

Reason for report:

EARNINGS

## ARDELYX, INC.

## 1Q in Line; Key Updates Mainly Around Initiation of Ph. 3 for Tenapanor in IBS

• **Bottom Line:** On Tuesday ARDX reported its 1Q15 earnings including cash-burn of ~\$3.5m, in line with our estimates of ~\$3.8m. In the company's earnings press release, mgmt. reiterated that it stands ready to develop tenapanor with or without its current partner AZN (MP), which must decide whether to continue developing the drug by June 29. In the PR, ARDX states "we continue to work with AstraZeneca as they evaluate the data in totality from the tenapanor development program." Given AZN's historical presence in the gastroenterology category, we would not dismiss the possibility that AZN opts into further development. Up next - ARDX has an end-of-phase 2 meeting with the FDA in June to discuss a pivotal Phase 3 study design. ARDX ended 1Q with a cash balance of \$98m. We reiterate our Outperform rating with a price target of \$22/shr.

• **Tenapanor still has the potential to be developed for multiple indications.** In the PR, mgmt. provided reassurance that it fully intends to develop tenapanor in both IBS-C (effect on stool form) and ESRD-Pi (reduced phosphate absorption), following Ph. 2 studies where the drug demonstrated efficacy in both indications. In our model, we are valuing shares primarily on these two indications. Given that both programs remain heavily risk adjusted in our forecast model -- we believe there is significant upside to shares upon further clinical de-risking. On the data front, ARDX plans to provide more detailed IBS data on at Digestive Disease Week (mid-May).

• **ARDX mgmt. projects 4Q15 initiation of IBS-C Ph III.** ARDX is preparing the continuation of its tenapanor programs under a variety of scenarios. We believe ARDX is capable of generating value with its partnership with AZN or a go-it-alone strategy (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 subsequently monetize the asset after generating positive Ph.3 top-line data. As for ARDX's scheduled EOP-2 meeting, we would not expect many surprises as the clinical trial protocol for IBS-C drugs is pretty well validated.

• **Upcoming R&D day will shed light on ARDX's proprietary pipeline.** The company's inaugural R&D day planned for 6/16 in NYC 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.

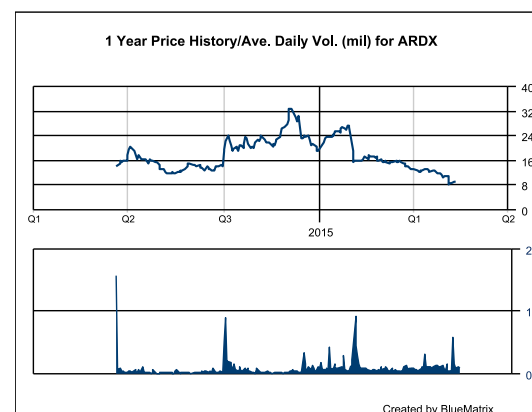
## Key Stats:

(NASDAQ:ARDX)

S&P 600 Health Care Index: 1,606.69  
Price: \$9.06  
Price Target: \$22.00  
Methodology:

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

52 Week High: \$35.48  
52 Week Low: \$7.95  
Shares Outstanding (mil): 18.6  
Market Capitalization (mil): \$168.5  
Book Value/Share: \$0.00  
Cash Per Share: \$5.28  
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 - New	5.9A	9.3	20.3	14.5	50.0	( 0.19)A	( 0.18)	0.42	( 0.18)	( 0.13)	NM
2015E - Old	8.7	9.3	20.3	11.7	50.0	( 0.18)	( 0.16)	0.36	( 0.14)	( 0.11)	NM
2016E - New	--	--	--	--	60.0	--	--	--	--	0.49	18.5x
2016E - Old	--	--	--	--	60.0	--	--	--	--	0.43	NM

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.

## CHANGES TO MODEL

### EPS & Total Sales Forecasts (2014-20E) (\$MM, except per share data)

Total Sales Forecasts 2014-20E							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	32	50	60	60	90	18	33
Old	<u>32</u>	<u>50</u>	<u>60</u>	<u>60</u>	<u>90</u>	<u>19</u>	<u>36</u>
Difference	-	-	-	-	-	(1)	(3)
Total EPS Forecasts 2014-20E							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	<u>(0.31)</u>	<u>(0.13)</u>	<u>0.49</u>	<u>0.52</u>	<u>1.72</u>	<u>0.19</u>	<u>0.72</u>
Old	<u>(0.31)</u>	<u>(0.11)</u>	<u>0.43</u>	<u>0.45</u>	<u>1.51</u>	<u>0.21</u>	<u>0.73</u>
Difference	-	(0.02)	0.06	0.06	0.21	(0.02)	(0.01)
Diluted share count 2014-20E							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	<u>10</u>	<u>19</u>	<u>19</u>	<u>21</u>	<u>22</u>	<u>22</u>	<u>23</u>
Old	<u>10</u>	<u>21</u>	<u>22</u>	<u>24</u>	<u>25</u>	<u>25</u>	<u>26</u>
Difference	-	(3)	(3)	(3)	(3)	(3)	(3)

