Ardelyx, Inc. (ARDX)

Reports 1Q15 Results

MARKET OUTPERFORM | Price: $9.06 | Target Price: $24.00

MARKET DATA

Price	$9.06
52-Week Range:	$7.95 - $35.48
Shares Out. (M):	18.0
Market Cap ($M):	$163.1
Average Daily Vol. (000):	111.0
Cash (M):	$98
Cash/Share:	$5.45
Enterprise Value (M):	$60
Float (M):	15.4
LT Debt (M):	$0
Short Interest:	1.9%

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014A	2015E	2016E
Revenue ($M)	1Q	$8.6	$5.9A	$5.9
	2Q	$9.1	$5.9	$6.1
	3Q	$7.6	$6.1	$31.2
	4Q	$6.3	$31.2	$49.1
	FY	**$31.6**	**$49.1**	**$99.6**
EPS	1Q	($0.23)	($0.19)A	($0.25)
	2Q	$0.18	($0.25)	($0.29)
	3Q	$0.00	($0.29)	$1.01
	4Q	($0.21)	$1.01	$0.28
	FY	**($0.20)**	**$0.28**	**$2.58**
	P/E	NM	32.4x	3.5x
	Previous FY	NC	$2.41	$2.72

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Ardelyx Inc. reports 1Q15 earnings results, highlighting strong cash runway and advancing development pipeline; remain optimistic regarding upcoming AstraZeneca decision and reiterate our Market Outperform rating, with a $24 price target based on DCF and SOTP valuation methodologies. The advancement of the Ardelyx pipeline and execution against development milestones for its lead candidate tenapanor is a more relevant metric than earnings, in our view. The company reported earnings of ($0.19) per basic and diluted share, worse than JMP estimates of $0.05 per share due to lower-than-expected collaboration and amortized revenues. The company ended the quarter with cash and cash equivalents of $98.3MM. We expect this level of cash to be sufficient to continue operations through 2016, but this time frame is dependent on the AZ decision which will occur on or before June 29th. Operating expenses were $3.5MM, greater than our expectations of $0.8MM due to lower-than-expected licensing revenue from amortized upfront payments. Please see Figures 2 and 3 for our estimates as well as changes to our model based on our expectations regarding operational expenses and revenue. With a number of key catalysts having recently punctuated the last two quarters including positive IBS-C and hyperphosphatemia data, we anticipate the next major catalyst will be the upcoming AstraZeneca decision regarding its rights to tenapanor, due on or before June 29.

We remind investors that if AZN opts out, getting the rights back to tenapanor would be a very attractive scenario for ARDX, in our opinion. As a reminder, tenapanor demonstrated significant effects in IBS-C with a high responder rate in a placebo-controlled trial, as compared to historical Linzess (linaclotide, IRWD, NC) response rates. Additionally, tenapanor has demonstrated significant reductions in serum phosphorous in Phase IIb trials in dialysis patients with hyperphosphatemia. Given the likely incorporation of dose titration in a Phase III trial design, we believe tenapanor continues to present a compelling value proposition in the ESRD hyperphosphatemia market. In particular, diarrhea, constipation and other adverse effects are common in currently marketed phosphate binders.

From a competitive standpoint, tenapanor's small pill burden is an important advantage. ARDX has indicated if the company were to regain rights to tenapanor, management would plan to continue development in IBS-C and ESRD/hyperphosphatemia. Given the greater economics in regaining control of a Phase III ready compound with compelling efficacy, we would view reacquiring the drug as a significant positive event, providing the company with the opportunity to both add value and to re-monetize. Additionally, we look forward to the complete presentation of the IBS-C dataset at the upcoming Digestive Disease Week on May 19 being held in Washington, D.C.

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We anticipate that this presentation will remind investors of the compelling value proposition that tenapanor presents in this indication.

Changes to our model. We adjust our model based on current-quarter results and our expectations of operational expenses and revenue from amortized upfront payments. These changes are reflected in Figure 2 and our income statement in Figure 3.

We maintain our Market Outperform rating on shares of ARDX. Ardelyx is well capitalized with cash and equivalents of just under $100MM, along with a differentiated technology platform capable of churning out multiple clinical development candidates. The company also has a Phase III-ready asset that admittedly has had a difficult gestation period, but possesses a unique mechanism of action with a potentially differentiated profile and addresses large opportunities. The key challenge for the shares in the near term will be: anticipation of a decision by AZN as to which indication, if any, it wants to opt into, and; lack of positive data catalysts. For those small cap biotech investors who are willing to be patient, we believe buying the stock will be well-rewarded.

