Ardelyx Inc. (ARDX)

CKD Study Misses Primary Endpoint, but Data Further Confirms Tenapanor Benefit in ESRD and IBS-C, Lowering PT to $22 and Maintaining OUTPERFORM Rating

- **Tenapanor missed CKD endpoint in Phase 2.** Top-line data from the double-blind, placebo-controlled Ph 2a trial in 154 stage 3 CKD patients with Type II diabetes and albuminuria show that tenapanor missed the primary endpoint of a decrease in urine albumin to creatinine ratio (UACR) from baseline to week 12 (16% vs 11% for placebo). Tenapanor also missed secondary endpoints including improvements in blood pressure and kidney function (as measured by eGFR). Consistent with tenapanor's mechanism, a decrease from baseline was observed in mean urinary sodium excreted (-9.6mmol/day vs -1.5mmol/day for placebo). We note that CKD is a complex disorder that is difficult to treat, which is why we had viewed the CKD study as the riskiest of ARDX's Ph 2 programs.
- **Improvements in outcome measures tied to phosphate levels and stool form/frequency supports further development in ESRD and IBS-C.** Patients in the tenapanor group had softer stool and increased bowel movement frequency, and decreased urinary phosphorus levels from baseline (-118.6mg/day vs +53.1mg/day increase for placebo). Although it is difficult to translate the magnitude of the urinary phosphorus reduction into the ESRD population, the CKD results clearly indicate that tenapanor is diverting a substantial amount of phosphorus into the stool. Patients in the CKD study were treated with 15mg bid tenapanor, and could dose-titrate up to 60mg bid if tolerated or down to 5mg bid. Diarrhea was reported in two-thirds of patients, although this was patient-reported and may not have met clinical definitions. No other safety signals were observed, which separates tenapanor from other available phosphate binders, which are associated with increased rates of nausea and vomiting. We await additional data from the study, potentially available by June 16 (ARDX's R&D Day), to provide granularity on the diarrhea rates and urinary phosphorus reduction observed with tenapanor.
- **We are removing sales in CKD from our model and reducing our PT to $22.**
- **Deadline for Astra to decide on retaining tenapanor partnership is June 29. At current market cap, we see limited downside risk to ARDX if Astra pulls out.**
- **Maintain OP and reducing PT to $22 (from $31).** Our PT is derived by applying a 6 and 15 multiple to ARDX's share of 2022 tenapanor US sales and ex-US royalty.

FYE Dec	2014A	2015E			2016E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	8.6A	10.6E		$10.9E	29.6E		14.0E
Q2 Jun	9.1A	10.6E		11.3E	30.1E		34.7E
Q3 Sep	7.6A	17.1E		24.0E	30.5E		40.6E
Q4 Dec	6.3A	19.1E		23.8E	31.0E		102.6E
Year*	**31.6A**	**57.4E**		**70.0E**	**121.2E**		**101.8E**
Change	9%	81%			--		
	2014A	**2015E**			**2016E**		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	($2.44)A	$0.15E		$0.01E	$0.62E	$0.63E	$0.01E
Q2 Jun	$0.20A	$0.13E		$0.18E	$0.36E		$1.15E
Q3 Sep	$0.00A	$0.29E	$0.30E	$0.90E	$0.27E	$0.28E	$1.40E
Q4 Dec	($0.21)A	$0.22E	$0.23E	$0.50E	$0.18E		$2.41E
Year*	**($0.31)A**	**$0.80E**		**$1.53E**	**$1.43E**		**$1.38E**
P/E	--	--			--		
Change	95%	354%			--		

Consensus estimates are from Thomson First Call. * *Numbers may not add up due to rounding.*

May 6, 2015

Price
$10.91

Rating
OUTPERFORM

12-Month Price Target
$22 **(from $31)**

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Company Information

Shares Outst (M)	18.6
Market Cap (M)	$202.9
52-Wk Range	$10.40 - $35.48
Book Value/sh	$3.26
Cash/sh	$5.89
Enterprise Value (M)	$93.3
LT Debt/Cap %	0.0
Cash Burn (M)	$0.0

Company Description

Ardelyx Inc. is developing small-molecule drugs for the treatment of cardio-renal, GI and metabolic diseases. Its lead product candidate, tenapanor, is in three ongoing Phase II trials for ESRD, CKD and IBS-C.

