Ardelyx, Inc. (ARDX)

Positive Phase IIB Results Announced in Irritable Bowel Syndrome; Increasing Price Target to $32 from $26

MARKET DATA

Price	$14.21
52-Week Range:	$11.37 - $21.60
Shares Out. (M):	17.1
Market Cap ($M):	$243.0
Average Daily Vol. (000):	32.0
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	34.7x	5.1x

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $14.21 | Target Price: $32.00

INVESTMENT HIGHLIGHTS

Ardelyx announced top-line results today in a Phase IIB study of patients with constipation associated with Irritable Bowel Syndrome (IBS-C); we reiterate our Market Outperform rating and increase our year-end price target to $32 from $26 based on our DCF and SOTP valuation methodologies. The company announced that tenapanor 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 CSBM/abdominal pain (50% vs. 23.6%, p<0.001).

Tenapanor results compare favorably to Linzess. Currently, the leader in IBS-C treatment is Linzess, which is marketed by Ironwood (IRWD, NC), a company valued at roughly $1.8bil. With the caveat of cross-trial comparisons, the comparison of results from the Linzess Phase III trials with the tenapanor Phase IIb trial results reflects well for tenapanor. The tenapanor response rate in the dual endpoint composite score of CBSM/abdominal pain was 50%, compared to 33.6% and 33.7% for the two Phase III Linzess trials, with placebo responses of 23.6%, 21%, and 13.9%, respectively, for 6 of 12 weeks (Figure 2). We also note that symptom relief was 63.1% versus 39.4% for placebo, which compares favorably to Linzess reports of 50.1% vs. 37.5% and 48.9% vs. 34.5% in the two Phase III trials. It is important to note that the dose response seen in this trial, with significance at the 50 mg BID dose, is far from the maximum tolerated dose. Previous trials explored the use of up to 960mg in patients with good tolerability. It is possible that tenapanor response rates could increase with higher or more frequent dosing.

Safety and adverse events show tenapanor to be well tolerated with potential differentiation compared to Linzess. The adverse event profile of Linzess is a major driver of its discontinuation, with a 9% overall discontinuation rate and 5% due to diarrhea. Tenapanor had a 4.5% discontinuation rate during these trials (equating to a total of four patients). Overall, diarrhea rates for tenapanor were 11.2%, compared to 20% for Linzess. We believe this will likely be an important differentiating factor.

ARDX will meet with AstraZeneca in the coming weeks to discuss their mutual development strategy. Management detailed its plans to meet with AstraZeneca by the end of the month to discuss how the two companies will move the tenapanor program forward. We remind investors that ARDX still retains the option to buy into a higher royalty rate by way of a $40MM payment that increases the rate by an additional 3%. After adjusting the discount rate in our SOTP valuation from 30% to 25%, accounting for the favorable Phase IIB results, our valuation of the IBS-C program increases from

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$4.16 to $6.28 for a NPV of $107.19MM up from $71MM. Our DCF blended discount rate changes from 30% to 28.1%, resulting in a DCF valuation change from $24.03 to $30.07. The details of these valuations are shown in Figures 5-7. Making this adjustment to our valuation synthesis increases our price target to $32 from $26.

Tenapanor is poised to capture considerable market share by treating symptoms of IBS-C and renal insufficiency. The various read-outs from multiple Phase II clinical studies offer attractive value inflection points that, in our opinion, could drive market valuation to levels seen in companies with similar products that are approved or are in development. The recent capital raise, along with collaboration fees and milestones received from partnerships with AstraZeneca and Sanofi, make us bullish on ARDX shares.

