

Reason for report:  
**EARNINGS**

## ARDELYX, INC.

### 3Q14 Recap: Updates On Tenapanor Programs; Remain OP

• **Bottom Line:** ARDX reported 3Q'14 net income of ~\$74k vs. our est of -\$1.7m. The increase was primarily driven by the increased recognition of licensing revenue related to milestone payments from AZN (MP). On the CC, mgmt provided updates on: (1) tenapanor's clinical programs noting tenapanor's Ph.2b trial for ESRD-Pi is now expected to read out in 1Q'15; (2) tenapanor's recent IBS-C data will be presented at Digestive Disease Week in May and; (3) progress on ADRX's Ph.2b trial in CKD pts which remains on track to read out in 2H'15. We are updating our model to reflect the updated financials and cash guidance. ADRX ended the qtr with approx. ~\$112m in cash. We remain OP with a \$36/shr price target.

• **Tenapanor's ESRD-Pi trial now expected to read out in 1Q'15.** On the CC, mgmt provided an update on the co.'s Ph.2b program evaluating Tenapanor in ESRD-Pi (hyperphosphatemia) in dialysis pts. They now expect topline results from tenapanor's trial for ESRD-Pi in 1Q'15 vs prior guidance of 1H'15. We view this as another important de-risking event for the co. as we view this as a significant market oppty (the 2013 phosphate binder market was approx. ~\$1B). Given tenapanor's profile - we expect physicians to favor it over current meds due to: (1) similar efficacy to current treatments; (2) reduced pill burden to current phosphate binders &; (3) reduced sodium absorption which MEDACorp specialists have indicated as an important feature. ARDX plans to present data at American Society of Nephrology meeting next week comparing tenapanor for ESRD-Pi vs. sevelamer in healthy subjects showing tenapanor increased fecal phosphorus at lower doses. We est. heavily risk adjusted (POS: 35%) peak sales of ~\$125m and believe a positive ESRD-Pi trial could be an incremental ~\$4 to the stock. Mgmt also reiterated data from the CKD program is still expected by the end of FY'15.

• **Mgmt expects to present Ph. 2 IBS-C data at DDW in May.** Some of the questions investors have had about the recent IBS-C data centers around the pain endpoint as ARDX did not report any specific data only saying it showed a "clinically meaningful improvement" on pain. While the Ph.2b study was not powered for efficacy, it still showed a stat sig increase in the CSBM (complete spontaneous bowel movement) responder rate - 60% vs. 33% for PBO - which we view as very encouraging. Mgmt expects to present additional data including the pain data at DDW in May.

• **Model changes.** We are updating our model to reflect (1) increased licensing revenue for the qtr; (2) slightly increasing our G&A exp. for a more normalized progression and; (3) updated share count.

#### Key Stats:

(NASDAQ:ARDX)

<b>S&amp;P 600 Health Care Index:</b>	<b>1,370.82</b>
<b>Price:</b>	<b>\$24.01</b>
Price Target:	\$36.00
Methodology:	Sum-of-the-parts DCF analysis, 15% discount rate
52 Week High:	\$25.23
52 Week Low:	\$11.37
Shares Outstanding (mil):	19.1
Market Capitalization (mil):	\$458.6
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
2013A	--	--	--	--	29.0	--	--	--	--	( 0.65)	NM
2014E - New	8.6A	9.1A	7.6A	7.7	33.0	( 0.23)A	0.18A	0.00A	( 0.20)	( 0.17)	NM
2014E - Old	8.6A	9.1A	6.5	8.8	33.0	( 0.23)A	0.18A	( 0.08)	( 0.05)	( 0.11)	NM
2015E - New	8.7	19.3	10.3	11.7	50.0	( 0.17)	0.30	( 0.10)	( 0.20)	( 0.12)	NM
2015E - Old	--	--	--	--	50.0	--	--	--	--	( 0.02)	NM
2016E - New	--	--	--	--	60.0	--	--	--	--	0.45	53.4x
2016E - Old	--	--	--	--	60.0	--	--	--	--	0.40	NM

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

## INVESTMENT THESIS

We rate ARDX with an Outperform rating and a \$36 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). While AZN owns WW commercialization rights on tenapanor, ARDX may receive up to ~\$225m in development milestones and tiered royalties (in “teens”). We are bullish ahead of Phase II data for tenapanor, which MEDACorp Key Opinion Leaders (KOL) believe will help establish tenapanor's profile as a blockbuster drug, based on potential for: (1) efficacy similar to marketed phosphate binders; (2) reduction in sodium absorption; & (3) reduce the pill burden associated with current meds. Longer term, ARDX plans to invest in its proprietary drug discovery platform and develop wholly owned assets.

