

Reason for report:

COMPANY UPDATE

## ARDELYX, INC.

Exploratory CKD Study Fails, Other Programs Still Viable; Remain OP, PT to \$22

• **Bottom Line:** This afternoon ARDX reported top line results from its Ph. 2a exploratory trial studying tenapanor (NHE3 inhibitor) in chronic kidney disease (CKD) patients w/diabetes and albuminuria. The study failed to meet its primary endpoint of decreasing the urinary albumin-creatinine ratio vs. PBO. We believe the study was heavily discounted given the lack of a validated endpoint and the lengthy clinical trial requirements. In our model, we attributed a POS of ~35% and ~\$10/shr to the CKD indication. We now value shares solely on the IBS-C and ESRD-Pi indications where tenapanor showed both positive efficacy and safety data; we value ARDX shares at \$22 (from \$32). We continue to see upside to ARDX's current valuation as we believe they can monetize tenapanor either through the continuation of the AZN (MP) partnership or a go-it-alone strategy. Next up: (1) R&D day on 6/16 to showcase ARDX's wholly-owned pipeline assets; and (2) 6/29 -- deadline for AZN to move forward with the ARDX partnership for the tenapanor program(s) in IBS-C and/or ESRD-Pi.

• **We believe ARDX is well positioned to generate significant upside at its current valuation.** On 6/29, AZN faces a deadline on whether or not they plan to move forward for one, both or none of the tenapanor programs. We believe ARDX can still generate value under either scenario as: (1) if AZN commits, the IBS-C and/or ESRD-Pi programs trigger either a ~\$10m or ~\$20m (if both programs) in development milestones; or (2) under a go it alone strategy -- ARDX has enough capital to fund a Ph. 3 IBS-C trial alone and is able to monetize the asset on positive Ph.3 topline data. In the latter scenario, mgmt would seek out a commercial partner after the Ph. 3 data read out.

• **CKD Ph. 2a study failure has no read through to other programs.** There is no read through on efficacy from today's CKD study results relative to the IBS-C and ESRD-Pi indications, which have completely different efficacy endpoints. In both the IBS-C and ESRD-Pi Ph. 2b trials, tenapanor met stat sig on the primary endpoints in the respective studies. Additionally, the CKD study further validates tenapanor's consistent safety profile. Across all three studies, tenapanor has demonstrated no difference in adverse events when compared to PBO except for diarrhea. We continue to believe the high diarrhea rates seen in the Ph. 2b ESRD-Pi trial were due to the trial design which allowed for only a fixed dosage (vs. escalating dosages in IBS-C), although ARDX did see lower rates of diarrhea and met stat sig at the 10mg dose in the ESRD-Pi trial.

• **Upcoming R&D day will shed light on ARDX's proprietary pipeline.** The company's R&D day planned for 6/16 is set to showcase ARDX's pipeline outside of tenapanor. We believe ARDX could have several opportunities for value creation by either fully developing these assets or through additional partnership opportunities.

## Key Stats:

(NASDAQ:ARDX)

S&P 600 Health Care Index: 1,591.60  
Price: \$10.91  
Price Target: \$22.00 from \$32.00  
Methodology:

Sum-of-the-parts DCF analysis, 15% discount rate

52 Week High: \$35.48  
52 Week Low: \$10.40  
Shares Outstanding (mil): 18.5  
Market Capitalization (mil): \$201.8  
Book Value/Share: \$0.00  
Cash Per Share: \$5.80  
Net Debt to Total Capital: 0%  
Dividend (ann): \$0.00  
Dividend Yield: 0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2014A	8.6	9.1	7.6	6.3	32.0	( 0.23)	0.18	0.00	( 0.21)	( 0.31)	NM
2015E	8.7	9.3	20.3	11.7	50.0	( 0.18)	( 0.16)	0.36	( 0.14)	( 0.11)	NM
2016E	--	--	--	--	60.0	--	--	--	--	0.43	25.4x

Source: Company Information and Leerink Partners LLC Research  
Revenue in \$MM.

