN TRANSITION		36	8.13%		36	8.13%	0	0%
TOTAL:		443	100%		443	100%	116	26.19%

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 guarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



Ardelyx, Inc. (ARDX)



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