## CHANGES TO MODEL

### EPS & Total Sales Forecasts (2013-19E) (\$MM, except per share data)

Total Sales Forecasts 2014-19E							
	2013	2014E	2015E	2016E	2017E	2018E	2019E
New	29	33	50	60	60	94	33
Old	29	33	50	60	60	94	33
Difference	-	-	-	-	-	-	-
Total EPS Forecasts 2014-19E							
	2013	2014E	2015E	2016E	2017E	2018E	2019E
New	(\$0.65)	(0.17)	(0.12)	0.45	0.47	1.71	0.69
Old	(0.65)	(0.11)	(0.02)	0.40	0.42	1.54	0.62
Difference	-	(0.06)	(0.10)	0.04	0.05	0.17	0.07
Diluted share count 2014-19E							
	2013	2014E	2015E	2016E	2017E	2018E	2019E
New	10	18	21	21	24	24	25
Old	10	20	23	23	26	27	27
Difference	-	(2)	(2)	(2)	(3)	(3)	(3)

Source: Leerink Partners LLC estimates, company information

## VALUATION

Our ~\$36/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%, 40%, and 5% in the ESRD-Pi, sodium, and fluid overload chronic kidney disease (CKD) and IBS-C indications, respectively.

Risks to Valuation: (1) tenapanor drives our valuation and clinical/regulatory failure would significantly impact

## RISKS TO VALUATION

Risks include (1) tenapanor drives our valuation and clinical/regulatory failure would significantly impact our valuation; (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)