Source: Thomson Reuters

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Biotechnology/Biopharmaceuticals

We are removing sales in CKD from our model and reducing our price target to $22. If tenapanor is approved for ESRD we do expect some off-label sales in pre-dialysis patients, given that hyperphosphatemia commonly occurs in this population. We note that although the FDA has indicated that phosphate reduction alone is not an approvable endpoint in CKD, it is in ESRD. A >1.5mg/dL decrease in serum phosphate levels is considered the approvable endpoint for treating hyperphosphatemia in ESRD, a rate which was met with an acceptable safety profile in our view by the 10mg bid tenapanor dose in the Ph 2b ESRD study.

Deadline for Astra to decide on retaining tenapanor partnership is June 29. If Astra returns the ww rights to tenapanor, we believe ARDX has sufficient funds (>$100M estimated on-hand) to continue the clinical advancement of tenapanor, at least until the generation of data catalysts that could support a financing or attract another partner. ARDX is scheduled to hold an EoP2 meeting with FDA in June for IBS-C, and is prepared to start a Ph 3 IBS-C study for tenapanor in 4Q15 by itself if need be. Under this alternative scenario, we see ARDX developing tenapanor through to a positive data catalyst, and then licensing out ex-US rights as well as US co-promotion rights to the IBS-C indication (we expect ARDX to retain full US rights for ESRD). Assuming typical small-molecule partnership terms ($75M upfront, and $100M in near-term milestones), the impact to our valuation would be modest (PT would fall to $18).

At its current market cap, we see the downside risk to ARDX if Astra pulls out as limited. Although ARDX shares could see temporary weakness if Astra returns tenapanor rights, we expect a recovery as investors realize that ARDX has the capabilities to advance tenapanor on its own. With a <$100M EV and partial (or potentially complete) rights to a Ph 3 ready asset for two large indications, we see ARDX as having an excellent risk/reward ratio moving forward.

Maintain Outperform and reducing PT to $22 (from $31). Our price target is derived by applying a 6 multiple to ARDX's share of 2022 tenapanor sales in the US, added to a 15 multiple of the royalty ARDX is expected to receive in 2022 for ex-US sales of tenapanor. We model for sales in ESRD and IBS-C only, and assume the AstraZeneca partnership is maintained.

Risks to our price target include AstraZeneca choosing to withdraw from the tenapanor collaboration, clinical failure for tenapanor going forward, and failure to achieve regulatory approval and sales estimates for tenapanor.

Milestones

June	End of Ph2 meeting with FDA
June 16	ARDX R&D Day
June 29	Deadline for AstraZeneca to decide on maintaining tenapanor partnership

Source: Wedbush Securities

Financial Model

5/5/2015
Ticker: (ARDX:Nasdaq)
Ardelyx, Inc

Wedbush PacGrow Life Sciences
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	2014	Q1E	Q2E	Q3E	Q4E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenues:													
US Product Sales	$0	$0	$0	$0	$0	$0	$0	$0	$10,264	$98,034	$200,943	$368,058	$539,003
ex-US royalties	$0	$0	$0	$0	$0	$0	$0	$0	$0	$5,482	$23,062	$41,596	$66,850
Licensing and other revenue	$18,394	$8,109	$8,109	$11,680	$11,680	$39,578	$84,720	$52,284	$52,284	$66,000	$66,000	$42,000	$42,000
Collaborative development revenue	$13,229	$2,454	$2,454	$5,454	$7,454	$17,816	$36,438	$44,290	$50,010	$54,132	$58,594	$63,424	$68,653
Total Revenues	**31,623**	**10,563**	**10,563**	**17,134**	**19,134**	**57,394**	**121,158**	**96,574**	**112,558**	**223,647**	**348,599**	**515,079**	**716,506**
Cost and Expenses:													
Cost of Sales	0	0	0	0	0	0	0	0	1,026	9,803	20,094	36,806	53,900
R&D	25,900	5,387	5,563	8,749	11,947	31,646	73,121	119,194	152,628	183,685	222,152	269,913	329,339
SG&A	7,287	3,057	3,240	3,435	3,641	13,373	16,884	21,315	29,476	66,452	92,179	133,958	176,694
Total Operating Expenses	**33,187**	**8,444**	**8,803**	**12,184**	**15,588**	**45,019**	**90,004**	**140,509**	**183,130**	**259,941**	**334,426**	**440,677**	**559,934**
Operating Income (Loss)	(1,564)	2,119	1,760	4,950	3,546	12,375	31,154	(43,935)	(70,573)	(36,293)	14,173	74,402	156,572
Net Interest Income (Expense)	10	805	822	843	882	3,351	4,427	4,796	7,142	5,302	4,525	5,259	7,820
Other non-operating Income (Expense)	0	0	0	0	0	0	0	0	0	0	0	0	0
Income Before Income Taxes	(1,554)	2,924	2,582	5,792	4,428	15,727	35,580	(39,138)	(63,431)	(30,991)	18,697	79,661	164,392
Provision for Income Taxes	67	155	137	307	235	834	8,797	0	0	0	1,063	4,222	47,645
Net Income (Loss)	(1,621)	2,769	2,445	5,485	4,194	14,893	26,783	(39,138)	(63,431)	(30,991)	17,634	75,439	116,747
GAAP EPS	**(0.31)**	**0.15**	**0.13**	**0.29**	**0.22**	**0.80**	**1.43**	**(1.71)**	**(2.76)**	**(1.34)**	**0.76**	**3.24**	**4.99**
Weighted Basic Shares Outstanding	10,248	18,598	18,623	18,648	18,673	18,673	18,773	22,873	22,973	23,073	23,173	23,273	23,373
Cash Burn	0	0	0	0	0	0	0	(24,207)	(60,732)	(38,746)	0	0	0
Cash Balance	107,286	109,619	112,339	117,618	121,391	121,391	147,409	238,522	177,789	139,043	145,714	201,342	297,863

