

Reason for report:

COMPANY UPDATE

## ARDELYX, INC.

### New Path Forward Includes Two Fully Owned Late Stage Assets; Raising PT to \$25

• **Bottom Line:** ARDX made two important announcements altering the direction of its late-stage pipeline with: (1) the termination of AZN (MP) partnership on tenapanor – ARDX now has worldwide rights; (2) a \$75.8m net capital raise through a private placement and joint announcement the company will initiate Ph. 3 development of RDX'022 and tenapanor for hyperkalemia and constipation, respectively. We are updating our model to reflect a go-it-alone strategy that includes ARDX launching tenapanor and '022 into nephrology indications with a small nephrology sales force. Our tenapanor-constipation sales estimates now flow through our model under a presumed partnership which pays ARDX a mid-20% royalty. Net of these transactions, ARDX will have \$150m in cash, sufficient to fund two important Ph. 3 programs to data readout. Our \$25 price target (from \$22) is based on a risk-adjusted DCF analysis.

• **Clawing back rights to tenapanor provides certainty and accelerated development of tenapanor with IBS Ph. 3's set to start in 4Q'15.** Under the termination of the AZN agreement, ARDX will owe AZN a potential \$90m in (capped) payments, which includes \$15m upfront, 10% royalty on sales, and 20% on additional licensing revenue. The deal allows ARDX to develop tenapanor for IBS and hyperphosphatemia alone, after which a commercial partner for IBS will be sought. In addition to a 4Q'15 IBS-C start, ARDX expects to initiate a Ph. IIb for tenapanor in dialysis patients with hyperphosphatemia.

• **ARDX's current net cash position is sufficient to get Ph. III programs to completion.** Current net cash will be split evenly to cover Ph. III costs for tenapanor and RDX022's Ph. 3 costs for '022. Mgmt. projects costs of ~\$60-\$85m for its two IBS-C programs and will update these estimates following its end of Ph. II meeting with the FDA for the Ph. III IBS-C study design. Ph. 2b hyperphosphatemia costs are expected to be small. We continue to see upside to ARDX's valuation and estimate an NPV of ~\$335m for the tenapanor franchise on a risk-adjusted basis. Upon completion of its Ph. III programs, we expect ARDX to seek additional capital to fund the launch activities for RDX022.

• **RDX022 provides ARDX with opportunity to become commercial stage company by 2018.** Mgmt. announced RDX022 for hyperkalemia will advance into Ph. 3 under the 505(b)(2) regulatory pathway. ARDX did not disclose many details on '022, which will be highlighted at the upcoming analyst day (7/14), but tolerability and more convenient dosing vs. potassium scavengers will be desired attributes. Our current model reflects a fairly conservative valuation for '022 until the company better articulates the product profile and shares more data. We are forecasting risk adj. sales of ~\$150m in 2027E and estimate a risk-adj. NPV of ~\$135m for RDX022.

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	0.0	0.0	0.0	5.9	( 0.19)A	( 0.23)	( 0.59)	( 1.07)	( 2.07)	NM
2015E - Old	5.9A	9.3	20.3	14.5	50.0	( 0.19)A	( 0.18)	0.42	( 0.18)	( 0.13)	NM
2016E - New	--	--	--	--	0.0	--	--	--	--	( 4.09)	NM
2016E - Old	--	--	--	--	60.0	--	--	--	--	0.49	NM

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

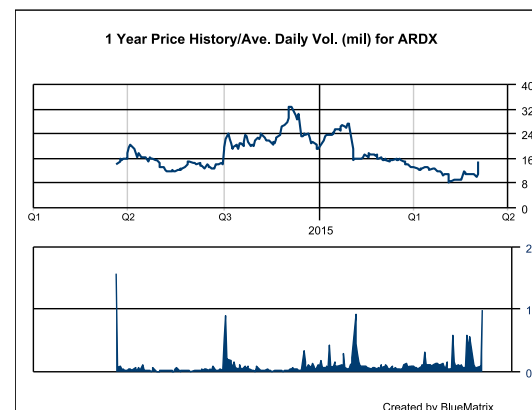
## Key Stats:

(NASDAQ:ARDX)

S&P 600 Health Care Index: 1,688.17  
Price: \$14.95  
Price Target: \$25.00 from \$22.00  
Methodology:

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

52 Week High: \$35.48  
52 Week Low: \$7.95  
Shares Outstanding (mil): 18.6  
Market Capitalization (mil): \$278.1  
Book Value/Share: \$0.00  
Cash Per Share: \$8.06  
Net Debt to Total Capital: 0%  
Dividend (ann): \$0.00  
Dividend Yield: 0.0%



## INVESTMENT THESIS

We rate ARDX with an Outperform rating and a \$25 price target in 12 months. ARDX' leading clinical asset is 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). 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	6	-	-	25	73	127
Old	32	50	60	60	90	19	36
Difference	-	(44)	(60)	(60)	(65)	54	90
Total EPS Forecasts 2014-20E							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	(0.31)	(2.07)	(4.09)	(3.45)	(1.65)	(0.10)	1.73
Old	(0.31)	(0.11)	0.43	0.45	1.51	0.21	0.73
Difference	-	(1.96)	(4.52)	(3.90)	(3.15)	(0.31)	1.00
Diluted share count 2014-20E							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	10	19	19	21	22	22	23
Old	10	21	22	24	25	25	26
Difference	-	(3)	(3)	(3)	(3)	(3)	(3)

Source: Company information, Leerink Partners estimates

## VALUATION

Our ~\$25/shr price target on ARDX shares is based on our risk-adjusted, sum-of-the-parts DCF analysis through 2030E. We used a 15% discount rate, and we estimate tenapanor will achieve market shares of ~30% and ~4% in the ESRD-Pi and IBS-C indications, respectively. We also estimate a total NPV of \$134m for RDX022.

## RISKS TO VALUATION

Tenapanor drives our valuation and clinical/regulatory failure would significantly impact our valuation; (2) RDX022 opportunity in hyperkalemia.