FIGURE 1. Upcoming Milestones

Timing	Program	Catalyst
16-Jun		R&D Day NYC
29-Jun	Tenapanor	AZN Decision on continued development
19-May	Tenapanor	Presentation of final results of Ph. IIB IBS-C data at DDW (Washington, DC)
2H15	Tenapanor	AZN go/no go decision
2H15	Tenapanor	Initiation of Ph. III trial in ESRD-Pi (triggers $50 million milestone payment)
4Q15	Tenapanor	Results of CKD data to be presented by AZN at ASN meeting (San Diego,CA)

Source: Company presentations

FIGURE 2. Results versus Estimates

1Q15 JMP Estimates vs. Actual ($MM, except where noted)	1Q15	1Q15 JMP Estimates	Actual vs. JMP Estimates
License and milestone revenue			
Total Revenues	5.9	13.3	
Research and development	6.2	9.3	3.1
Selling, general and administrative	3.2	3.2	0.0
Total operating expenses	9.4	12.5	3.1
Operating Profit (Loss)	(3.5)	0.8	(4.3)
Other Income (expense)	-	-	
Pre-tax Income	(3.5)	0.8	(4.3)
Provision for income taxes			
% Tax Rate			
Net profit (Loss) allocable to common stockholders			-
Basic shares outstanding	18.6	17.1	1.5
Diluted shares outstanding	18.6	17.1	1.5
Basic GAAP net loss per common share	$ (0.19)	$ 0.05	$ (0.23)
Diluted GAAP net loss per common share	$ (0.19)	$ 0.05	$ (0.23)

Source: JMP Securities LLC

FIGURE 3. Changes to Our Model

Changes to JMP Model ($MM, except where noted)	2Q15E		3Q15E		4Q15E		FY15E		FY16E	
	OLD	NEW	OLD	NEW	OLD	NEW	OLD	NEW	OLD	NEW
License and milestone revenue	6.3	3.9	26.3	3.9	31.3	28.9	70.0	40.6	88.3	90.6
Total Revenues	14.0	5.9	34.7	6.1	40.6	31.2	102.6	49.1	124.2	99.6
Research and development	10.3	6.8	11.3	7.4	12.4	8.0	43.3	28.4	54.4	32.1
Selling, general and administrative	3.5	3.5	3.8	3.8	4.2	4.2	14.7	14.7	19.1	19.2
Total operating expenses	13.7	10.3	15.1	11.2	16.6	12.2	58.0	43.2	73.6	51.2
Operating Profit (Loss)	0.2	(4.4)	19.6	(5.1)	24.0	19.0	44.6	6.0	50.6	48.4
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	0.2	(4.4)	19.6	(5.1)	24.0	19.0	44.6	6.0	50.6	48.4
Provision for income taxes										
% Tax Rate										
Net profit (Loss) allocable to common stockholders	0.2	(4.4)	19.6	(5.1)	24.0	19.0	44.6	6.0	50.6	48.4
% Net Margin										
Basic shares outstanding	17.1	17.3	17.1	17.5	17.1	17.6	17.1	17.4	17.2	17.7
Diluted shares outstanding	17.1	17.3	17.1	17.5	17.1	18.7	18.5	18.0	18.6	18.8
Basic GAAP net loss per common share	$ 0.01	$ (0.25)	$ 1.15	$ (0.29)	$ 1.40	$ 1.08	$ 2.61	$ 0.34	$ 2.95	$ 2.73
Diluted GAAP net loss per common share	$ 0.01	$ (0.25)	$ 1.15	$ (0.29)	$ 1.40	$ 1.01	$ 2.41	$ 0.28	$ 2.72	$ 2.58