	2012A	2013	1Q14	2Q14	3Q14	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	19-23E
Tenapanor ESRD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	4	8	17	29	36	37	24%
Tenapanor CKD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	10	27	51	70	90	37%
Tenapanor IBS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5	15	25	46	62	65	23%
<b>Total tenapanor royalties</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	<b>9</b>	<b>33</b>	<b>69</b>	<b>126</b>	<b>168</b>	<b>191</b>	<b>28%</b>
Licensing revenue	3	8	3.2	6.5	4.8	4.5	19	1.2	1.3	1.3	1.2	5	-	-	-	-	-	-	-	-	na
Collaborative development revenue	2	21	5.3	2.6	2.8	3.2	14	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>5</b>	<b>29</b>	<b>8.6</b>	<b>9.1</b>	<b>7.6</b>	<b>7.7</b>	<b>33</b>	<b>8.7</b>	<b>19.3</b>	<b>10.3</b>	<b>11.7</b>	<b>50</b>	<b>60</b>	<b>60</b>	<b>94</b>	<b>33</b>	<b>69</b>	<b>126</b>	<b>168</b>	<b>191</b>	<b>28%</b>
% y/y growth	na	na	na	na	na	na	na	na	na	na	na	na	na	nm	57%	-65%	107%	83%	33%	14%	
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
% of sales	0	0%	na	na	na	na	0%	na	na	na	na	0%	0%	0%	0%	0%	0%	0%	0%	0%	
Gross Income	5.4	28.9	8.6	9.1	7.6	7.7	33.0	8.7	19.3	10.3	11.7	50.0	60	60	94	33	69	126	168	191	28%
% of net sales	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
Discovery research	6.3	7.7	2.4	2.6	2.5	2.0	9.4	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	2.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
AZN collaboration dev expense	1.9	20.3	5.3	2.6	3.2	6.9	18.0	8.6	8.8	8.6	9.0	35	35	35	35	-	-	-	-	-	na
Total R&D	10.2	28.1	7.6	5.2	5.7	8.9	27.4	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	188%	nm	89%	57%	75%	115%	83%	125%	58%	107%	97%	89%	74%	72%	46%	24%	12%	6%	5%	4%	
G&A	4.0	3.7	1.4	1.2	1.8	1.6	6.0	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	75%	13%	na	na	na	na	18%	na	na	na	na	14%	12%	12%	8%	23%	11%	6%	4%	4%	
Selling & Marketing	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
Total operating expenses	14.2	31.8	9.0	6.4	7.5	10.5	33.4	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>(8.8)</b>	<b>(2.9)</b>	<b>(0.5)</b>	<b>2.8</b>	<b>0.1</b>	<b>(2.8)</b>	<b>(0.4)</b>	<b>(3.6)</b>	<b>6.9</b>	<b>(2.0)</b>	<b>(2.8)</b>	<b>(1.5)</b>	<b>8.0</b>	<b>9.5</b>	<b>43.8</b>	<b>17.7</b>	<b>53.4</b>	<b>110.4</b>	<b>152.4</b>	<b>175.5</b>	<b>39%</b>
% of sales	-163%	nm	na	na	na	na	-1%	na	na	na	na	-3%	13%	16%	46%	53%	77%	88%	91%	92%	
Other income	(1.0)	(3.6)	(2.6)	1	(0)	(1.0)	(2.6)	(0.25)	(0.25)	(0.25)	(0.25)	(1.0)	-	-	-	-	-	-	-	-	na
Interest expense/income	-	-	-	-	-	-	-	0.02	0.02	0.02	0.05	0.1	1.3	1.5	2.1	2.3	2.6	3.4	4.3	5.3	23%
<b>Net financial expense</b>	<b>(1.0)</b>	<b>(3.6)</b>	<b>(2.6)</b>	<b>1.0</b>	<b>(0)</b>	<b>(1.0)</b>	<b>(2.6)</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>(9.8)</b>	<b>(6.4)</b>	<b>(3.1)</b>	<b>3.8</b>	<b>0.1</b>	<b>(3.8)</b>	<b>(3.0)</b>	<b>(3.8)</b>	<b>6.7</b>	<b>(2.2)</b>	<b>(3.0)</b>	<b>(2.4)</b>	<b>9.3</b>	<b>11.0</b>	<b>45.9</b>	<b>20.0</b>	<b>56.0</b>	<b>113.8</b>	<b>156.7</b>	<b>180.8</b>	<b>37%</b>
% Pre-tax Margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	18.4%	48.7%	60.2%	81.3%	90.4%	93.3%	94.7%	
Taxes (benefit)	-	0.1	-	-	-	-	-	-	-	-	-	-	-	-	4.6	3.0	11.2	28.4	47.0	63.3	55%
% Tax rate	0.0%	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>(10)</b>	<b>(7)</b>	<b>(3.1)</b>	<b>3.8</b>	<b>0.1</b>	<b>(3.8)</b>	<b>(3.0)</b>	<b>(3.8)</b>	<b>6.7</b>	<b>(2.2)</b>	<b>(3.0)</b>	<b>(2)</b>	<b>9</b>	<b>11</b>	<b>41</b>	<b>17</b>	<b>45</b>	<b>85</b>	<b>110</b>	<b>118</b>	<b>32%</b>
% of net sales	NM	NM	N/M	41%	N/M	N/M	NM	N/M	34%	N/M	N/M	nm	15.6%	18.4%	43.8%	51.1%	65.1%	67.8%	65.3%	61.5%	
<b>Diluted EPS</b>	<b>(\$1.26)</b>	<b>(\$0.65)</b>	<b>(\$0.23)</b>	<b>\$0.18</b>	<b>\$0.00</b>	<b>(\$0.20)</b>	<b>(\$0.17)</b>	<b>(\$0.17)</b>	<b>\$0.30</b>	<b>(\$0.10)</b>	<b>(\$0.20)</b>	<b>(\$0.12)</b>	<b>\$0.45</b>	<b>\$0.47</b>	<b>\$1.71</b>	<b>\$0.69</b>	<b>\$1.78</b>	<b>\$3.32</b>	<b>\$4.19</b>	<b>\$4.40</b>	<b>30%</b>
Y/Y	NM	NM					NM					NM	NM	5%	267%	-60%	159%	87%	26%	5%	
Weighted Avg Diluted Shares (MM)	7.8	10.2	13.3	20.3	19.1	18.8	17.9	22.3	22.5	22.6	14.9	20.6	21.0	23.7	24.2	24.7	25.2	25.7	26.2	26.7	1%
% growth	NM	31%					76%					15%	2%	13%	2%	2%	2%	2%	2%	2%	

