

Reason for report:  
**ESTIMATE CHANGE**

## ARDELYX, INC.

### Tenapanor Ph. 2 Data Mixed & Likely Extend Time to Market; Lowering PT \$32/shr

• **Bottom Line:** We are lowering our price target to \$32/share (from \$36/share) based on mixed Ph. 2 data for tenapanor in ESRD-Pi (hyperphosphatemia) which included statistically significant efficacy but higher-than-expected (undisclosed) rates of diarrhea. As a result, we are pushing out our timelines for the ESRD-Pi and CKD (chronic kidney disease) indications by 1 year (2019E) and 2 years (2021E), respectively. Going forward, for tenapanor, we see a drug that has now demonstrated efficacy in two high value indications which should motivate partner AZN's (MP) to continue investing behind the program. Next up – in 2Q'15 ARDX will provide an update on Ph. 2 data for tenapanor in CKD (chronic kidney disease), after which we'd expect further updates on tenapanor clinical development plan. We remain OP-rated.

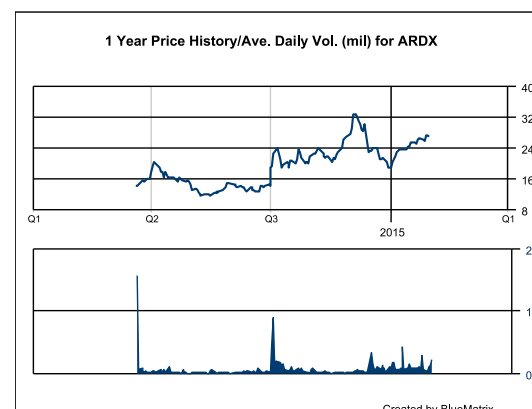
• **We believe today's sell-off is overdone.** We believe today's ARDX sell-off (-29%) was overdone for three reasons: (1) tenapanor established efficacy in ESRD--Pi pts, which was statistically significant and demonstrated a dose-related decrease in serum phosphate; (2) ARDX mgmt. indicated rates of diarrhea are not ideal, but remain optimistic about the viability of the program; (3) tenapanor has now demonstrated efficacy in two indications with large markets, irritable bowel syndrome (IBS) and end-stage renal disease (ESRD). Although the brevity of ARDX's press release raised investor concerns, we ultimately believe any "show stopping" rates of adverse event would have required greater specificity in the PR. Our updated view is that additional Ph. 2 work will be required to identify dosing strategy that can mitigate the rate of diarrhea in renal disease patients. We now forecast tenapanor time to market for ESRD-Pi and CKD in 2019 and 2021, respectively. We now value ESRD-Pi and CKD at ~\$5 and ~\$9, respectively, of our \$32/share price target.

• **We expect AZN will determine the next steps for the tenapanor platform after the Ph. 2 CKD data read out in 2Q'15.** At present, mgmt. believes it is too early to know whether material updates on the tenapanor program will be provided on the 4Q'14 CC. We believe AZN will likely assess the full set of Ph. 2 data across the three indications (ESRD-Pi, CKD, and IBS-C) to determine the path forward for each of the programs. Mgmt noted more detailed ESRD-Pi data may be presented later this year at a medical meeting, assuming AZN chooses to publish.

• **Tenapanor's profile in IBS-C remains attractive and we view it as a pot'l competitor to Linzess.** According to ARDX, AZN remains interested in the IBS-C indication for tenapanor and continues to perform diligence on this opportunity. We view IBS-C as a ~\$1.5b market opportunity for Linzess by '20E and see room for an additional market entrant with a differentiated profile and strong mktg presence.