Source: Leerink Partners LLC estimates

## 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.

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

	2013	2014	1Q15	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	18	3.9	1.3	1.3	(1.5)	5	-	-	-	-	-	-	-	-	na
Collaborative development revenue	21	13	2.0	8.0	9.0	16.0	35	35	35	35	-	-	-	-	-	na
AZN milestones	-	-	-	-	10	-	10	25	25	50	-	-	-	-	-	na
<b>Total Revenue (MM)</b>	<b>29</b>	<b>32</b>	<b>5.9</b>	<b>9.3</b>	<b>20.3</b>	<b>14.5</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	nm	50%	-80%	82%	85%	34%	10%	
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
% of sales	0%	0%	na	na	na	na	0%	0%	0%	0%	0%	0%	0%	0%	0%	na
Gross Income	28.9	31.6	5.9	9.3	20.3	14.5	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%	
Discovery research	7.7	12.7	4.2	2.4	2.4	0.5	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	13.2	2.0	8.8	8.6	15.6	35.0	35.0	35.0	35.0	-	-	-	-	-	na
Total R&D	28.1	25.9	6.2	11.2	11.0	16.1	44.5	44.5	43.0	43.0	8.0	8.0	8.0	8.0	8.0	0%
% of sales	nm	82%	105%	121%	54%	111%	89%	74%	72%	48%	44%	24%	13%	10%	9%	
G&A	3.7	7.3	3.2	1.2	1.3	1.3	7.0	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	0%
% of sales	13%	23%	na	na	na	na	14%	12%	12%	8%	41%	23%	12%	9%	8%	
Selling & Marketing	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
Total operating expenses	31.8	33.2	9.4	12.4	12.3	17.4	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>(1.6)</b>	<b>(3.5)</b>	<b>(3.1)</b>	<b>8.0</b>	<b>(2.9)</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	-5%	na	na	na	na	-3%	13%	16%	44%	15%	53%	75%	81%	83%	
<b>Net financial expense</b>	<b>(3.6)</b>	<b>(1.6)</b>	<b>(0.0)</b>	<b>(0.2)</b>	<b>(0.2)</b>	<b>(0.4)</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>(3.5)</b>	<b>(3.3)</b>	<b>7.8</b>	<b>(3.3)</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	18.4%	46.4%	27.2%	61.3%	80.2%	86.4%	88.8%	
Taxes (benefit)	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>(3.2)</b>	<b>(3.5)</b>	<b>(3.3)</b>	<b>7.8</b>	<b>(3.3)</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	N/M	-36%	N/M	N/M	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>(\$0.31)</b>	<b>(\$0.19)</b>	<b>(\$0.18)</b>	<b>\$0.42</b>	<b>(\$0.18)</b>	<b>(\$0.13)</b>	<b>\$0.49</b>	<b>\$0.52</b>	<b>\$1.72</b>	<b>\$0.19</b>	<b>\$0.72</b>	<b>\$1.59</b>	<b>\$2.10</b>	<b>\$2.17</b>	<b>42%</b>
Y/Y	NM	NM					NM	NM	5%	234%	-89%	279%	122%	32%	3%	
Weighted Avg Diluted Shares (MM)	1.1	10.2	18.6	18.6	18.6	18.6	18.6	19.0	21.4	21.9	22.3	22.8	23.2	23.7	24.2	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