## INVESTMENT THESIS

We rate ARDX with an Outperform rating and a \$22 price target in 12 months. ARDX is partnered with AZN on its lead program, tenapanor, a small molecule inhibitor of NHE3, which is one of the main transporters of sodium in the GI tract. With emerging data suggesting maintenance of a low sodium diet can provide therapeutic benefit in kidney disease patients, tenapanor holds the promise of addressing an important unmet need in the multi-billion dollar kidney disease market, as well as potential utility in constipation predominant irritable bowel syndrome (IBS-C). While AZN owns WW commercialization rights on tenapanor, ARDX may receive up to ~\$225m in development milestones and tiered royalties (in "teens"). Longer term, ARDX plans to invest in its proprietary drug discovery platform and develop wholly owned assets.

## VALUATION

Our ~\$22/shr price target on ARDX shares is based on our risk-adjusted, sum-of-the-parts DCF analysis through 2025E. We used a 15% discount rate, and we estimate tenapanor will achieve market shares of ~30% and ~5% in the ESRD-Pi and IBS-C indications, respectively.

## RISKS TO VALUATION

Risks include: (1) tenapanor drives our valuation and clinical/regulatory failure would significantly impact our valuation; and (2) AZN may not commit to funding all the currently envisioned indications, depending on strength of future data.

<b>AZN Partnership</b>	<b>Base</b>
Tenapanor ESRD Pi peak share	30%
Tenapanor launch price/day	\$15
2025 tenap ESRD global sales	860
ESRD % POS	25%
<b>Risk adj NPV tenapanor ESRD</b>	<b>64</b>
Tenapanor CKD peak share	40%
Tenapanor launch price/day	\$15
2025 tenap CKD global sales	3005
CKD % POS	0%
<b>Risk adj NPV tenapanor CKD</b>	<b>0</b>
Tenapanor IBS peak share	5%
Tenapanor launch price/day	\$15
2025 tenap IBS US sales	950
IBS % POS	60%
<b>Risk adj NPV tenapanor IBS</b>	<b>186</b>
<b>Risk Adj AZN Milestones</b>	
Ph 2 b data, \$20m, 50% POS	0
start Ph 3 ESRD, \$50m, 50% POS	13
Est. approval milestone, \$100m, 35% POS	25
NDA filing, \$50m	13
All other, \$2.5m	1
<b>Discounted, risk adj AZN milestones</b>	<b>30</b>
Total NPV of AZN partnership	<b>280</b>
Total NPV of SNY p/s milestones	<b>26</b>

Source: Company info., Leerink Partners Research est.

Shares Outstanding	18.5
Net cash	112
Discount Rate	15%

ARDX	Valuation	Per shr	% of value
AZN p/s (risk adj royalties + m'stones)	280	\$ 15	69%
SNY p/s (milestones)	26	\$ 1	6%
Cash (less near-term burn)	100	\$ 5	25%
<b>Total</b>	<b>406</b>	<b>\$ 22</b>	<b>100%</b>

Current market price	\$ 9.00
Implied upside/downside	144%

Source: Company info., Leerink Partners Research est.