FIGURE 1. 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)

FIGURE 2. Tenapanor vs. Linzess – Composite CSBM/Abdominal Pain

	Dual Composite Endpoint *versus* placebo				
	Week 2	**Week 3**	**Week 4**	**Week 6**	**Week 9**
Tenapanor 100 mg dose Phase IIA	30% *vs.* 15%*	31% *vs.* 20%	32% *vs.* 19%	N/A	N/A
Tenapanor 50 mg BID dose Phase IIB (90 pts.)				50.0% vs. 23.6%**	
Linzess 290 mcg dose Phase III #1 (405 pts.)	*N/A*	*N/A*	*N/A*	33.6% vs 21%	12.1 % *vs.* 5.1%
Linzess 290 mcg dose Phase III #2 (401 pts.)	*N/A*	*N/A*	*N/A*	33.7% vs. 13.9%	12.7% *vs.* 3%

* p= < 0.05
**p=< 0.001

Source: Company Reports

FIGURE 3. Relief of IBS-C Symptoms

	Relief of IBS-C symptoms	
	Week 9	Week 12
Tenapanor 50 mg BID dose Phase IIB		63.1% vs 39.4%
Linzess 290 mcg dose Phase III #1	50.1% vs. 37.5%	
Linzess 290 mcg dose Phase III #2	48.9% vs. 34.5%	

Source: Company Reports

FIGURE 4. Adverse Events

	Adverse Events	
	Tenapanor (50 mg BID)	Linzess (290 mcg)
Diarrhea	11.2% vs. 0%	20.0% vs 3%

Source: Company Reports

FIGURE 5. Price Target Synthesis

Synthesis of Valuation Approaches	
Approach	Valuation
DCF Analysis	$ 30.07
SOTP	33.95
Price Target	**$ 32.00**

Source: JMP Securities LLC

FIGURE 6. DCF Valuation

Residual Value of CF	$	390
+ Cash and Cash Equivalents	$	124
Value of Company	$	513
- LT Debt		
Value of Equity	$	513
Price/share=	$	30.07

Assumptions	
Blended Discount Rate	28.1%
Cash and Cash Equivalents (YE 2014 estimate	$ 123.5
Terminal Growth Rate 2025	0%
Shares Outstanding (YE 2014 estimate)	17.1

Source: JMP Securities LLC

FIGURE 7. Sum-of-the-Parts Analysis

Sum of the Parts Valuation		
Market	($ MM)	$/Share
ESRD	$ 30.49	$ 1.79
CKD	61.52	3.60
IBS-C	107.19	6.28
Milestones	256.94	15.05
Cash	123.54	7.24
Value of Equity	$ 580	$ 33.95

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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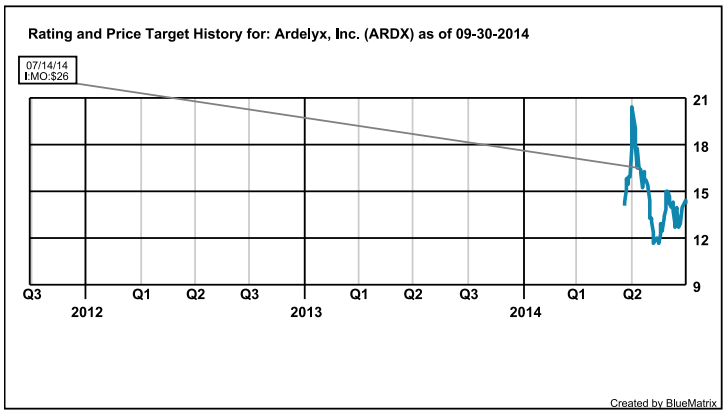
MARKET OUTPERFORM	Buy	274	*60.62%*	Buy	274	*60.62%*	100	*36.50%*
MARKET PERFORM	Hold	139	*30.75%*	Hold	139	*30.75%*	19	*13.67%*
MARKET UNDERPERFORM	Sell	3	*0.66%*	Sell	3	*0.66%*	0	*0%*
COVERAGE IN TRANSITION		36	*7.96%*		36	*7.96%*	0	*0%*
TOTAL:		452	*100%*		452	*100%*	119	*26.33%*

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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