**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 product sales	-	-	-	-	-	-	-	-	-	-	21	43	67	92	119	28%
Tenapanor IBS royalties	-	-	-	-	-	-	-	-	-	9	19	32	46	83	87	24%
<b>Total tenapanor sales + royalties</b>	-	-	-	-	-	-	-	-	-	<b>9</b>	<b>40</b>	<b>75</b>	<b>113</b>	<b>175</b>	<b>206</b>	<b>26%</b>
RDX022 (hyperkalemia)	-	-	-	-	-	-	-	-	-	16	33	52	72	87	103	18%
Licensing revenue	8	18	3.9	-	-	-	4	-	-	-	-	-	-	-	-	na
Collaborative development revenue	21	13	2.0	-	-	-	2	-	-	-	-	-	-	-	-	na
AZN milestones	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
<b>Total Revenue (MM)</b>	<b>29</b>	<b>32</b>	<b>5.9</b>	-	-	-	<b>6</b>	-	-	<b>25</b>	<b>73</b>	<b>127</b>	<b>185</b>	<b>262</b>	<b>309</b>	<b>23%</b>
% y/y growth	na	na	na	na	na	na	na	na	nm	nm	195%	74%	46%	42%	18%	
COGS	-	-	-	-	-	-	-	-	-	2	6	9	14	18	22	19%
% 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	-	-	-	5.9	-	-	22	67	117	171	244	287	23%
% of net sales	100%	100%	100%	nm	nm	nm	100%	nm	nm	90%	91%	93%	93%	93%	93%	
Discovery research	7.7	12.7	4.2	2.8	2.4	0.1	9.5	9.5	9.0	9.0	9.0	9.0	9.0	9.0	9.0	0%
Clinical development expense - tenapanor	-	-	-	-	-	10.0	10.0	32.0	34.0	20.0	10.0	8.0	8.2	8.5	8.7	-2%
Clinical development expense - RDX'022	-	-	-	-	7.0	8.0	15.0	30.0	25.0	8.0	5.0	5.0	5.0	5.0	5.0	
AZN collaboration dev expense	20.3	13.2	2.0	-	-	-	2.0	-	-	-	-	-	-	-	-	na
Total R&D	28.1	25.9	6.2	2.8	9.4	18.1	36.5	71.5	68.0	37.0	24.0	22.0	22.2	22.5	22.7	-1%
% of sales	nm	82%	105%	nm	nm	nm	621%	nm	nm	150%	33%	17%	12%	9%	7%	
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	119%	nm	nm	30%	10%	6%	4%	3%	2%	
Selling & Marketing	-	-	-	-	-	-	-	-	-	20	40	41	42	44	45	2%
Total operating expenses	31.8	33.2	9.4	4.0	10.7	19.4	43.5	79.0	75.5	64.5	71.5	70.7	72.2	73.7	75.3	1%
<b>Operating (loss)/gain</b>	<b>(2.9)</b>	<b>(1.6)</b>	<b>(3.5)</b>	<b>(4.0)</b>	<b>(10.7)</b>	<b>(19.4)</b>	<b>(37.6)</b>	<b>(79.0)</b>	<b>(75.5)</b>	<b>(42.2)</b>	<b>(4.9)</b>	<b>46.5</b>	<b>99.0</b>	<b>170.4</b>	<b>211.6</b>	na
% of sales	nm	-5%	na	na	na	na	-640%	nm	nm	-171%	-7%	37%	54%	65%	68%	
<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>	13%
<b>Pre-tax Income</b>	<b>(6.4)</b>	<b>(3.1)</b>	<b>(3.5)</b>	<b>(4.2)</b>	<b>(10.9)</b>	<b>(19.9)</b>	<b>(38.5)</b>	<b>(77.7)</b>	<b>(74.0)</b>	<b>(40.0)</b>	<b>(2.6)</b>	<b>49.2</b>	<b>102.4</b>	<b>174.7</b>	<b>216.9</b>	na
% Pre-tax Margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	-162.0%	-3.6%	38.8%	55.3%	66.7%	70.2%	
Taxes (benefit)	0.1	0.1	-	-	-	-	-	-	-	(4.0)	(0.4)	9.8	25.6	52.4	65.1	na
% Tax rate	0.0%	0.0%	-	-	-	-	0.0%	0.0%	0.0%	10.0%	15.0%	20.0%	25.0%	30.0%	30.0%	
<b>Net Income/(loss) (MM)</b>	<b>(7)</b>	<b>(3.2)</b>	<b>(3.5)</b>	<b>(4.2)</b>	<b>(10.9)</b>	<b>(19.9)</b>	<b>(39)</b>	<b>(78)</b>	<b>(74)</b>	<b>(36)</b>	<b>(2)</b>	<b>39</b>	<b>77</b>	<b>122</b>	<b>152</b>	na
% of net sales	NM	NM	N/M	nm	N/M	N/M	nm	nm	nm	-145.8%	-3.1%	31.0%	41.5%	46.7%	49.1%	
<b>Diluted EPS</b>	<b>(\$5.82)</b>	<b>(\$0.31)</b>	<b>(\$0.19)</b>	<b>(\$0.23)</b>	<b>(\$0.59)</b>	<b>(\$1.07)</b>	<b>(\$2.07)</b>	<b>(\$4.09)</b>	<b>(\$3.45)</b>	<b>(\$1.65)</b>	<b>(\$0.10)</b>	<b>\$1.73</b>	<b>\$3.31</b>	<b>\$5.16</b>	<b>\$6.29</b>	na
Y/Y	NM	NM					NM	NM	-16%	-52%	-94%	-1821%	91%	56%	22%	
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%	