**ARDX Annual P&L Summary (Adj. Basis)**  
 (figures in \$m, except per share data)

	2013	1Q14	2Q14	3Q14	4Q14	2014	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	19-23E
Tenapanor ESRD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	8	15	21	26	36%
Tenapanor CKD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
Tenapanor IBS	-	-	-	-	-	-	-	-	-	-	-	-	-	5	15	25	46	62	65	23%
<b>Total tenapanor royalties</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	<b>5</b>	<b>18</b>	<b>33</b>	<b>61</b>	<b>82</b>	<b>91</b>	<b>26%</b>
Licensing revenue	8	3.2	6.5	4.8	3.9	18	1.2	1.3	1.3	1.2	5	-	-	-	-	-	-	-	-	na
Collaborative development revenue	21	5.3	2.6	2.8	2.5	13	7.5	8.0	9.0	10.5	35	35	35	35	-	-	-	-	-	na
AZN milestones	-	-	-	-	-	-	-	-	10	-	10	25	25	50	-	-	-	-	-	na
<b>Total Revenue (MM)</b>	<b>29</b>	<b>8.6</b>	<b>9.1</b>	<b>7.6</b>	<b>6.3</b>	<b>32</b>	<b>8.7</b>	<b>9.3</b>	<b>20.3</b>	<b>11.7</b>	<b>50</b>	<b>60</b>	<b>60</b>	<b>90</b>	<b>18</b>	<b>33</b>	<b>61</b>	<b>82</b>	<b>91</b>	<b>26%</b>
% y/y growth	na	na	na	na	na	na	na	na	na	na	na	na	nm	50%	-80%	82%	85%	34%	10%	
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
% of sales	0%	na	na	na	na	0%	na	na	na	na	0%	0%	0%	0%	0%	0%	0%	0%	0%	na
Gross Income	28.9	8.6	9.1	7.6	6.3	31.6	8.7	9.3	20.3	11.7	50.0	60	60	90	18	33	61	82	91	26%
% of net sales	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
Discovery research	7.7	2.4	2.6	2.5	5.3	12.7	2.3	2.4	2.4	2.4	9.5	9.5	8.0	8.0	8.0	8.0	8.0	8.0	8.0	0%
Clinical development expense - tenapanor	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
AZN collaboration dev expense	20.3	5.3	2.6	3.2	2.1	13.2	8.6	8.8	8.6	9.0	35.0	35.0	35.0	35.0	-	-	-	-	-	na
Total R&D	28.1	7.6	5.2	5.7	7.4	25.9	10.9	11.2	11.0	11.4	44.5	44.5	43.0	43.0	8.0	8.0	8.0	8.0	8.0	0%
% of sales	nm	89%	57%	75%	117%	82%	125%	121%	54%	97%	89%	74%	72%	48%	44%	24%	13%	10%	9%	
G&A	3.7	1.4	1.2	1.8	2.9	7.3	1.4	1.2	1.3	3.1	7.0	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	0%
% of sales	13%	na	na	na	na	23%	na	na	na	na	14%	12%	12%	8%	41%	23%	12%	9%	8%	
Selling & Marketing	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
Total operating expenses	31.8	9.0	6.4	7.5	10.3	33.2	12.3	12.4	12.3	14.5	51.5	52.0	50.5	50.5	15.5	15.5	15.5	15.5	15.5	0%
<b>Operating (loss)/gain</b>	<b>(2.9)</b>	<b>(0.5)</b>	<b>2.8</b>	<b>0.1</b>	<b>(3.9)</b>	<b>(1.6)</b>	<b>(3.6)</b>	<b>(3.1)</b>	<b>8.0</b>	<b>(2.8)</b>	<b>(1.5)</b>	<b>8.0</b>	<b>9.5</b>	<b>39.7</b>	<b>2.7</b>	<b>17.7</b>	<b>45.8</b>	<b>66.8</b>	<b>75.4</b>	<b>61%</b>
% of sales	nm	na	na	na	na	-5%	na	na	na	na	-3%	13%	16%	44%	15%	53%	75%	81%	83%	
<b>Net financial expense</b>	<b>(3.6)</b>	<b>(2.6)</b>	<b>1.0</b>	<b>(0)</b>	<b>0.0</b>	<b>(1.6)</b>	<b>(0.2)</b>	<b>(0.2)</b>	<b>(0.2)</b>	<b>(0.2)</b>	<b>(0.9)</b>	<b>1.3</b>	<b>1.5</b>	<b>2.1</b>	<b>2.3</b>	<b>2.6</b>	<b>3.4</b>	<b>4.3</b>	<b>5.3</b>	<b>13%</b>
<b>Pre-tax Income</b>	<b>(6.4)</b>	<b>(3.1)</b>	<b>3.8</b>	<b>0.1</b>	<b>(3.9)</b>	<b>(3.1)</b>	<b>(3.8)</b>	<b>(3.3)</b>	<b>7.8</b>	<b>(3.0)</b>	<b>(2.4)</b>	<b>9.3</b>	<b>11.0</b>	<b>41.8</b>	<b>5.0</b>	<b>20.3</b>	<b>49.2</b>	<b>71.2</b>	<b>80.8</b>	<b>49%</b>
% Pre-tax Margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	18.4%	46.4%	27.2%	61.3%	80.2%	86.4%	88.8%	
Taxes (benefit)	0.1	-	-	-	0.1	0.1	-	-	-	-	-	-	-	4.2	0.7	4.1	12.3	21.4	28.3	68%
% Tax rate	0.0%	-	-	-	-	0.0%	-	-	-	-	0.0%	0.0%	0.0%	10.0%	15.0%	20.0%	25.0%	30.0%	35.0%	
<b>Net Income/(loss) (MM)</b>	<b>(7)</b>	<b>(3.1)</b>	<b>3.8</b>	<b>0.1</b>	<b>(4.0)</b>	<b>(3.2)</b>	<b>(3.8)</b>	<b>(3.3)</b>	<b>7.8</b>	<b>(3.0)</b>	<b>(2)</b>	<b>9</b>	<b>11</b>	<b>38</b>	<b>4</b>	<b>16</b>	<b>37</b>	<b>50</b>	<b>53</b>	<b>43%</b>
% of net sales	NM	NM	41%	NM	NM	NM	NM	-36%	NM	NM	nm	15.6%	18.4%	41.7%	23.2%	49.0%	60.2%	60.5%	57.7%	
<b>Diluted EPS</b>	<b>(\$5.82)</b>	<b>(\$0.23)</b>	<b>\$0.18</b>	<b>\$0.00</b>	<b>(\$0.21)</b>	<b>(\$0.31)</b>	<b>(\$0.18)</b>	<b>(\$0.16)</b>	<b>\$0.36</b>	<b>(\$0.14)</b>	<b>(\$0.11)</b>	<b>\$0.43</b>	<b>\$0.45</b>	<b>\$1.51</b>	<b>\$0.17</b>	<b>\$0.63</b>	<b>\$1.39</b>	<b>\$1.84</b>	<b>\$1.90</b>	<b>42%</b>
Y/Y	NM					NM					NM	NM	5%	234%	-89%	279%	122%	32%	3%	
Weighted Avg Diluted Shares (MM)	1.1	13.3	20.3	19.1	18.5	10.2	21.1	21.3	21.4	21.2	21.2	21.7	24.5	25.0	25.5	26.0	26.5	27.0	27.6	1%
% growth	-85%					809%					15%	2%	13%	2%	2%	2%	2%	2%	2%	