Source: Company filings, JMP Securities LLC

FIGURE 4. ARDX Income Statement

Ardelyx Income Statement	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties															
Tenapanor - WW Royalties					-	-	-	2.9	25.2	79.2	131.5	168.9	193.4	210.6	220.3
Total Sales and Royalties					-	-	-	2.9	25.2	79.2	131.5	168.9	193.4	210.6	220.3
Licensing revenue (amortization of upfront payments)	3.9	3.9	3.9	3.9	15.6	15.6	6.3	6.3	6.3	6.3	6.3	0.8	-	-	-
Milestones	-	-	-	25.0	25.0	75.0	65.0	117.5	130.0	225.0	106.8	70.0	-	-	-
Collaborative development revenue (reimbursment from AZN)	2.0	2.0	2.2	2.3	8.6	9.0	11.7	16.4	19.7	21.7	22.8	22.8	22.8	22.8	22.8
Total Revenues	5.9	5.9	6.1	31.2	49.1	99.6	83.0	143.1	181.2	332.2	267.3	262.4	216.1	233.3	243.1
% change															
Research and development	6.2	6.8	7.4	8.0	28.4	32.1	38.8	45.5	41.7	47.3	53.4	61.0	70.6	82.6	97.5
Selling, general and administrative	3.2	3.5	3.8	4.2	14.7	19.2	23.0	25.3	27.8	30.6	33.7	37.0	40.7	44.8	49.3
Total operating expenses	**9.4**	**10.3**	**11.2**	**12.2**	**43.2**	**51.2**	**61.8**	**70.7**	**69.5**	**77.8**	**87.0**	**98.1**	**111.3**	**127.4**	**146.8**
Operating Profit (Loss)	**(3.5)**	**(4.4)**	**(5.1)**	**19.0**	6.0	48.4	21.2	72.3	111.7	254.3	180.3	164.3	104.8	106.0	96.3
Margin(%)						*48.5%*	*25.5%*	*50.6%*	*61.6%*	*76.6%*	*67.4%*	*62.6%*	*48.5%*	*45.4%*	*39.6%*
Other income (expense)	(0.0)														
Total other income	(0.0)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of preferred stock warrant liability															
Pretax income	**(3.5)**	**(4.4)**	**(5.1)**	**19.0**	6.0	48.4	21.2	72.3	111.7	254.3	180.3	164.3	104.8	106.0	96.3
Provsion for income taxes					-	-	-	-	-	12.7	18.0	32.9	36.7	37.1	33.7
% Tax Rate										*5.0%*	*10.0%*	*20.0%*	*35.0%*	*35.0%*	*35.0%*
Net profit (loss) and comprehensive income	**(3.5)**	**(4.4)**	**(5.1)**	**19.0**	6.0	48.4	21.2	72.3	111.7	241.6	162.2	131.5	68.1	68.9	62.6
Basic shares outstanding	18.6	17.3	17.5	17.6	17.4	17.7	17.8	17.8	17.9	17.9	18.0	18.0	18.1	18.1	18.2
Diluted shares outstanding	18.6	17.3	17.5	18.7	18.0	18.8	18.8	18.9	19.0	19.1	19.1	19.2	19.3	18.1	19.5
Basic GAAP EPS	**$ (0.19)**	**$ (0.25)**	**$ (0.29)**	**$ 1.08**	**$ 0.34**	**$ 2.73**	**$ 1.19**	**$ 4.06**	**$ 6.25**	**$ 13.48**	**$ 9.03**	**$ 7.29**	**$ 3.77**	**$ 3.80**	**$ 3.44**
Diluted GAAP EPS	**$ (0.19)**	**$ (0.25)**	**$ (0.29)**	**$ 1.01**	**$ 0.28**	**$ 2.58**	**$ 1.12**	**$ 3.83**	**$ 5.88**	**$ 12.68**	**$ 8.48**	**$ 6.84**	**$ 3.53**	**$ 3.80**	**$ 3.21**

Source: Company filings, 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

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 (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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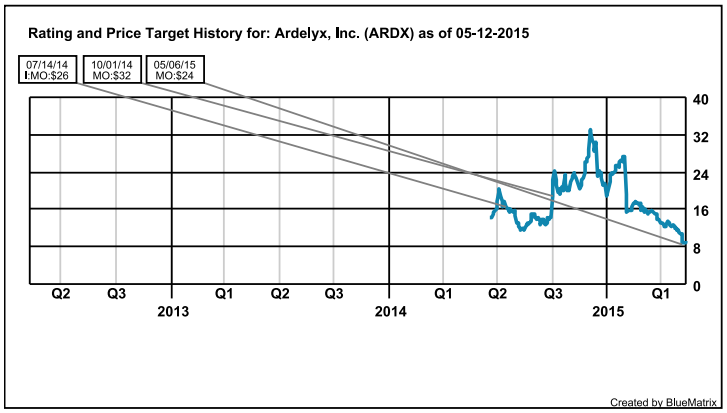
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	279	*62.00%*	Buy	279	*62.00%*	95	*34.05%*
MARKET PERFORM	Hold	140	*31.11%*	Hold	140	*31.11%*	17	*12.14%*
MARKET UNDERPERFORM	Sell	9	*2.00%*	Sell	9	*2.00%*	0	*0%*
COVERAGE IN TRANSITION		21	*4.67%*		21	*4.67%*	4	*19.05%*
TOTAL:		450	*100%*		450	*100%*	116	*25.78%*

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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