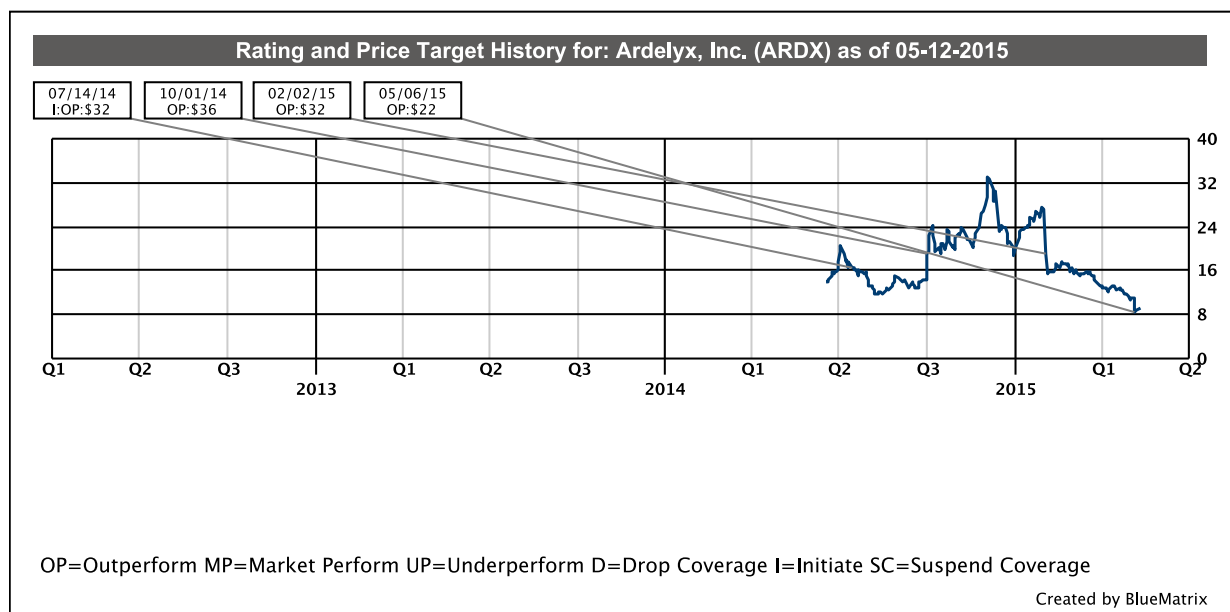
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

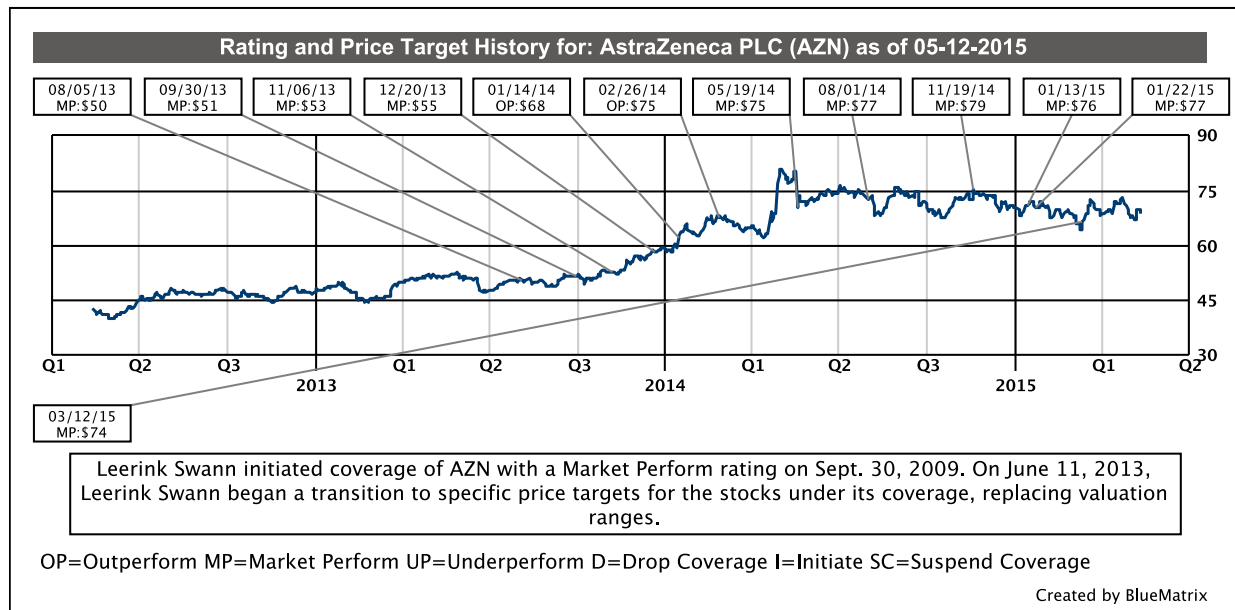
### Valuation

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### 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 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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