Source: Wedbush Securities Inc.

Analyst Biography

David Nierengarten, Ph.D.

David is an Analyst covering stocks in the Biotechnology/Biopharmaceuticals/BioDefense sector. His prior sell-side research experience at Robert W. Baird & Co. covered biotechnology companies of all market capitalizations, with a focus on oncology and rare diseases.

David received his B.S. (Biochemistry) from the University of Wisconsin-Madison and Ph.D. (Molecular and Cell Biology) from the University of California-Berkeley.

David's Edge: David's early stage venture capital investing experience gives him a balanced perspective on developmental-stage biotechnology companies and their ultimate risk/reward potential. His experience on the other side of that equation in a clinical-stage, venture backed biotechnology company provides him with insights into corporate operations. The combination of experiences creates a focus on value creation in this event-driven space.

Analyst Certification
I, David M. Nierengarten, Ph.D., Dilip Joseph, Robert Driscoll, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

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Outperform:55% Neutral: 43% Underperform: 2%	Outperform:31% Neutral: 3% Underperform: 0%

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Company	Disclosure
Ardelyx Inc.	1,3,4,5

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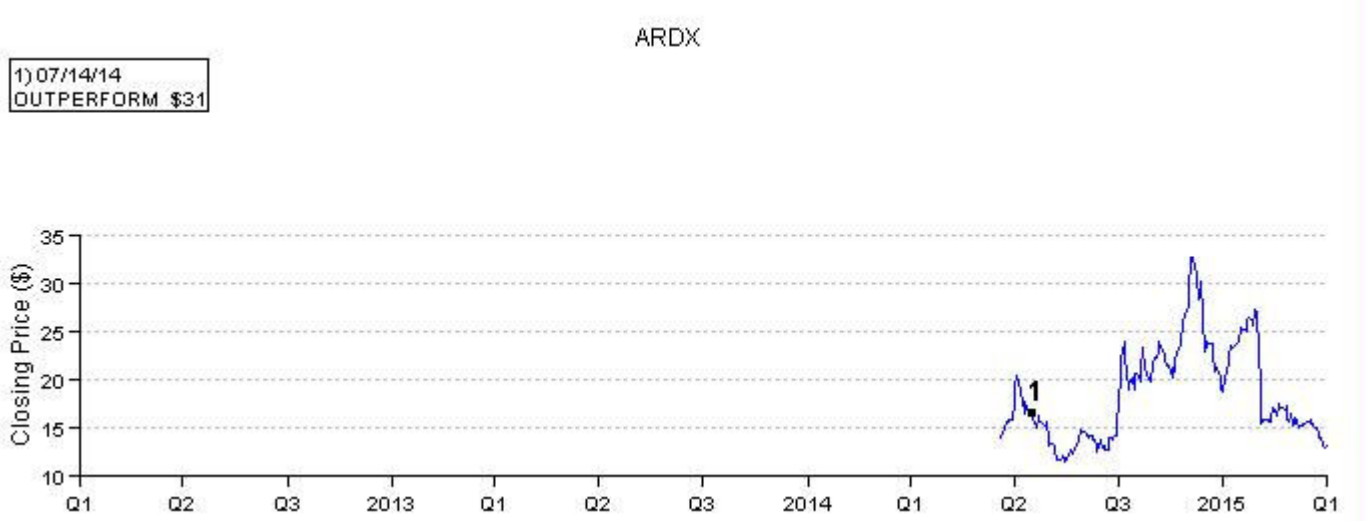

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