#### Key Stats: (NASDAQ:ARDX)

<b>S&amp;P 600 Health Care Index:</b>	<b>1,451.01</b>
<b>Price:</b>	<b>\$19.25</b>
Price Target:	\$32.00 from \$36.00
Methodology:	Sum-of-the-parts DCF analysis, 15% discount rate
52 Week High:	\$35.48
52 Week Low:	\$11.37
Shares Outstanding (mil):	18.8
Market Capitalization (mil):	\$361.9
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	8.6A	9.1A	7.6A	7.7	33.0	( 0.23)A	0.18A	0.00A	( 0.20)	( 0.17)	NM
2015E	8.7	19.3	10.3	11.7	50.0	( 0.17)	0.30	( 0.10)	( 0.20)	( 0.12)	NM
2016E	--	--	--	--	60.0	--	--	--	--	0.45	42.8x

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

## INVESTMENT THESIS

We rate ARDX with an Outperform rating and a \$32 price target (from \$36) 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 OUR MODEL

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

Total Sales Forecasts 2014-20E							
	2014E	2015E	2016E	2017E	2018E	2019E	2020E
New	33	50	60	60	90	19	36
Old	<u>33</u>	<u>50</u>	<u>60</u>	<u>60</u>	<u>94</u>	<u>33</u>	<u>69</u>
Difference	-	-	-	-	(4)	(14)	(32)
Total EPS Forecasts 2014-20E							
	2014E	2015E	2016E	2017E	2018E	2019E	2020E
New	<u>(0.17)</u>	<u>(0.12)</u>	<u>0.45</u>	<u>0.47</u>	<u>1.56</u>	<u>0.21</u>	<u>0.75</u>
Old	<u>(0.17)</u>	<u>(0.12)</u>	<u>0.45</u>	<u>0.47</u>	<u>1.71</u>	<u>0.69</u>	<u>1.78</u>
Difference	-	-	-	-	(0.15)	(0.48)	(1.03)
Diluted share count 2014-20E							
	2014E	2015E	2016E	2017E	2018E	2019E	2020E
New	<u>18</u>	<u>21</u>	<u>21</u>	<u>24</u>	<u>24</u>	<u>25</u>	<u>25</u>
Old	<u>18</u>	<u>21</u>	<u>21</u>	<u>24</u>	<u>24</u>	<u>25</u>	<u>25</u>
Difference	-	-	-	-	-	-	-

Source: Leerink Partners, Company Information

**PROBABILITY WEIGHTED NPV ANALYSIS OF TENAPANOR PROGRAMS**

<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	35%
<b>Risk adj NPV tenapanor ESRD</b>	<b>89</b>
Tenapanor CKD peak share	40%
Tenapanor launch price/day	\$15
2025 tenap CKD global sales	3005
CKD % POS	25%
<b>Risk adj NPV tenapanor CKD</b>	<b>164</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	10
start Ph 3 ESRD, \$50m, 50% POS	25
Est. approval milestone, \$100m, 35% POS	25
NDA filing, \$50m	18
All other, \$2.5m	1
<b>Discounted, risk adj AZN milestones</b>	<b>46</b>
Total NPV of AZN partnership	<b>486</b>
Total NPV of SNY p/s milestones	<b>26</b>

Source: Company info., Leerink Research est.

**DISCOUNTED CASH FLOW ANALYSIS**

Shares Outstanding	18.8			
Net cash	112			
Discount Rate	15%			
<b>ARDX</b>		<b>Valuation</b>	<b>Per shr</b>	<b>% of value</b>
AZN p/s (risk adj royalties + m'stones)		486	\$ 26	79%
SNY p/s (milestones)		26	\$ 1	4%
Cash (less near-term burn)		100	\$ 5	16%
<b>Total</b>		<b>611</b>	<b>\$ 32</b>	<b>100%</b>
<b>Current market price</b>	\$ 19.25			
<b>Implied upside/downside</b>	69%			

Source: Company info., Leerink Research est.