## Disclosures Appendix

### Analyst Certification

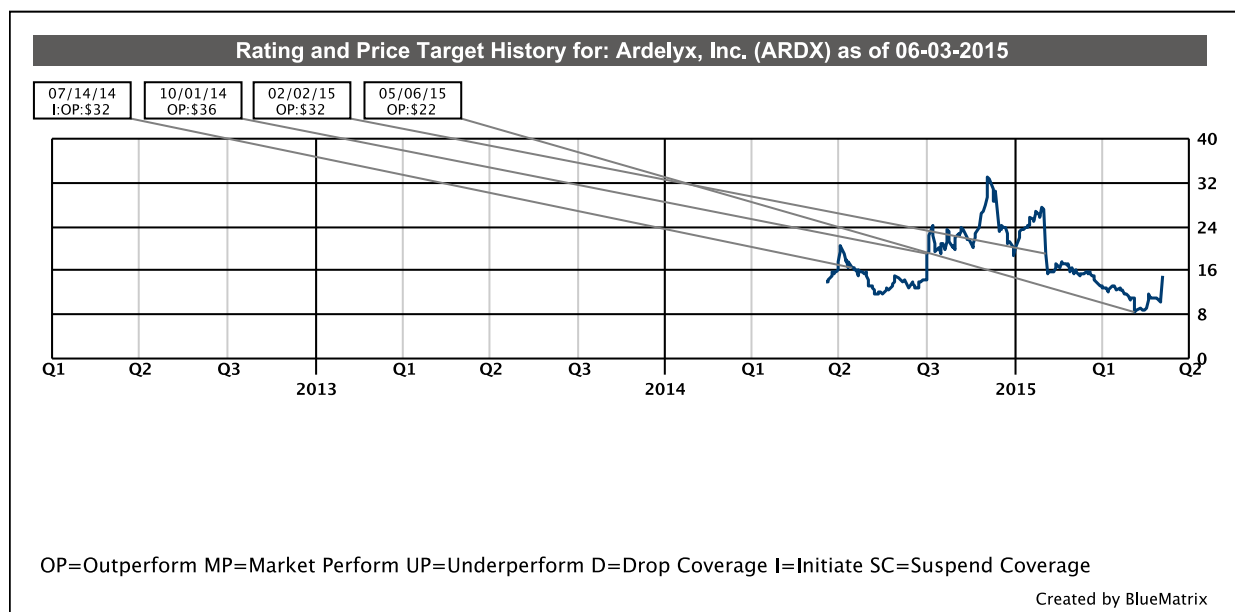
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

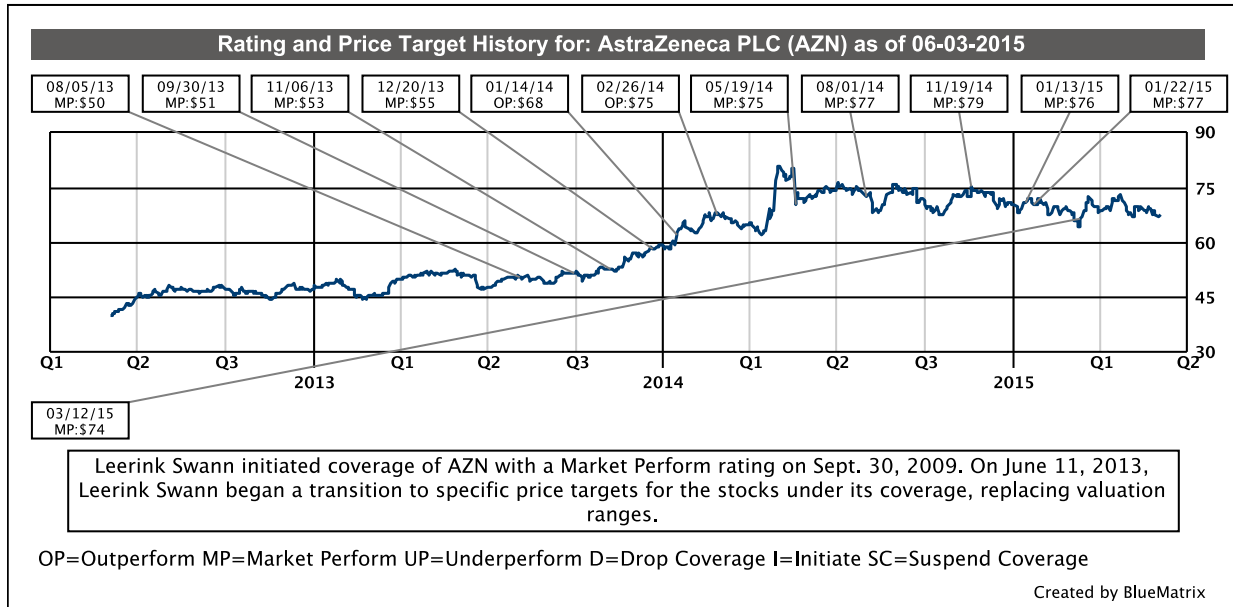
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Distribution of Ratings/Investment Banking Services (IB) as of 03/31/15				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	151	70.20	55	36.00
HOLD [MP]	64	29.80	2	3.00
SELL [UP]	0	0.00	0	0.00

## 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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