Source: Leerink Partners, LLC estimates and company reports

## Disclosures Appendix

### Analyst Certification

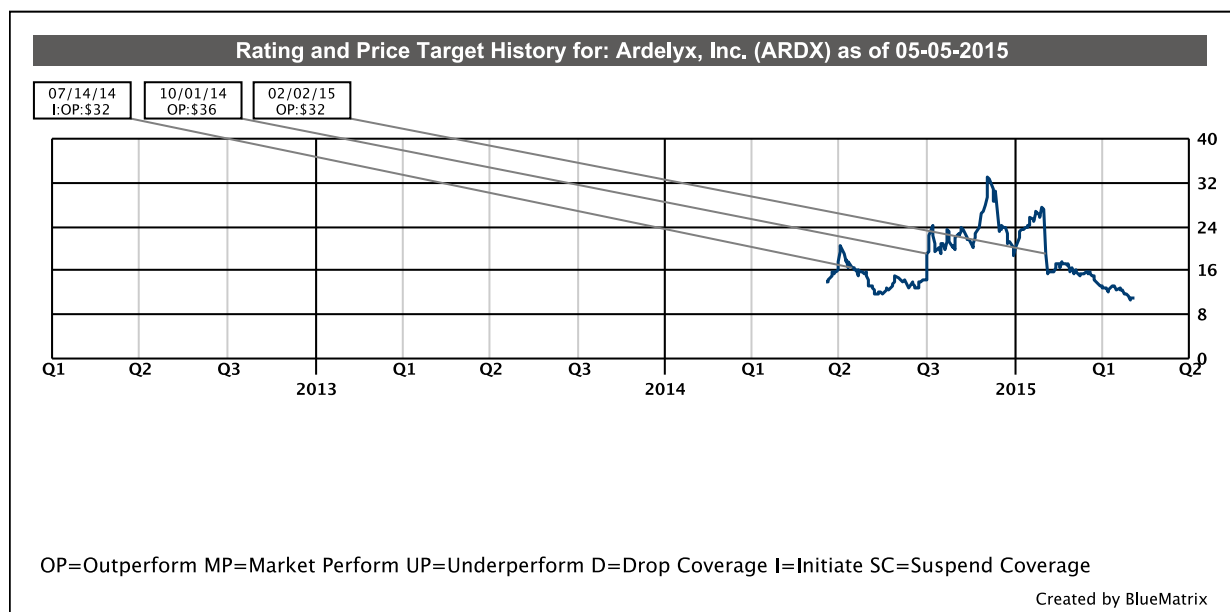
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