## VALUATION

Our ~\$32/shr price target (from \$36) 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

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)

	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	11	21	29	37	36%
Tenapanor CKD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	17	35	54	na
Tenapanor IBS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5	15	25	46	62	65	23%
<b>Total tenapanor royalties</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	<b>5</b>	<b>19</b>	<b>36</b>	<b>85</b>	<b>126</b>	<b>155</b>	<b>35%</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>90</b>	<b>19</b>	<b>36</b>	<b>85</b>	<b>126</b>	<b>155</b>	<b>35%</b>
% y/y growth	na	na	na	na	na	na	na	na	na	na	na	na	na	nm	50%	-79%	88%	132%	49%	24%	
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
% of sales	0	0%	na	na	na	na	0%	na	na	na	na	0%	0%	0%	0%	0%	0%	0%	0%	0%	na
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	90	19	36	85	126	155	35%
% 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%	48%	41%	22%	9%	6%	5%	
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%	39%	21%	9%	6%	5%	
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>39.7</b>	<b>3.9</b>	<b>20.9</b>	<b>69.0</b>	<b>110.1</b>	<b>139.7</b>	<b>67%</b>
% of sales	-163%	nm	na	na	na	na	-1%	na	na	na	na	-3%	13%	16%	44%	20%	57%	82%	88%	90%	
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>41.8</b>	<b>6.1</b>	<b>23.6</b>	<b>72.4</b>	<b>114.5</b>	<b>145.0</b>	<b>57%</b>
% Pre-tax Margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	18.4%	46.4%	31.7%	64.7%	85.7%	91.1%	93.5%	
Taxes (benefit)	-	0.1	-	-	-	-	-	-	-	-	-	-	-	-	4.2	0.9	4.7	18.1	34.3	50.7	77%
% 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>38</b>	<b>5</b>	<b>19</b>	<b>54</b>	<b>80</b>	<b>94</b>	<b>51%</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%	41.7%	26.9%	51.8%	64.3%	63.8%	60.7%	
<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>\$1.56</b>	<b>\$0.21</b>	<b>\$0.75</b>	<b>\$2.12</b>	<b>\$3.06</b>	<b>\$3.53</b>	<b>49%</b>
Y/Y	NM	NM					NM					NM	NM	5%	234%	-86%	254%	182%	45%	15%	
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%	

Source: Leerink Partners, LLC estimates and company reports

## Disclosures Appendix

### Analyst Certification

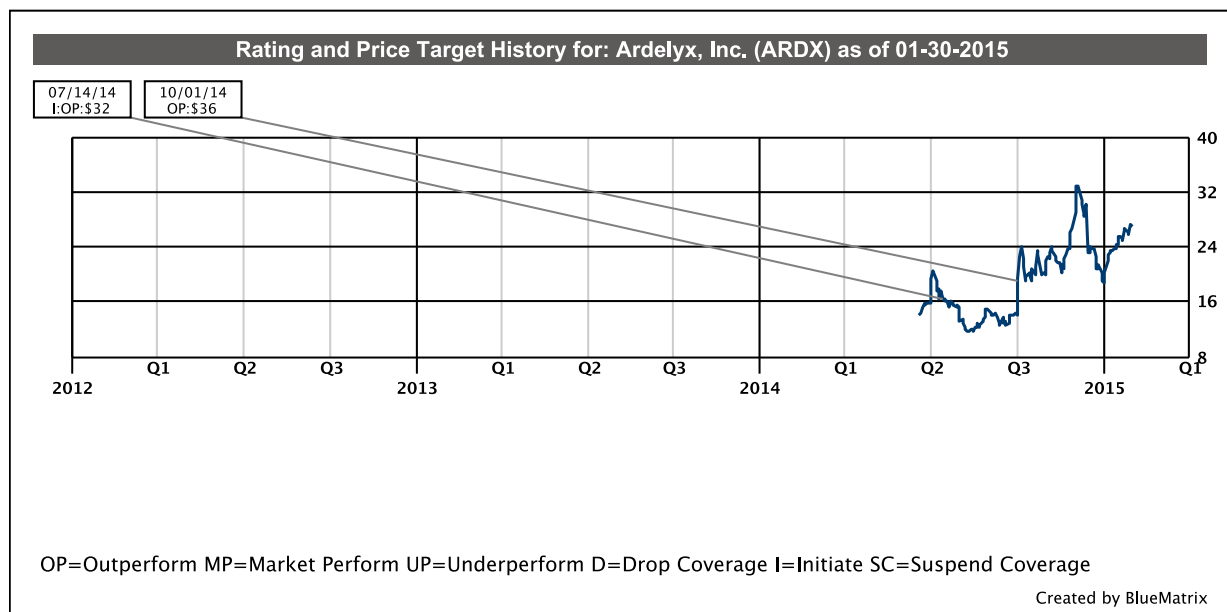
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### Valuation