## Disclosures Appendix

### Analyst Certification

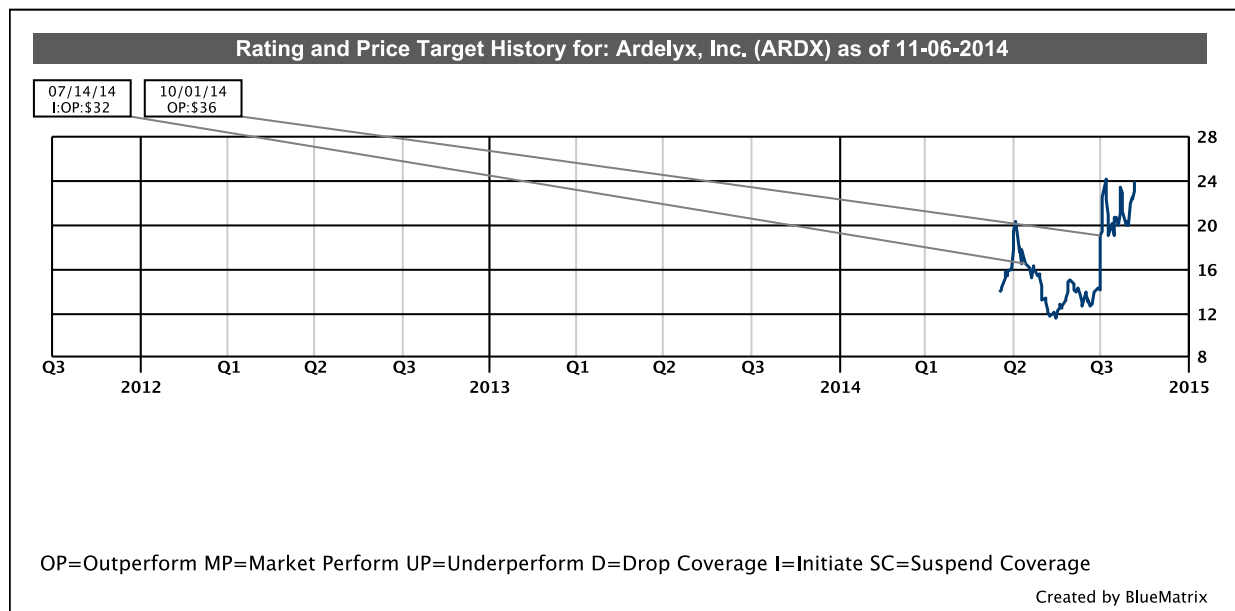
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

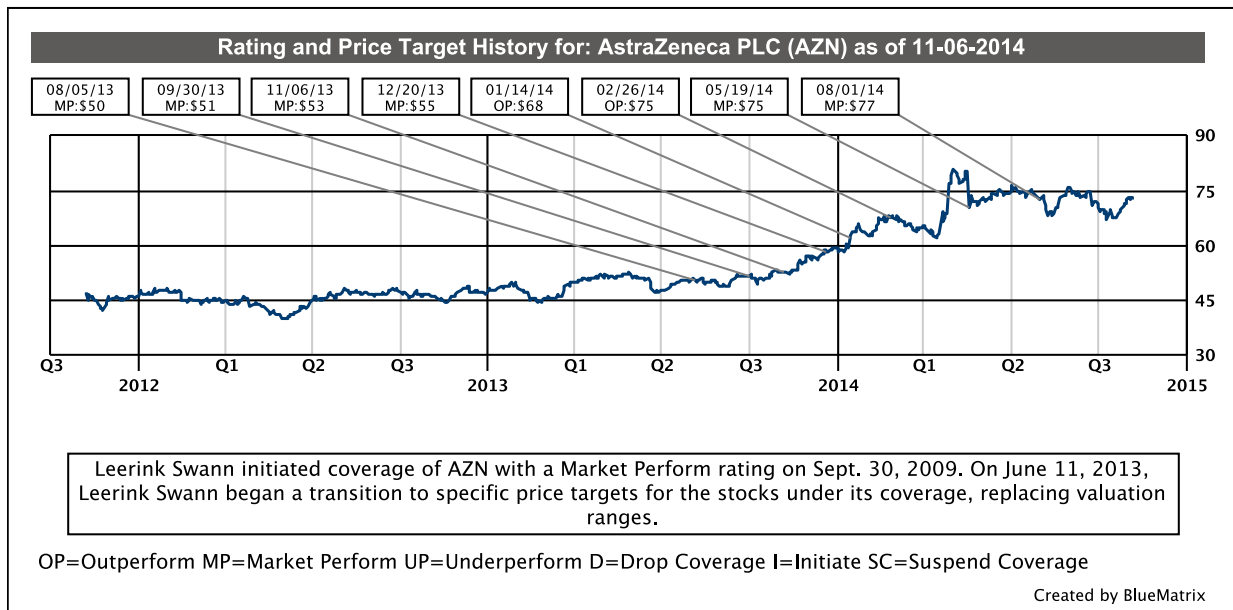
### Valuation

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### Risks to Valuation

Risks to Valuation: (1) tenapanor drives our valuation and clinical/regulatory failure would significantly impact our valuation; (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 09/30/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	138	69.30	51	37.00
HOLD [MP]	61	30.70	2	3.30
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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