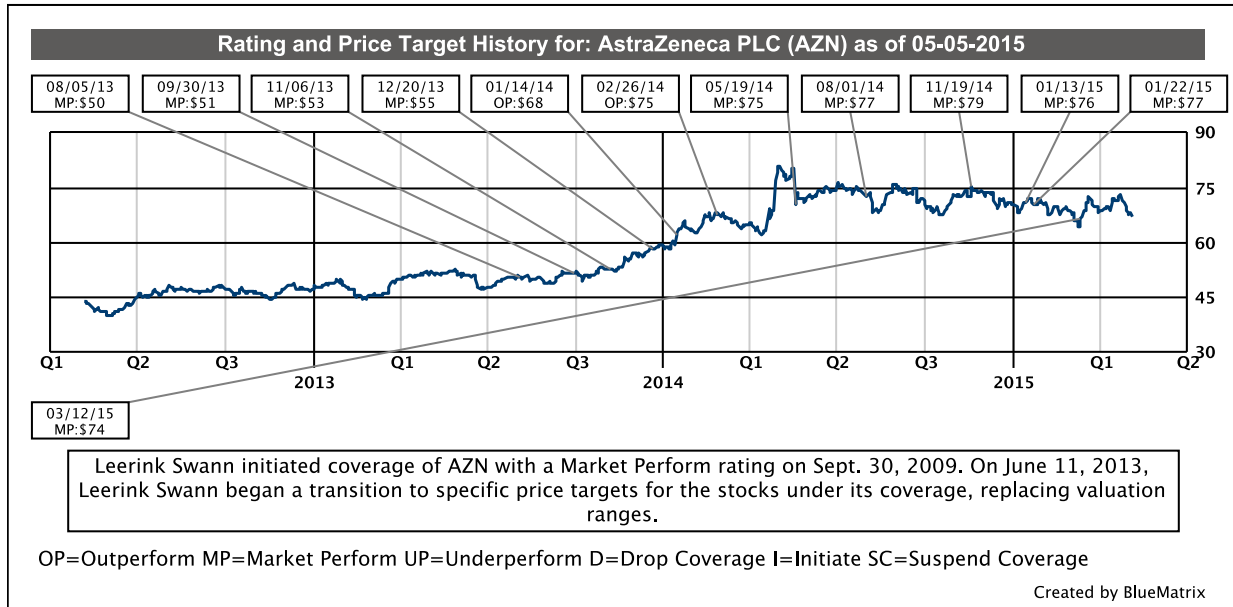
### Valuation

Our ~\$22/shr price target on ARDX shares is based on our risk-adjusted, sum-of-the-parts DCF analysis through 2025E. We used a 15% discount rate, and we estimate tenapanor will achieve market shares of ~30% and ~5% in the ESRD-Pi and IBS-C indications, respectively.

### Risks to Valuation

Risks include: (1) tenapanor drives our valuation and clinical/regulatory failure would significantly impact our valuation; and (2) AZN may not commit to funding all the currently envisioned indications, depending on strength of future data.





Distribution of Ratings/Investment Banking Services (IB) as of 03/31/15				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	151	70.20	55	36.00
HOLD [MP]	64	29.80	2	3.00
SELL [UP]	0	0.00	0	0.00

## Explanation of Ratings

**Outperform (Buy):** We expect this stock to outperform its benchmark over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.



## Important Disclosures

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In the past 12 months, the Firm has received compensation for providing investment banking services to Ardelyx, Inc. .

Leerink Partners LLC makes a market in Ardelyx, Inc.

Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of AstraZeneca PLC and Sanofi on a principal basis.

Leerink Partners LLC has acted as the manager for a public offering of Ardelyx, Inc. in the past 12 months.

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