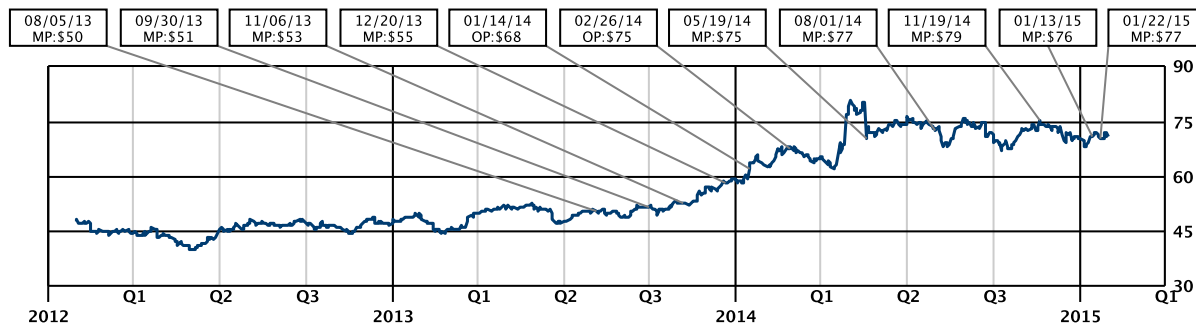
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### Risks to Valuation

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### Rating and Price Target History for: AstraZeneca PLC (AZN) as of 01-30-2015

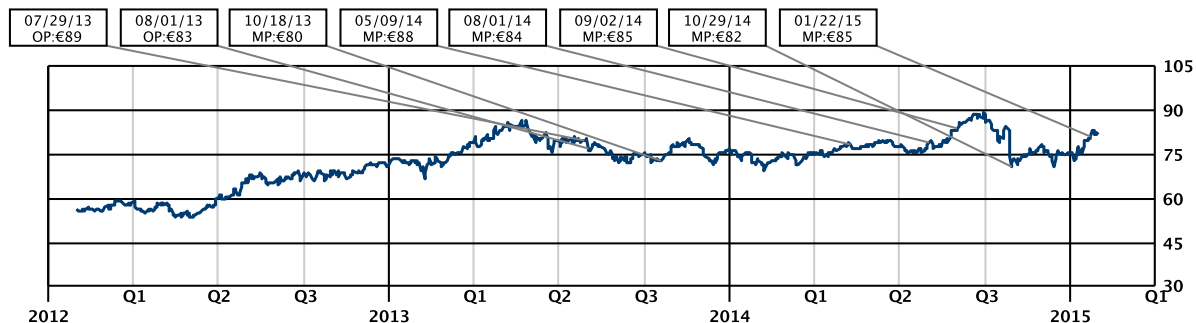


Leerink Swann initiated coverage of AZN with a Market Perform rating on Sept. 30, 2009. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

### Rating and Price Target History for: Sanofi (SAN FP) as of 01-30-2015



Leerink Swann initiated coverage of SAN FP with an Outperform rating on February 26, 2010. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	150	70.00	61	41.00
HOLD [MP]	64	30.00	0	0.00
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

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Editorial Department at One Federal Street, 37th Floor, Boston, MA 02110.

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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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**Leerink Partners LLC Equity Research**


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